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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 5 March 2024 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Assigned Lead Reviewers** |
| 11.30am-12.00pm | 2024 FULL 19695 | Clinical trial of V940 and pembrolizumab in people with resectable locally advanced cutaneous squamous cell carcinoma | Dr Gareth Rivalland | Ms Kate O’Connor & Mrs Leesa Russell |
| 12.00pm-12.30pm | 2024 FULL 19004 | Manaaki Mamao (Remote Care) | Mrs Tiffany Neary | Mr Barry Taylor & Dr Amber Parry-Strong |
| 12:30pm-1:00pm | 2024 FULL 19714 | Evaluation: Improving Access to Gender- Affirming Care – Community Drive Models of Care | Dr Tim Antric | Ms Joan Petit & Ms Alice McCarthy |
| 1:00pm-1:30pm | 2024 FULL 19007 | Home-based biofeedback training in children with cerebral palsy | Dr Ksenia Bykova | Ms Maakere Marr & Mr Barry Taylor |
| 1:30pm-2:00pm |  | Break 30 minutes |  |  |
| 2:00pm-2:30pm | 2024 FULL 18096 | Teaching Health Transition Skills in Schools | Dr Rachel Howlett | Mr Ewe Leong Lim & Mrs Leesa Russell |
| 2.30pm- 3.00pm | 2024 FULL 19550 | CA057-001: A clinical study comparing Mezigdomide, Bortezomib, and Dexamethasone Versus Pomalidomide, Bortezomib and Dexamethasone in participants with multiple myeloma | Dr Marie Hughes | Ms Kate O’Connor & Dr Amber Parry Strong |
| 3.00pm- 3.30pm | 2024 FULL 19634 | reACHin | Prof Paul Hofman | Ms Alice McCarthy & Ms Joan Petit |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Kate O’Connor | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |
| Mrs Leesa Russell | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Alice McCarthy | Lay (the Law) | 22/12/2021 | 22/12/2024 | Present |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Mr Ewe Leong Lim | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |

## Welcome

The Chair opened the meeting at 10am and welcomed Committee members, noting that no apologies had been received.

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 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 19695** |
|  | Title: | A Phase 2/3, adaptive, randomized, open-label, clinical study to evaluate neoadjuvant and adjuvant V940 (mRNA-4157) in combination with pembrolizumab (MK-3475) versus standard of care, and pembrolizumab monotherapy in participants with resectable locally advanced cutaneous squamous cell carcinoma (LA cSCC) (INTerpath-007) |
|  | Principal Investigator: | Dr Gareth Rivalland |
|  | Sponsor: | Merck Sharp & Dohme (Australia) Pty Ltd |
|  | Clock Start Date: | 22 February 2024 |

Mr Ray Ge, Ms Nivi Sinha and Dr Gareth Rivalland were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that there is only one site in New Zealand.
2. The Committee queried how the study would be equitable given the only site is a private clinic. The Committee was concerned about the equality of access and how this may be distributed given this is a personalised medicine that may come at some cost. The researcher noted that there was no cost to participants to participate in the trial because of funding from the sponsor. Oncologists nationally would be able to forward their patients to this clinic but the barriers extant in this case would largely be the ability to travel to the centre for the trial.
3. The Committee queried the Māori review process and was reassured that there was a person on call for contact for Māori cultural issues for those who may need it.
4. The Committee requested and received clarification as to the nature of the site and how the clinic worked, what kind of trials occur in this site, who works there and how the trials are run by the clinicians on staff.
5. The Committee clarified how medical emergencies were managed at the clinic.
6. The Committee clarified that should patients that are already privately funding surgeries be part of the trial this would go ahead as per that participants planning. The care for the patient would not be impacted. There may, however, be a change in the likelihood of surgery as a result of the study intervention.
7. The Committee clarified that travel would be compensated.
8. The Committee clarified that the referral would be equally available in both public and private specialist clinics.
9. The Committee clarified that all scans were contracted to a provider that would be separate from the public system so not to increase potential public system burden.
10. The Researcher noted that there is currently no standard of care for these participants beyond resection.

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 in the protocol there was mention of pictures being taken of the tumours. Given many of these tumours may be located around the face the Committee requested that there be a plan around deidentifying the images given how identifiable these images could be. Please also ensure that should Māori participants have Tā moko/Mataora/Moko Kauae that the cultural significance of this be acknowledged.
2. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
   1. Please specify where the deidentified data will be sent in the US.
   2. Please specify/identify what organisation or site policies and procedures are relevant. A privacy policy should be included alongside the rest of these.
   3. Please amend so that the “The [Biobank Name] Biobank” is specified. If there is no biobank, then this will need to be removed. If tissue is being used from a biobank for testing or comparator purposes, then this should be made clear.
   4. If there is to be future unspecified research on tissue this will need to be added to the application via the HDEC amendment pathway.

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

1. Please clarify that there is an experimental treatment and an approved one to be used in this study. Where referring to the experimental treatment please be consistent and use words such as “study drug” or “investigational drug” and not “treatment”.
2. Please clarify the statement “V940 and pembrolizumab are treatments that work with the body’s own immune system to fight cancer” to be in line with the above point around naming this an experimental or study drug and amend the intent to “fight” cancer.
3. Where describing the 2 experimental arms, please make it clear that the sequence is drug, surgery/RT and drug. Stating this is standard of care is not sufficient. Please make it clearer how there is no current standard of care for these participants.
4. Please ensure that the site-specific information is placed into the templated areas as appropriate as there is only going to be one site in New Zealand.
5. Please include contact details for the Māori cultural support. This should be done ahead of the meeting in future as documents reviewed by HDECs should be finalised.
6. Please clarify that the pre-existing plans for surgery of private or public funded participants would be done as planned. The research team would be conducting the study externally to the plans already in place.
7. Please make clear which procedures are research-only versus SOC.  If all are SOC, make that clear.
8. Make clear that participants may continue on the study drug they are randomized to; if they are in the SOC arm, there is no drug provided

**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 Ms Kate O’Connor and Mrs Leesa Russell.

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| **2** | **Ethics ref:** | **2024 FULL 19004** |
|  | Title: | Manaaki Mamao - to care from a distance |
|  | Principal Investigator: | Mrs Tiffany Neary |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 February 2024 |

Mrs Tiffany Neary, Kwan-Lyn Lim and Ms Bridget Dicker 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 queried whether the researcher was intending on doing quality assurance or research. The researcher noted that they wished to publish this 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 noted that the consent suggested in the initial leaflet about the service was not voluntary and not informed sufficiently. Therefore, the Committee requested sufficient justification as to the waiver of consent. As the information sheet is already in use then this cannot be reviewed by HDEC as this would be retrospective review. The Committee suggested reading the NEAC standards to see what is required for a waiver of consent, and incorporating these justifications into the Data Management Plan for retrospective patients.
2. The Committee noted that St John will need to be listed and confirmed as a sponsor for this study and provide authorisation to HDEC as an approved activity within the organisation.
3. The Committee clarified that there would need to be an amending to the documentation that had been provided and that the consent for research provided would not be able to be provided for HDEC and this would not be approved by the Committee.

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

1. Please amend the patient form to include a consent option for data use for research. Please note however that while this may better support the inclusion of prospective patients in the review of the service, this does not constitute HDEC approval of the information sheet.
2. Please include information around privacy and data use. The Committee also requested that if there was an opportunity for people to receive the service without giving consent to be included in the research that this be provided.

**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 Amber Parry-Strong and Mr Barry Taylor.

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| **3** | **Ethics ref:** | **2024 FULL 19714** |
|  | Title: | Improving Access to Gender- Affirming Care – Community Drive Models of Care |
|  | Principal Investigator: | Dr Tim Antric |
|  | Sponsor: | Hemishpere Inc |
|  | Clock Start Date: | 22 February 2024 |

Ms Brooke Hayward 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.

Mr Barry Taylor declared a potential conflict of interest and the Committee decided to continue with the member in the conversation as there was no actual conflict.

Summary of resolved ethical issues

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

1. The Committee clarified that the study was largely concerning the codesign of future pathways, while also collecting anonymous data from those who have already received services.

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 the recruitment of staff into the research and how their confidentiality would be protected. The Committee also queried the inclusion of a written participant information sheet/consent form (PIS/CF) for those staff participating. This form needs to be submitted for review. Please also include a recruitment plan for these staff participants in the protocol.
2. The Committee queried the use of the word “evaluation” in this study as there is no evaluative component of the study as such. It is presented as a process for generating new models of care.
3. The Committee noted that Hemisphere is the sponsor and should be identified and authorised by a Senior Executive of that organisation.
4. The Committee requested that future changes or creation of tools or new models of care be submitted for review for HDECs via the amendment pathway before they are implemented as part of research.
5. The Committee requested that the community focus group PIS/CF be provided for review.
6. The Committee requested that the peer review be provided in a format such as a PDF or a Word document. The Committee noted that the peer review was not adequate as it is not independent scientific review. Please ensure that this review is provided and adequately addresses the methodology and the science of this application.
7. The Committee requested the advertisements for review.
8. The Committee requested a safety plan and details of the support available for participants post-interview. This should be included in the protocol and also detailed in the PIS/CFs.
9. The Committee requested that the researcher be specific about the word “koha” and what they actually mean when referring to this.
10. The Committee requested that the survey states that it is completely anonymous.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please provide the advertisements. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*
5. Please provide an independent peer review. The [HDEC peer review template](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) can be used *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Joan Pettit and Mrs Alice McCarthy.

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| **4** | **Ethics ref:** | **2024 FULL 19007** |
|  | Title: | Feasibility and effectiveness of a home-based training protocol to enhance swallowing skills in children with cerebral palsy: A pilot project |
|  | Principal Investigator: | Dr Ksenia Bykova |
|  | Sponsor: | The University of Canterbury |
|  | Clock Start Date: | 22 February 2024 |

Ksenia Bykova 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 that participants in study 1 could roll over into study 2.

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 term “Kaupapa Māori” means by Māori, with Māori and for Māori. Given the way in which this is being conducted this is not accurate. There will also be Pasifika/Talanoa input as well as other groups. Hui as a concept is also not Māori specific and it largely related to a mode of engagement and communication and whilst a lot of thought has been put into this there is some fundamental misunderstanding of what this means.
2. The Committee requested an explanation as to the journey the model of care has been through and what makes it appropriate to become home-based. The researcher noted that this had been conducted in healthy children and adults with good efficacy. The Researcher noted that the home-based model works better with the lives of these participants as it can be difficult to transport these participants. Please include this relevant information in the Protocol and participant information sheet/consent form (PIS/CF) and please specify why this may be beneficial to participants and ensure there is a clear explanation that there will be clinical support should the parents require it. *National Ethical Standards* para *9.7a*- *9.8.*
3. The Committee queried what tests were standardised and validated and all of these tests should be validated prior to this study. The Committee recommended that the population, the tests and the people provided the treatment needs to be assessed and explored and documented prior to the undertaking of this trial. The researcher noted that this was being looked into in two other studies. The Committee noted that this should be robustly done and should be finalised prior to this study being undertaken. The Committee needs to be provided all of this information in detail to be sufficient for HDEC review.
4. The Committee requested independent scientific peer review from a paediatrician who works with children with Cerebral Palsy. Please note this is required for approval. *National Ethical Standards* para *9.25-9.32.*
5. The Committee queried what the potential cost of the phone app will be and who will be providing this. Please include this in the Protocol. *National Ethical Standards* para *9.7a & 9.8.*
6. The Committee requested information as to the incidence of cerebral Palsy in Māori and Pasifika people. *National Ethical Standards* para *3.1 & 3.10.*
7. The Committee informed the researcher that the collection of ethnicity data is required per the NEAC standards. *National Ethical Standards* para *9.10 & 9.20.*
8. The Committee requested provision of a researcher safety plan addressing the concerns raised by the Committee *National Ethical Standards* para *11.62*.
9. The Committee requested that the reimbursement provided for children is child-specific, compensation in fuel vouchers or supermarket vouchers. This should be an age-appropriate voucher so that the child could choose for themselves.
10. The Committee noted that the research manager in the research and innovation office needs to be named as the sponsor as this person is the one who should be named as sponsor, not the PI.
11. The Committee queried the use of students in the research. The Committee requested assurance that there would be protections for those students by the dean of their school or otherwise to ensure that they are not disadvantaged for working in the study.
12. The Committee queried how the competency of the parents and guardians to deliver the intervention by themselves at home will be assessed and maintained.
13. The Committee requested the use of the data management plan (DMP) per the guidance of the [HDEC DMP template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx). In particular, please provide more information as to the phone app, who owns and developed it, how parents will have or be given access to it, where the data is collected and stored, and who will have access to that data. *National Ethical Standards* para *9.7- 9.8.*
14. The Committee suggested that the application resubmission only include study 1. The second phase of the study should be undertaken after review of the safety from the first phase. Study 2 can be submitted as an amendment at a later date. *National Ethical Standards* para *8.3.*
15. The Committee noted that it should be mandatory for the participant’s general practitioner (GP) to be informed of their participation and that this should be amended per this recommendation in the PISCF. *National Ethical Standards* para *7.15.*
16. The Committee requested the provision of a consent form for participants over the age of 16. *National Ethical Standards* para *7.19 & 6.25- 6.27.*
17. The Committee suggested that in the sentence “You’ll see a video about bears” you make this a cartoon video as this may be a bit more interesting to the younger age group.

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

1. Please amend wording to ensure it reads as the parent giving consent for their child where this is the case. Please ensure this is separate from the consent the parents and guardians give as participants themselves. *National Ethical Standards* para *7.16.*

**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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| **5** | **Ethics ref:** | **2024 FULL 18096** |
|  | Title: | Assessing the acceptability and feasibility of using the Aotearoa New Zealand Health Transition Skills list to create a health transition learning goal as part of the individualized education plan of young people with neurodevelopmental disability. |
|  | Principal Investigator: | Dr Rachel Howlett |
|  | Sponsor: | Starship Childrens Hospital |
|  | Clock Start Date: | 22 February 2024 |

Dr Rachel Howlett and Ms Fiona Langridge were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the study was as part of the Starship Foundation Fellowship and part of the research PIs training/education. The researcher noted that this was not as part of a university qualification.
2. The researcher clarified how this project has translated the skills already as part of a toolkit developed by a number of clinicians at Starship.
3. The Committee noted that the justification for assenting children over the age of 16 was acceptable and accurate as a form of supported consenting for these participants who may be cognitively impaired.
4. The Committee queried why the children are not considered to be participants in the study. The Committee suggested perhaps there may be some way of the children providing feedback. The researcher noted that the young people will be asked for feedback in part of another study that could be an amendment to this 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 requested that the University of Auckland Research Office be consulted around being made or recognised as the sponsor. The Committee noted that this may be the most appropriate way forward even if their role is indirect in terms of governance.

**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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| **6** | **Ethics ref:** | **2024 FULL 19550** |
|  | Title: | A Phase 3, Two-Stage, Randomized, Multicenter, Open-label Study Comparing Mezigdomide (CC-92480), Bortezomib, and Dexamethasone (MeziVd) Versus Pomalidomide, Bortezomib and Dexamethasone (PVd) in Subjects with Relapsed or Refractory Multiple Myeloma (RRMM): Successor-1 |
|  | Principal Investigator: | Dr Marie Hughes |
|  | Sponsor: | Bristol Myers Squibb |
|  | Clock Start Date: | 22 February 2024 |

Dr Marie Hughes, Ms Danni Hacking, and Mr Charlie Stratton were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the endpoint including the number of participants whose lives have ended was due to the severity of those included in the study.
2. The Committee clarified that the median age for these participants would be 65 years old.
3. The Committee noted that as this study drug is a known teratogen (potential for risk to foetal development) the pregnant participant and pregnant partner forms had been reviewed.
4. The Committee noted that there was a potential advantage for participants as there are very few funded options for people with this disease.
5. The Committee suggested that per the disproportionate burden to Māori and Pasifika communities, over-recruiting of these populations would be encouraged.

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 a separate optional future unspecified research information sheet be provided for review. Please refer to the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/future-unspecified-use-tissue-piscf-template-v4.0april2023.doc) for this optional form.
2. The Committee noted that C4 of the application form seeks to know how Māori may benefit specifically. The Committee recommended including any statistics of the prevalence of the disease in Māori (or an explanation if unknown) when answering C4 for any future applications.
3. The Committee noted the answer to C4 in the application form was patronising and requested the Researcher be mindful of this for any future applications. The Committee explained that Te Tiriti ō Waitangi should not be cited as a health benefit and equal access to participate for Māori should not need to be stated as this is the default expectation. The Committee recommended including any statistics of the prevalence of the disease in Māori (or an explanation if unknown) when answering C4 for any future applications.
4. The Committee noted that ethnicity data would not be collected per the submission. Standard 9.10 and 9.20 states all researchers conducting health research in New Zealand must collect good quality ethnicity data unless there is valid justification as to why this is not necessary. As no justification has been supplied this study must collect this data.
5. The Committee noted the study is not significantly powered due to recruitment for the incidence per ethnicity to be concluded as a main outcome.
6. The Committee queried the reasoning for not blinding the participants to what arm they are in the study. The Committee requested justification of this from the research team and sponsor.
7. The Committee noted that Whole Genome Sequencing as mentioned in the submission is mandatory. Please justify this as part of the study’s primary objectives or amend as necessary as there is also optional tissue work in the additional PISCF. The genome sequencing should be optional if possible and cultural and data risks acknowledged.

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

1. Please refer to the study intervention and drug as such. Where “treatment”, “treatment arm” or “treatment visit” are mentioned, please change this to “study”, “study arm” and “study visit” etc.
2. Please amend the wording on page 2 “If you do not want to participate in any or all follow-up activities, you must inform your study doctor in writing and clearly identify the activities you do not want.”. Please remove “in writing”.
3. Please move the withdrawal information to later into the PISCF, as the purpose of the study should be moved before this. Please refer to the [HDEC PISCF template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for guidance on the expected order of information.
4. Please include information clarifying that withdrawal or not wishing to participate in optional research is done in a separate PISCF.
5. Please remove on page 6, "HIV test (only if this is required by applicable law)", and page 7 "screening test for HIV (only required if locally mandated)" as this is not relevant or applicable in the NZ context.
6. Please place emphasis on the statement on page 23 of “likely to cause birth defects in humans” This should be in bold at the very least.
7. Please include a table of study visits and procedures to show what will be expected of participants and when. This will help comprehension of the study for participants as well as serve as a good guide for them to refer back to over the course of their participation.
8. Please clarify if the study drugs approved to treat myeloma in NZ approved individually for monotherapy or if they are only approved in combination.
9. Please clarify if the approved drugs are being given in the Standard of Care (SOC) doses or if those doses are different.
10. Please clarify which tests are performed as SOC and which are only done as part of the study. Please provide this information in context of what benefit there is to participating with regards to what is publicly funded and what would need to be privately funded outside of 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 Ms Kate O’Connor and Dr Amber Parry-Strong.

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| **7** | **Ethics ref:** | **2024 FULL 19634** |
|  | Title: | A Phase 2, Multicenter, Double-Blind, Randomized, Placebo-controlled Trial, evaluating Safety, Tolerability, and Efficacy of Subcutaneous Doses of TransCon CNP Administered Once Weekly for 52 Weeks in Infants (0 to <2 years of age) with Achondroplasia followed by an Open Label Extension (OLE) period. |
|  | Principal Investigator: | Prof Paul Hofman |
|  | Sponsor: | Ascendis Pharma, Pharmaceutical Solutions Ltd |
|  | Clock Start Date: | 22 February 2024 |

Prof Paul Hofman 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 that this is part of a programme of work already undertaken in this population. This trial is being done in younger populations to see the potential efficacy of this study intervention in this age group.
2. The Committee noted that the drug is not a “Me-too” drug but is an analogue of a drug currently licensed in Aotearoa, but that there is potential in this study to provide competition to that drug in New Zealand.
3. The Committee clarified that the vendor for the travel arrangements would be done through the research team and then sent to the vendor for reimbursement.

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 there was an advisory group within the disabilities community. The Committee suggests that for the longevity of this project it may be wise to develop a close relationship with a group such as the Little People of NZ, rather than just some one-off consultation.
2. The Committee requested clarification as to when analysis of outcomes will be done. Please include this in the protocol.
3. The Committee requested that the organisational (university) data governance structures be included rather than the current investigator responsibilities in the data management plan.

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

1. Please include a brief description of this study, the standard of care as it currently exists and the benefits to participants in being on this trial.
2. Please specify if any of the study tests are standard of care and disseminate between what is SOC versus study-only.
3. Please remove all reference of “treatment”. Please refer to this instead as “study” related aspects.
4. Please clarify that it is the parents who will be providing injections.
5. Please be clear about the vitamin D supplementation and that it will be provided by the study.
6. Please be cautious of the narrative around “fixing” people as this creates a narrative around this disabled community.
7. Please remove the requirement of receipts for travel expenses or amend as necessary if this is for meals etc.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Joan Pettit and Ms Alice McCarthy.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 2 April 2024 |
| **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 3:20pm.