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| **Committee:** | Northern A Heath and Disability Ethics Committee |
| **Meeting date:** | 17th May 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 EXP 12593 | Experiences of injuries to the head and neck following domestic violence | Professor/Dr Alice Theadom | Dr Kate Parker & Ms Catherine Garvey |
| 1.00-1.30pm | 2022 FULL 12102 | TO EVALUATE OCRELIZUMAB IN PATIENTS WITH MULTIPLE SCLEROSIS | Doctor Kurien Koshy | Dr Andrea Forde & Mr Jonathan Darby |
| 1.30-2.00pm | 2022 FULL 12534 | Cymabay CB8025-31731-RE ASSURE | Dr Steven Johnson | Dr Sotera Catapang & Dr Leonie Walker |
| 2.00-2.30pm | 2022 FULL 12504 | Rectal concentrations of thioguanine in inflammatory bowel disease 2 | Professor Murray Barclay | Ms Jade Scott & Mr Jonathan Darby |
| 2.30-3:00pm |  | *Break (30 minutes)* |  |  |
| 3:00pm-3.30pm | 2022 FULL 11325 | SONIC - Study Of Neck Injuries In Children | Professor Stuart  Dalziel | Dr Kate Parker & Dr Leonie Walker |
| 3.30-4.00pm | 2022 FULL 11411 | ION-682884-CS13/Open-Label, Extension Study to Assess the Long-Term Safety and Efficacy of ION-682884 | Prof Edward (Ed) Gane | Dr Andrea Forde & Mr Jonathan Darby |
| 4.00-4.30pm | 2022 FULL 12162 | The CI-DEX Study | Associate Professor Holly Teagle | Dr Sotera Catapang & Ms Catherine Garvey |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Karen Bartholomew | Non-lay (Intervention studies) | 18/07/2016 | 18/07/2019 | Present |
| 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) | 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 |
| 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 |

## 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 19th April were confirmed.

## New applications

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| **1** | **Ethics ref:** | 2022 EXP 12593 |
|  | Title: | Experiences of injuries to the head and neck following domestic violence |
|  | Principal Investigator: | Professor/Dr Alice Theadom |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 9th May 2022 |

Dr Alice Theadom and Magedlena Durrant 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 was assured that potential participants are only approached after expressing their interest through advertisements.
2. The Committee was assured that a follow-up plan was in place for those who provide information to the researcher regarding their head or neck injury which indicates they may require follow up.
3. The Researcher’s ongoing efforts for engaging with Pacific communities for consultation were noted.

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 to see the webpage that is linked through the advertisements.
2. The Committee noted the inconsistency in the Data Management Plan (DMP) regarding data being shared with collaborators overseas. It states that New Zealand data will not be shared, however states elsewhere that de-identified data may be accessed and used by overseas collaborators. Please clarify and amend for consistency in the DMP and also make clear the intention to share de-identified data in the participant information sheet (PIS).
3. Please put in the DMP and PIS that the information for this part of the study will feed into the second part of the study.
4. The Committee requested a version of participant-facing information be developed in the event there are any impairments among potential participants as a result of their injuries.
5. Please clarify if there will be risks involved surrounding sensitive issues or stigmatising participants.

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

1. Please clarify the process for getting a copy of the transcription.
2. Please review for formatting such as headings clipping into paragraphs.
3. Please ensure participants know de-identified data will be going to overseas collaborators and where they are located.
4. Please ensure the limitations on counselling that may be available to participants through AUT are clearly explained. The consent form has reference to significant abnormal findings being sent to the participant’s GP. Given the study is not clinically assessing participants, please rephrase this or remove. If this item remains, this needs to be raised first in the main body of the PIS.

**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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Kate Parker & Ms Catherine Garvey.

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| **2** | **Ethics ref:** | **2022 FULL 12102** |
|  | Title: | TO EVALUATE OCRELIZUMAB IN PATIENTS WITH MULTIPLE SCLEROSIS. |
|  | Principal Investigator: | Doctor Kurien Koshy |
|  | Sponsor: | IQVIA RDS PTY LTD |
|  | Clock Start Date: | 09 May 2022 |

Kate Ives and Ruth Mylchreest 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 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 study is a 3-year extension of a registered medicine to collect long-term safety and efficacy data. They queried why this is going to SCOTT for review and why quality of life surveys are not included in a study on MS.
2. A significant ethical risk is of identification of the sole NZ participant.

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

1. Please quantify the risk of death in the PIS.
2. Risk of infection (URTI/LRTI) excludes Covid. This needs to be added if the data is available. There is also no mention of reactivation of Epstein-Barr virus (EBV).
3. The Committee suggested expansion on the live vaccinations as these seem US-centric.
4. The Committee noted that a study cannot be stopped in the commercial interests of the Sponsor in New Zealand. Please amend.
5. Please ensure headings are white text on blue bars for readability.
6. Under what are my rights, please include a statement that participants in research are also covered by the HDC code of rights.
7. The Committee requested that information from the Data and Tissue Management Plan (DTMP) that outlines where samples and imaging are going should be outlined in the PIS for the participant~~.~~

**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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Andrea Forde & Mr Jonathan Darby.

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| **3** | **Ethics ref:** | **2022 FULL 12534** |
|  | Title: | Cymabay CB8025-31731-RE ASSURE |
|  | Principal Investigator: | Dr Steven Johnson |
|  | Sponsor: | CymaBay Therapeutics, Inc. |
|  | Clock Start Date: | 09 May 2022 |

No Researcher 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 medicine is likely to benefit participants, although this is not stated in the submission. The Committee queried if it will be made available to participants at the conclusion of the study.
2. The Committee requested a contact card be provided to participants so they can easily contact the study team due to the side-effect profile, with some being severe, and to alert any treating physicians.
3. Please clarify the number of New Zealand participants who were on seladelpar and when that stopped (or if any resumed) as this will impact the wording in the participant information sheet (PIS).
4. Please clarify the correct study title. The application has RE ASSURE but PISs have ASSURE.
5. Please ensure that the insurance is New Zealand specific/names New Zealand as a territory.
6. The Committee raised the following concerns about the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8)*:
   1. Please clarify if participants from previous PBC study who took the drug dose which is safe, tolerable and effective for them will receive the same dose in this ASSURE study.
   2. The Committee also queried the dose adjustment and whether the adjustment from 10mg to 5 mg or vice-versa will not affect the primary objective to determine the dose which is safe, tolerable and effective to be used for long period of time.
   3. For participants who tolerated UDCA therapy, the study drug will be an add-on to this group, while for those with UDCA intolerance, the study drug will be given as monotherapy (heterogenous population). The Committee queried if this would affect the efficacy objective of the study.
   4. Please detail how missed doses and compliance at home will be handled aside from accountability during clinic visits.
   5. Please clarify how often a liver biopsy is required in practice.
   6. Please clarify if a liver biopsy performed no more than 6 months prior to the screening is sufficient to determine the status of the liver and if this could be used in the stead of subsequent biopsy in the screening process. Please clarify who will make contact if concerns are found in order to separate usual care from study physical to avoid potential compliance pressures.
   7. Please specify location of central laboratory mentioned under study procedures.
   8. Please specify back-up blood sample collection in terms of indication and amount per time point.
   9. The Committee queried if PK testing is an optional lab test that needs participant’s consent.

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

1. Page 2 mentions "This is an open-label study. You and your doctor will know which dose of seladelpar you will receive." but page 22 mentions "However, in order to protect the scientific integrity of the study, the treatment you received in this study needs to remain unknown (i.e., blinded) until the study data are analysed.” Please correct.
2. Please remove repetition of explanations regarding visit assessments and consider using a table of assessments/visits. Please cast the following into a table for better understanding and organization of events
   1. study visits and procedures
   2. the different laboratories overseas with the specific test/s to be performed
3. Please clarify if all liver biopsies are optional.
4. Please append consent to PK analysis which is mentioned in the information sheet.
5. Please delete choices in the consent form for informing GP/Local doctor since it is mandatory.
6. Please make a brief and concise description/s for each section/topic to avoid a lengthy PIS which may lead to participant’s misunderstanding or confusion or nonparticipation.
7. Please refer to previous studies by the names the participants will know them by.
8. Please ensure the document is fit for the New Zealand context e.g. around screening (presumably all would require if no-one is currently on, or very recently received seladelpar); remove reference to any third party vendors that aren't being used; replace racial origin with ethnicity; state if Fibroscan available.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Sotera Catapang & Dr Leonie Walker.

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| **4** | **Ethics ref:** | **2022 FULL 12504** |
|  | Title: | Rectal concentrations of thioguanine in inflammatory bowel disease 2 |
|  | Principal Investigator: | Professor Murray Barclay |
|  | Sponsor: | Barclay Gastroenterology |
|  | Clock Start Date: | 9th May 2022 |

Professor Murray Barclay 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 recommended ensuring the patients are aware another doctor independent of the study is available to answer questions and how they can contact a doctor. Please ensure the protocol has more detail about the informed consent process i.e. they will have time to consider their decision and someone to talk to with questions.

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

1. Please provide approximate length of day 8 appointment.
2. Under risk section there is no mention (as rare or unlikely it is) of perforation risk of flexible sigmoidoscopy. Please add.
3. Mention that deidentified data will be sent to Australia and the Netherlands. Please also add the HDEC templated wording around risks and cultural issues of data going overseas.
4. Please state how long the data will be retained.
5. Amend under compensation “may not” to “would not”
6. Please clarify whether fasting is needed before sigmoidoscopy or any blood tests.

**Decision**

This application was *approved with non-standard conditions* 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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| **5** | **Ethics ref:** | **2022 FULL 11325** |
|  | Title: | SONIC - Study Of Neck Injuries In Children |
|  | Principal Investigator: | Professor Stuart Dalziel |
|  | Sponsor: | N/A |
|  | Clock Start Date: | 9th May 2022 |

Professor Stuart Dalziel and Ms Eunicia Tan 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.

Dr Leonie Walker member declared a potential conflict of interest due to working with Australasian College of Emergency Medicine, however noted that she did not have any knowledge or direct working relationship with the clinicians involved. The Committee agreed this did not register as a conflict of interest and decided to proceed as normal.

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 approved the waiver of consent that is required to conduct this study, and the use of verbal consent for follow up. The Committee requested that any relevant information raised by the participants will be followed up directly with the participant.

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

1. The Committee noted that the current PIS may be too complicated for younger children to understand. The Researcher noted that they would discuss the PIS and/or assent form with the participants, however the Committee requested that a simplified version also be offered.
2. Please provide more detail explaining to participants that the study will not affect their normal standard of care.
3. Please review and update the advocacy emails as they are out of date.
4. Please consider removing any duplicate information (i.e. in the ‘how is the study designed’ section).

**Decision**

This application was *approved with non-standard conditions* 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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| **6** | **Ethics ref:** | **2022 FULL 11411** |
|  | Title: | ION-682884-CS13/Open-Label, Extension Study to Assess the Long-Term Safety and Efficacy of ION-682884 |
|  | Principal Investigator: | Prof Edward (Ed) Gane |
|  | Sponsor: | Ionis Pharmaceuticals Inc & Pharmaceutical Research Associates New Zealand Limited |
|  | Clock Start Date: | 9th May 2022 |

Prof Ed Gane & Jodi Van Dyk 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 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 administering the study drug at home for the eligible participant, and whether a caregiver administering the drug is an option. The Researcher explained that they anticipate that the participant will have access to a nurse who can administer the drug if the participant wants to take the option but in the parent study has been attending clinic for this. The Committee requested that there is appropriate cover from the study sponsor in the event of a caregiver possibly incorrectly administering the drug.
2. The Committee raised the statement regarding the Sponsor reserving the right to terminate the study due to commercial reasons, which is not permitted in New Zealand (National Ethical Standards for Health and Disability Research and Quality Improvement*, para 11.37*).
3. The Committee noted that it would be preferable for participants already taking part in a parent study to have an independent contact regarding rolling over into the extension study.
4. The Committee queried whether the identifiers listed on the participant’ identification card are necessary (i.e. full name and study number). The Researcher agreed that both identifiers did not need to be displayed and would discuss amending the Participant Card with the Sponsor.
5. Please replace references to teaspoon measurements to millilitres.

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

1. The Committee asked how long the compulsory in-person consultations were expected to take and requested that this is added to the PIS to ensure that the participant knows of the time commitments.

**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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| **7** | **Ethics ref:** | **2022 FULL 12162** |
|  | Title: | The CI-DEX Study |
|  | Principal Investigator: | Associate Professor Holly Teagle |
|  | Sponsor: | Cochlear Ltd |
|  | Clock Start Date: | 9th May 2022 |

Associate Professor Holly Teagle was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researcher clarified for the Committee that there are study sites in Auckland, Christchurch, and Wellington. This is due to recruiting through sites that are publicly funded to provide cochlear implants.
2. The researcher clarified that the Study Sponsor is the contracted preferred provider contract of cochlear implants for NZ.
3. The Committee asked for clarification on the availability of the cochlear implant and whether declining participation into the study would impact a person’s ability to access an implant. The Researcher confirmed that declining the study would not impact an individual’s ability to access an implant as it is a publicly funded service.

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 more information regarding the recruitment process, noting that the protocol states that there may be issues with cognitive impairment. The Researcher explained that each centre is a 12-month enrolment for each participant, with a balance of participants across all global sites. The Researcher explained that there is cognitive screening for potential participants, however this is not conducted as an exclusionary procedure; it is to identify clinical management and support for participants (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.7)*
   1. The Committee requested that special consideration is given towards participants ability to give informed consent if they are identified with having a cognitive impairment, such as ensuring that they are aware it is a blinded study, any potential risks and expected follow-ups from the study. Please consider using the *National Ethical Standards for Health and Disability Research and Quality Improvement* guidelines for supported decision making (*para 5.11*).
   2. The Researcher noted that there have been some minimal requirements which have been included in the study, however these will be confirmed by the study Sponsor.
2. The Committee asked for clarification on which follow-ups would be additional to the usual standard of care after a typical cochlear implant operation. The Researcher explained that there are two additional follow-ups for participants who receive the study device. The Committee requested that anything outside of the usual standard of care is explicitly outlined in the protocol and any participant-facing materials (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 18.9 – 18.10).*
3. The Committee noted that the representatives from the Sponsor will be involved in the study surgery and post-follow up sessions. The Researcher explained that the Sponsor are funding a clinical researcher (likely an Audiologist) to collect data for the study. The Researcher noted that this person will not have a role in the participant’s clinical care. The Committee requested that this is made clearer in participant-facing documentation.
4. The Committee queried the statements that the Sponsor will have access to participant’s identifiable data by virtue of the fact that they receive the Sponsor’s control or study device. Please reconsider this or ensure that this is clearly outlined and justified to participants.
5. The Committee noted that this is a first-in-human trial and noted that there was a pilot study using the dexamethasone eluting electrode. The Researcher confirmed this and explained that dexamethasone has been used in the past when fitting cochlear implants. The Committee noted that some participants may receive the control device without the eluting array and would not be able to receive dexamethasone administered into or near the ear. The Committee asked for clarification regarding standard of care in terms of location/mode of dexamethasone administration with a cochlear implant and whether in fact control participants would receive standard of care. The Committee also queried whether administering dexamethasone other than in or near the ear poses any risks. The Researcher stated that they would discuss this with the study Sponsor.
   1. The Committee asked for clarification on whether there is a risk of any increase in impedance without using dexamethasone in or near the ear. The Researcher noted that the use of dexamethasone varies across sites, however they would follow this up with the Sponsor and PI.
   2. Please clarify elution period 28 days or 30 days and the basis for this duration, and any impacts this timeframe may have on the dexamethasone (i.e. whether the dexamethasone will be replaced after 28 days in order to continue reduction of tissue growth). The Researcher explained that there would be no replacement dexamethasone and based on previous studies, evidence suggests that the impedance values for most recipients will be stable over time.
6. The Committee noted that pregnant and lactating parents are excluded from the study and requested more information. The Researcher stated that they would follow this up with their team.
7. Please provide evidence of New Zealand-specific insurance (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.5*).
8. Please consider using the Data Management Plan template on the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/), as this will ensure that all relevant sections are answered.
9. The Committee asked whether the trial would provide more opportunities for New Zealanders to receive cochlear implants or whether the trial might impact on the availability of cochlear implants to those who are on public lists but do not participate in the trial. The Researcher explained that the study may potentially increase the number of devices available in New Zealand, however noted that some of the funding would not cover more than the 60 allocated participants in the trial. Any remaining funds will be reserved for upgrades to the external and internal processors. The Committee requested that this is clarified in the study documents and any participant-facing materials.

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

1. Please provide a lay title for the study and ensure that this is used in participant-facing documents.
2. Please include a black box warning at the beginning of the PIS explaining that this is a first-in-human trial, and outline what this may mean to the participant.
3. Please provide more detail explaining the role of the Sponsor’s research assistant, especially outlining that they will not be involved in the participant’s clinical care.
4. Please outline what it may mean for the participant being unable to receive dexamethasone in or near the ear because of taking part in the study.
5. Please cast the study assessments and schedule of activities/visits in a table for a better understanding and organization.
6. Please provide more information on which follow-ups will be additional to the usual standard of care for taking part in the trial.
7. Please clearly state what information will be made available to the study sponsor (I.e., identifiable information, who has received the study device, etc). Please justify why the Sponsor needs access to identifiable information.
8. Please provide the name and address of the US core laboratory that will review the scan. Please also include information on what will happen after the review of the scan (i.e. will it stay in the US laboratory or sent back to New Zealand).
9. Please ensure that the standard of care information is relevant to New Zealand (i.e. vaccines that are required prior to cochlear implants).
10. Please provide more information of any expected expenses and what will be covered by the study, the participant as out of pocket costs, or DHB.
11. The Committee requested that an independent person be made available for the participant to discuss the study with prior to consenting.
12. Please ensure that anything mentioned in the CF is reflected and discussed in the PIS.
13. Please remove reference to the Medicines Industry Guidelines from the compensations section as these do not cover devices.

**Decision**

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

## General business

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

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| **Meeting date:** | 21st June 2022 |
| **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 4:30pm.