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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 16th August 2022. |
| **Zoom details:** | https://mohnz.zoom.us/j/9481145912 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12.30pm-1.00pm | 2022 FULL 13270 | Novel white crowns for drill-free treatment of dental caries in children | Dr Joanne Choi | Dr Kate Parker & Mr Jonathan Darby |
| 1.00pm-1.30pm | 2022 FULL 12972 | Early identification of children with disequilibrium | Dr Michael Maslin | Dr Leonie Walker & Ms Jade Scott |
| 1.30pm-2.00pm | 2022 FULL 13045 | Comparison of two felodipine tablets under fasting conditions | Dr Noelyn Hung | Ms Catherine Garvey & Dr Andrea Forde |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Kate Parker | Non-lay (Observational studies) | 11/11/2015 | 11/11/2023 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey | Lay (the Law) (Chair) | 11/08/21 | 11/08/2024 | 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 |
| Dr Leonie Walker | Lay (Ethical/Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |
| Mr Derek Chang | Non-lay (Intervention studies) | 18/07/2022 | 18/07/2025 | Present |

## Welcome

The Chair opened the meeting at 12pm 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 19 July 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 13270** |
|  | Title: | Novel white crowns for drill-free treatment of dental caries in children |
|  | Principal Investigator: | Dr Joanne Choi |
|  | Sponsor: |  |
|  | Clock Start Date: | 4th August 2022 |

Dr Joanne Choi was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that this was a resubmission of a declined study.
2. The Committee clarified with whom the Intellectual Property rights of the dental crowns would lie. The researcher confirmed the study is investigator-led and the University of Otago would hold IP rights. No company has been set up for the commercialisation of this research although this is a possibility in the future. The University of Otago should be named as the sponsor and clarity should be added around the potential that ACC will not cover this study, and in that event the University will have insurance for this.

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 this is a first in human study and that this needed to be clearly stated in the Protocol, participant information sheet (PIS) and Application. (*National* *Ethical Standards* para *7.15 & 7.16)*
2. The Committee noted that there would be randomisation to either a silver crown or white crown arm of the study and that the investigators must ensure that they obtain informed consent prior to randomisation, and the process for this is included in the protocol. (*National Ethical Standards* para *9.7a & 9.8.)*
3. The Committee requested that one consent form be used for both arms of the trial as the participant needs to have consented prior to the randomisation process (which should be detailed in the PIS).
4. The Committee noted that there were several inaccuracies in the application form (i.e., the ticking of boxes noting Double-blinding, Kaupapa methodology and needing to tick Feasibility and note that this is a first in human study). (*National* *Ethical Standards* para *7.)*
5. The Committee noted that the application was missing a study title.
6. The Committee noted that the dental therapists would need to be consented as they are participants and will need to be informed and consented. This should also be included in the protocol, together with provision of the questionnaires to be used. *(National Ethical Standards* para *7.19)*
7. The Committee would like to see a statement in the response detailing that the manufacturer or distributor of the study device will not have sway or rights over the research and the data.
8. The Committee requested the following changes to the Protocol (*National* *Ethical Standards* para *9.7a & 9.8)*:
   1. The Committee requests a detailed protocol as per the NEAC guidelines on what is required of an application to HDEC.
   2. The Committee noted that the HRC application appeared to be for more than just the feasibility study, this study is only the feasibility section and the protocol needs to be focused as such.
   3. The Committee requested that the manufacturing process be explained in the Protocol. This should address the materials used and any potential risks associated with using the study crown.
   4. Please include detail as to the randomisation process.
9. The Committee requested the following changes to the Data Management Plan (DMP):
10. Please note that the storage requirements of data in New Zealand requires data to be kept for 10 years after the youngest participant turns 16-years old. (*National* *Ethical Standards* para *6.28).*
11. Please note that the HDEC reference needs to be changed to 13270.
12. Please include sponsor details.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *National* *Ethical Standards* para *7.15-7.18)*:

1. Please include information as to who the sponsor is.Please ensure that there is clarity around participant responsibilities no matter how minor.
2. Please provide Māori cultural support contact details.
3. Please clarify whether the researchers will disseminate research results publicly, and whether published results will identify participants directly or indirectly
4. Please specify who will be conducting the consenting.
5. Please specify the timings of follow-ups and what procedures will be done.
6. Please specify how researchers will communicate the research findings to the participants and the communities involved.
7. A suitable statement as to ACC compensation, and the availability of compensation through the University of Otago is required.

**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:** | **2022 FULL 12972** |
|  | Title: | Early identification of children with disequilibrium |
|  | Principal Investigator: | Dr Michael Maslin |
|  | Sponsor: | School of Psychology, Speech and Hearing. University of Canterbury |
|  | Clock Start Date: | 4th August 2022 |

No one from the research team was present via videoconference for discussion of this application. The Committee waited for 10 minutes before continuing to consider the 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 queried whether the researcher would be conducting the interviews.
2. The Committee requested independent peer review by a paediatric musculoskeletal specialist. The Committee also requested to see evidence of any research similar to this carried out in this population (i.e., evidence of the screening test being of diagnostic use in this age group, rather than highlighting variance in child development). *HDEC* *Standard Operating Procedures para 11*
3. The Committee noted that there was no explicit information in the advertising material as to where the study would take place or the time commitment that would be required. Please amend this.
4. The Committee noted that there may need to be a new title to the study if the feasibility of the study device in this age group is the only aim or objective under investigation. It was the Committee's impression that the study also wishes to see whether the vHIT may be useful in identifying disequilibrium, as it is not currently known whether it will be.
5. The Committee requested the following changes to the Protocol (*National* *Ethical Standards* para *9.7a & 9.8)*:
   1. Please describe what action(s) would be taken in the event a balance impairment is found, specifically detail pathways for referral.
   2. Please detail whether the research team have any experience in this age of participant and whether there are any particular considerations for this age group.
   3. Please note that ethnicity must be recorded in research conducted in New Zealand.
   4. Please specify the responses to distress both in the participants and the parents in this study.
   5. Please specify what will happen to the audio recording once it has been recorded, how it will be stored, destroyed, transcribed, who will have access to it etc.
   6. Please note that the referral to an Ear, Nose and Throat doctor in the public system could take some time to occur and there should be a plan in place for the interim care of participants with identified issues.
   7. Please specify the measurable outcome/end-point of each objective.
   8. Please specify a plan for how infants who cannot sustain the test duration will be managed.
   9. Please specify how the happiness of the infant will be assessed.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National* *Ethical Standards* para *7.15-7.18)*:

1. Please review for lay language and remove instances of technical language.
2. Please provide a clear plan for referral and follow up should an issue be detected in the testing phase of this study.
3. Please include a page number and version name in the footer.
4. Please include a statement to the effect that this is a NZ only trial, and the study locations.
5. Please state who is funding the research.
6. Please specify how long results will take to be returned.
7. Please make it clearer where the researcher signs and ensure that there is a statement that declares that the researcher has seen and informed the participants prior to consent for an example please see the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v3.0july2022.doc).
8. Please clearly specify the study objectives, so that participants are clearly advised of the distinction between the feasibility of using the vHIT in infants aged from 6 months from a practical perspective and the effectiveness of the technique for diagnosing disequilibrium in this population.
9. Please amend to state that data will be retained for 10 years after the participant turns 16.
10. The consent form refers to a thesis. If some or all of the study is to be used towards a qualification this should be outlined in the Protocol and PIS.

**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:** | **2022 FULL 13045** |
|  | Title: | Comparison of two felodipine tablets under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Arrotex Pharmaceuticals Pty Limited |
|  | Clock Start Date: | 4th August 2022 |

Dr Noelyn Hung and Mrs Linda Folland 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 statement made in the submission that there would be benefit to Māori through increased access to the medicine. The study would not benefit Māori specifically as compared to other ethnicities.
2. The Committee clarified that the product would likely be also registered in New Zealand and not just Australia.
3. The Committee clarified that the use of pain medication (such as ibuprofen and paracetamol) would be tracked by the research team but that it would not be restricted should there be a need for some form of pain relief.
4. The Committee clarified the pre-dose blood samples would be to develop a standard curve to validate the dosing.
5. The Committee clarified the required duration for fasting was four hours and this would be sufficient and would not affect the absorption of the study drug.
6. The Committee clarified the fasting and sampling intervals.

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

1. The Committee queried who the manufacturer of the generic drug would be. Please detail this in the PIS.
2. Please specify how many people will be in each bedroom for the extended stay and how the rooms will be organised by age and gender.

**Decision**

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

* 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:** | 20th September 2022 |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting.

* Dr Andrea Forde

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 2:05pm.