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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 13 December 2022 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 10.30-11.00am | 2022 EXP 11947 | The LOLIPOP Trial | Dr Robyn Billing | Mr Dominic Fitchett and Dr Devonie Waaka |
| 11.00-11.30am | 2022 EXP 11434 | Hauora Manawa mō ngā Kaumātua me Whānau | Dr Andree Pearson | Ms Neta Tomokino and Ms Amy Henry |
| 11.30am-12.00pm | 2022 FULL 13860 | Paraprobiotics for sleep quality, stress, and gut health | Dr Jody Miller | Ms Dianne Glenn and Mr Barry Taylor |
| 12.00-12.30pm | 2022 FULL 13953 | AB-10-8001: A Study Evaluating AHB-137 in Healthy Participants and Participants with Chronic Hepatitis B. | Professor Ed Gane | Mr Dominic Fitchett and Dr Devonie Waaka |
|  |  | *Break (30)* |  |  |
| 1.00-1.30pm | 2022 FULL 13814 | The ENIVO Study | Dr Michelle Locke | Ms Dianne Glenn and Dr Patries Herst |
| 1.30-2.00pm | 2022 FULL 13947 | First in Human and Early Feasibility Clinical Study of the FloStent System | Professor Peter Gilling | Ms Neta Tomokino and Dr Devonie Waaka |
| 2.00-2.30pm | 2022 FULL 13797 | BN42489: A Phase II, dose-finding study in prodromal and early manifest Huntington’s disease patients | Professor Tim Anderson | Mr Dominic Fitchett and Mr Barry Taylor |
|  |  | *Break (10)* |  |  |
| 2.40-3.10pm | 2022 EXP 13841 | Testing a well-being app New Zealand high school students | Dr Hiran Thabrew | Ms Neta Tomokino and Ms Amy Henry |
| 3.10-3.40pm | 2022 FULL 13872 | ApproaCH: A phase 2b clinical trial to evaluate efficacy and safety of weekly doses of TransCon CNP compared with placebo in participants with achondroplasia aged 2 to 11 years of age | Dr. Paul Hofman | Ms Dianne Glenn and Dr Patries Herst |

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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 |
| Assc Prof Mira Harrison-Woolrych | Non-lay Intervention/Observational studies) | 28/06/2019 | 28/06/2020 | Apologies |
| Mr Anthony Fallon | Lay (Consumer/Community perspectives) (Chair) | 13/08/2021 | 13/08/2024 | Present |
| Mr Dominic Fitchett | Lay (the Law) | 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 | Present |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The Chair opened the meeting at 10am and welcomed Committee members, noting that apologies had been received from Associate Professor Nicola Swain and Associate Professor Mira Harrison-Woolrych  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Patries Herst and Mr Barry Taylor confirmed their eligibility and were co-opted by the Chair as a member 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 08 November 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 EXP 11947** |
|  | Title: | The Long-term Outcomes of Lidocaine Infusions for Post-Operative Pain Trial - The LOLIPOP Trial. |
|  | Principal Investigator: | Dr Robyn Billing |
|  | Sponsor: | Monash University |
|  | Clock Start Date: | 08 November 2022 |

Davina McCallister 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 there was some change to standard of care as indicated in the application. Clarification was provided as to the use of lidocaine in current standard of care, which was typically for acute pain management, whereas this use is primarily to prevent chronic pain that is largely unreported upon short term follow-up.
2. The Committee noted that the potential for direct benefit of the study in future applications can be reported even where the result of the study is uncertain as this will only be seen by the Committee and is not falsely promising results.
3. The Committee queried the main cultural issues that may arise during the study as C5 had not been answered in the application. The Researcher explained that they were cognisant of the fact that Māori and Pasifika patients tend to not share that they have breast cancer or surgery for this cancer with their whanau and communities. The Researcher noted that steps were being taken to help with this and improve the feelings of acceptance and improving the socialization around breast cancer and the diagnosis to recovery pathway.
4. The Committee clarified that, whilst the researchers would be utilising internal cultural support resources, the turn-around for these patients can limit their chances of receiving this support.
5. The Committee clarified that the sub-study will not be taking place in tandem with the main study. The Committee requested that, when this is undertaken, the cultural issues concerning biobanking, such as data as a tāonga, and the cultural significance of tissue, etc are dealt with at that time. The Researcher noted this will be sent through as an amendment.
6. The Committee noted that the study is intending to trial an approved medicine so none of the questions have been answered regarding compensation for participants in relation to study related injuries (due to the answer for question E9.2). The Committee determined that this study is covered by ACC as this is not a commercial study and the study is not being conducted principally for the benefit of the manufacturer or distributer of the medicine being trialled.
7. The Committee asked about the public website and the reference to the Australian information sheet, highlighting that once the study has HDEC approval, the participant information sheet for New Zealand participants should be uploaded to the website. The Researcher clarified it will be uploaded.

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 the following changes to the Data Management Plan (DMP):
2. Please amend the typo on page 4 (“breech” instead of “breach”).
3. Please remove square brackets throughout the data management plan.
4. Please ensure that there is consistency around whakapapa and that there is no confusion of use between Ngāi Tahu and Ngati Tahu.

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

1. On page 1, please replace ‘level’ with ‘incidence’.
2. On page 2, please replace ‘Participant Information and Consent Form’ with ‘PICF’ (as this has been defined previously).
3. On page 2, please correct typo “and a copy placed will be kept in your medical notes”.
4. On page 3, please correct typo “may have some of them effects listed below”.
5. On page 3, please delete reference to taking a blood sample.
6. On page 4, please delete reference to optional sub studies.
7. On page 4, please rephrase to make it clear that information collected up to the time of withdrawal will be kept and analysed (this is mandatory as per the application).
8. On page 5, please mention the koha when talking about reimbursement.
9. On page 5, please acknowledge the New Zealand lead site and New Zealand lead doctor(s).
10. On page 6, please remove square brackets.
11. On page 8, please delete bullet point relating to blood samples.
12. Please make it clear that the participant and research team will not know whether the participant has received lidocaine or placebo, and tate whether the participant can be informed of the study drug arm allocation once the study has ended.

**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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| **2** | **Ethics ref:** | **2022 EXP 11434** |
|  | Title: | Hauora Manawa mō ngā Kaumātua me Whānau/Heart Health in Kaumātua and Whānau |
|  | Principal Investigator: | Dr Andree Pearson |
|  | Sponsor: | Research and Enterprise, University of Otago |
|  | Clock Start Date: | 01 December 2022 |

Various members of the study team 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 data for the younger participants will be analysed and kept together with other age groups for more broad insight into the effects of age with heart disease.
2. The Committee noted that participants may whakapapa to several places and as such it may be necessary to acknowledge this and plan to document this across the participants by collecting multiple ethnicities.
3. The Committee clarified that there will only be internal advertisement until the number of participants can be more accurately identified. At that point some external marae-based adverts may be created but these would be done with consultation with that population. The Committee reminded the research team that these should be submitted if needed as an amendment.
4. The Committee queried the peer review and the gap in relationship development with local iwi. The Researcher explained that the study team still has someone that has a good relationship with the iwi and the study team also has another advisory group that assists in guiding them throughout the stages of the study.
5. The Committee clarified that the qualitative portion of the overall study will be a separate application, this will be guided at a later stage by the advisory group and with more co-design.
6. The Committee queried the optional genetic blood sampling and if it is a part of the study or standard of care offered outside of the study. The Researcher explained that participants requested genetic blood sampling and that they had agreed to facilitate the testing but that this would not be part of the study. The Researchers noted that at most they would request access to the results of this, but this is not a part of the study in itself.
7. The Committee clarified that the study documents will be offered in Te Reo for those who request/require it.
8. The Committee asked about the data bank and who has access to the data. The Researcher explained that the data is stored on a database which is housed in the hospital and is deemed secure with only study members having access to it.

**Summary of outstanding ethical issues**

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

1. Given there is the potential for several actionable clinical abnormalities to be identified, the Committee queried whether the researchers have a clear actionable pathway and timeline for response to said abnormalities. The Committee requested that the researchers include mandatory informing of the participant’s General Practitioner (GP) should there be incidental findings as part of the study.
2. The Committee noted that, as this is an observational study, participants should retain the right to withdraw data from the research dataset prior to analysis even though results will remain part of the participant's clinical record. Please amend all applicable study documentation accordingly.
3. The Committee requested that some thought be put into potential Whakamā that may result from participants being told that they are overweight.
4. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
   1. Page 5 states “all data and tissue collected for the main study will be securely retained locally” and page 10 states “all tissue collected for the purposes of this study will be retained by the Christchurch Heart Institute”. Please resolve discrepancy with page 3 of the main PIS which states “some samples provided by you may be sent to overseas laboratories and analysed by people who are collaborating with the CHI”.
   2. Please include any and all information as to the location of overseas laboratories, adding this as it become available and informing HDEC if necessary.
5. The Committee requested that the protocol state the koha amount for the Marae and whether there will there be a koha available to the participants, and whether this will include any reimbursement for travel.

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

Main PIS/CF:

1. Please ensure that the Participants are aware that their records will be held for a period of 20 years.
2. Please make it clear that genetic analysis offered will be performed outside of the research setting but that any results will be included in the research database. This needs to be suitably detailed as currently there is insufficient clear information included in the consent form. Please note that no new information should be introduced in the consent form that is not already explained in the information sheet.
3. Please include a statement noting that the location of overseas laboratories may not have yet been determined but the research team may be contacted for more information in this regard.
4. Please note the possible risks section needs to include the risks of finding out information regarding participant’s health through the study and the risk of a data breach.
5. Please describe electrocardiogram (ECG) and Echocardiogram for participants the first time these terms appear, this explanation can be brief.
6. Please clarify if there will be a possibility for gender matching of clinicians for study procedures.
7. Please specify how privacy will be maintained during the study procedures.
8. Please state the availability of a clinician on-site if a serious abnormality is found.
9. Please describe the possible uses of the ‘databank’ and who will have access to this data, how it will be stored and for what purpose it may be used. It may be better to describe this as storage of data rather than as a ‘databank’.
10. On page 5 please state what is important to know about this study, consider the statement: ‘you are encouraged to consult with your whanau, hapū, iwi or Māori health support worker’. Please note that participants may want to consult with their usual doctor, or nurse or seek legal advice from persons who may also happen to be Māori.
11. Please consider providing a Te Reo Māori version of the PIS/CF and noting that this version and translation services may be provided upon request.
12. Please provide a name for the Māori cultural support person.
13. Please remove the consent option for informing the participant's GP of significant abnormal findings as this is mandatory.
14. Please specify what genetic testing is and the potential risks of genetic testing.
15. On page 7, if the text and tick box “Retained for an indefinite period for further heart disease research studies approved by an ethics committee” relate to the future unspecified research dealt with in the separate consent form, this text and tick box should be removed from the main consent form.
16. Please amend the statement pertaining to the withdrawal of data.
17. Please review page 2 for medical terminology (cardiovascular, morbidity, mortality)
18. Please explain on page 2 where the carotid artery is in the body.
19. Please describe in detail what the 6-minute walk test involves.
20. On page 3 please clarify whether results could affect ability to get insurance, affect the cost of medical insurance and how it will affect employment.
21. Please review the 'Databank' section on page 3 for repeated information and inconsistencies.
22. Please review 'What is important to know about this study' for repetitions.
23. Please update contact details for HDC and HDEC.
24. Please clarify the question in the consent forms around if their sample is taonga. This appears to be 2 questions in one. Please simplify or amend to be clearer as to what the participant is saying ‘yes’ to.

Future Unspecified Research PIS/CF:

1. Please remove all reference to genetic tests.
2. On page 2 please clarify that information collected about the participant is restricted to information collected in the main study or sub study.
3. On page 3 please amend the withdrawal of tissue as it does not require notification in writing.
4. On page 4 please update contact details for HDC and HDEC.
5. On page 3 please explain what is meant by 'unidentified or de-linked' samples in lay terms.

**Decision**

This application was *approved* with nonstandard 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).*
* 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).*

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| **3** | **Ethics ref:** | **2022 FULL 13860** |
|  | Title: | Investigating the effect of heat-inactivated Lactobacillus gasseri CP2305 on sleep, stress and gastrointestinal health in adults with  insomnia and elevated stress levels: a randomised, controlled trial |
|  | Principal Investigator: | Dr Jody Miller |
|  | Sponsor: | Asahi Quality and Innovations Ltd |
|  | Clock Start Date: | 01 December 2022 |

Dr Jody Miller 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 the ratio of study drug and placebo is 1:1 and confirmed that this is a normal randomisation ratio.

**Summary of outstanding ethical issues**

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

2. The Committee requested clarification of local iwi practices around karakia being available at the time of the stool sample being sent to Ireland.

3. The Committee requested a SCOTT review and to see the approval for the study drug given there is a therapeutic claim.

4. The Committee requested registration of the study on a WHO approved clinical trials registry.

5. The Committee requested an amendment to the informed consent process. The Committee recommended a change in procedures such that the researcher provides the potential participant with the study information and, if interest remains, this is followed by a pre-screening questionnaire. After those documents are filled out, potential participants would come into the clinic where the study team would go through the information sheet to ensure potential participants understand the study and therefore can provide informed consent.

6. The Committee requested evidence of professional indemnity.

7. The Committee requested insurance documentation, noting that the applicant was aware that this had not yet been provided.

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

8. Please amend comments relating to participants having the option to continue the study drug once the study has finished.

9. Please amend the informed consent procedure.

10. Please simplify exclusion criteria in lay terms.

11. Please clearly explain that the study team will not know if participants are receiving the study drug or placebo.

12. Please explain in lay terms what the headband device is and provide a picture of someone wearing it.

13. Please explain how stool samples will be stored if participants store them at home.

14. Please amend comment relating to samples being anonymous, clarify that their participants study number will be connected but no other identifiable information.

15. Please include city and country of the overseas laboratory.

16. Please include tick boxes beside the karakia / no karakia option on the consent form (page 12).

**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 supply evidence of ACC-equivalent compensation available to all participants in the event of injury during the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
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 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 Ms Dianne Glenn and Mr Barry Taylor.

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| **4** | **Ethics ref:** | **2022 FULL 13953** |
|  | Title: | A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND  PHARMACOKINETICS OF AHB-137 WITH SINGLE ASCENDING DOSES AND MULTIPLE ASCENDING DOSES IN HEALTHY  VOLUNTEERS AND CHRONIC HEPATITIS B PATIENTS |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Ausper Biopharma Co., Ltd |
|  | Clock Start Date: | 01 December 2022 |

Julia O’Sullivan, Holly Thirwall, Daniel Green and Courtney Rowse 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 requested clarification on the data management plan around future research on samples. The researchers clarified that future research will only be performed on samples from participants who give additional optional consent.

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

1. The Committee requested amendment of the future unspecified research (FUR) sheet to only provide relevant information for this study. The Committee notes that there are currently multiple sections in the document which reference the collection of additional samples which is not the case, please clarify what is intended and delete any extraneous information.
2. Please clarify what genetic testing will entail by informing potential participants whether it involves their entire genetic code or genome.
3. Please review for typos and amend spacing errors.

**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).*
* please update the Data and Tissue Management Plan, 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)*

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| **5** | **Ethics ref:** | **2022 FULL 13814** |
|  | Title: | Pilot Evaluation of the ENIVO System in Simple Unilateral Mastectomy |
|  | Principal Investigator: | Dr Michelle Locke |
|  | Sponsor: | Aroa Biosurgery Limited |
|  | Clock Start Date: | 01 December 2022 |

Dr Michelle Locke, Nina Slabkevich, Isaac Mason, Sharon Cheung, and Dr Barnaby May 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.

Mrs Dianne Glenn noted that she was once a member of Counties Manukau District Health Board and, after discussion, the Committee concluded that this was not a substantial conflict and that she could proceed as reviewer for this application.

**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 what Māori committee the Researcher will be working with for this application. The Researcher responded that they did not consult a committee and will use an independent consultant instead.
2. The Committee asked about the participant information sheet and the use of sheep tissue, and if the Researchers are expecting negative reactions from the participants. The Researcher explained that when people are told some do have a negative response and do not want to have the procedure. Some people may not want to participate in the study when this is disclosed due to personal preferences. The Committee asked if there is another option for those who do not want to use the sheep tissue. The Researcher explained that they cannot, this is an integral part of the treatment; the product is biological.
3. The Committee queried the rationale for the ages of 21 and above. The Researcher explained that it is rare for this type of cancer to be seen in younger ages and it is not anticipated that this age cut-off will exclude anybody.
4. The Committee asked about participants who struggle to monitor and care for their drain without assistance and if they would be excluded from the study or will they be referred to other services. The Researcher explained that nurses will be conducting follow up and for those who struggle with caring for the drain home visits can be arranged.
5. The Committee asked if there is someone available for participants with concerns to contact. The Researcher explained that all participants will get the name of their research nurse for this care in addition to the CI.

**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 study will need to be registered in a WHO approved clinical trials registry prior to commencement.
2. The Committee noted there are no plans for sentinel administration but requested formalisation in the protocol for the first few participants, leaving enough time between the first procedures to ensure no unanticipated safety issues prior to moving onto other participants.
3. The Committee requested it is stated clearly in the advertisement that this study is for an investigational or experimental device.

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

1. Please proofread for typos and repeated information.
2. A large heading is on each page, please remove from everything but the first page as this takes up valuable space and makes the PIS/CF unnecessarily long.
3. Please remove “first study in people undergoing simple mastectomy” as this is the first study in any people.
4. Please soften benefit statements, i.e., “will” to “may” as the benefits cannot be known yet
5. On page 3, please remove the statement “all information collected will be deidentified to the study team…” Participants think of the study team as the research nurse and surgeon, etc. It is currently covered later in the document and is not required here.
6. Please address the risk of sending data overseas. There is a standard statement that can be taken from the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
7. The Committee noted that payments for studies can be interpreted as income if it is payment for “your time.” A koha should be phrased as for inconvenience, not time to avoid this issue.
8. On page 8, please clarify that the reimbursement is in addition to the koha.
9. It is hard to justify in an open-label study withholding participant’s access to their study data as it will not unblind anyone and bias results. Please remove the statement on page 12 regarding this.
10. Please outline expectations clearly around what can or cannot be discussed. Currently it is contradictory and unclear, as they are encouraged to discuss participation with their friends and family, but then requested not to discuss this study with anyone. If the confidentiality is to do with the specifics of the device, then make this clear.
11. Please state that, if participants choose to withdraw from the study, the drain cannot be removed or replaced.

**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).*
* 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).*

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| **6** | **Ethics ref:** | **2022 FULL 13872** |
|  | Title: | ApproaCH: A phase 2b clinical trial to evaluate efficacy and safety of weekly doses of TransCon CNP compared with placebo in participants with achondroplasia aged 2 to 11 years of age |
|  | Principal Investigator: | Dr Paul Hofman |
|  | Sponsor: | Ascendis Pharma Growth Disorders A/S |
|  | Clock Start Date: | 01 December 2022 |

Dr 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 asked if the study been submitted to SCOTT for peer review. The Researcher confirmed it has.
2. The Committee asked about the pubertal stage visit and how is that assessed. The Researcher explained that parents are always present and is not invasive.
3. The Committee asked why the parents are asked before children. The Researcher explained that children will be asked as well and be actively involved.
4. The Committee asked about the safety plan for kids who are anxious and depressed from the questioning. The Researcher explained that this will go back to the CI and someone in the clinical team will arrange appropriate psychological support who are likely to be supporting these patients anyway.
5. The Researcher clarified that the participants are recruited from a previous observational study based in Auckland.
6. The Committee noted the contradictory responses in the application around addressing ethnic inequities and that the correct response was, due to the small sample size, the study will not be able to answer that.

**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 about the exploratory biomarkers and if they pertain to future unspecified research (FUR). The Researcher explained that the biomarkers are various factors that could affect drug responsiveness. The Committee noted that this is not part of FUR as what is being explored is very specific. The Committee is concerned about any FUR being done on these samples and the Researcher will ask the Sponsor to remove this FUR information sheet.
2. The Committee queried access to the study drug once the trial has been completed. The Researcher noted that there is no current formal agreement but have been advised this will be available. The Committee referred the Researcher and Sponsor to Standards 10.15-10.17 which outlines the expectation that there is continued access if there is benefit shown.
3. The Committee noted that if social media posts are used for recruitment these will need to be approved by the HDEC prior to use. This can be done via an Amendment submission after approval of the application.
4. The Committee stated that the data and tissue management plan will require revision as it currently does not reflect the study. Specifically, they directed the Researcher to Section 8.3 to make sure future use of tissue matches what has been discussed. Please also address what happens to raw recordings.
5. The Committee noted that the CI indemnity provided was a practicing certificate. Please submit evidence of professional indemnity i.e., MPS certificate.
6. Locality authorisation has already been provided ahead of ethics approval. The Committee queried if the cultural review has been performed in this case. The Researcher stated they were not sure and will clarify if this has taken place. The Committee noted that another submission of signature for locality using the post-approval form will likely be required.
7. The Committee noted that additional consent for pregnancy follow-up is required if that does arise. This should also be submitted as an Amendment for review if that occurs.
8. The Committee noted the ethnicity data collected as required by the sponsor differs to that of New Zealand. Please ensure at a site level, ethnicity data relevant to New Zealand is collected in addition.

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

All:

1. Please amend the lay title to ‘The ApproaCH Study’ across all PISs.

Main PIS/CF

1. Please use consistent numbering of pages throughout the documents.
2. The study drug is incorrectly referred to as a vaccine throughout, please amend.
3. Please explain how the drug works in lay terms, some of the information in the protocol could be useful.
4. Under ‘what will my participation involve’, please state that the study drug is administered through subcutaneous injection once a week by the parent.
5. On page 2, the last paragraph is repeated. Please remove.
6. Please move the table summarising the visits to be after the explanation of what the visits are about. Please amend the table for assessments and use lay terms.
7. Please amend Māori health support to Māori cultural support.
8. Please amend the statement “child’s personal data is held by” to state that the data is coded.
9. The Committee noted the cultural statement is outdated, please update according to the current [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
10. Please do not use the term “early termination” as this can be interpreted differently. “Withdrawal” is appropriate.
11. Please use millilitres for amounts of blood.
12. Please amend “health insurance company or provider” statement to reflect the New Zealand health system.
13. Please include information about the exit interview within the PIS or as a supplementary information sheet.
14. Please state what is done with voice or visual recordings to avoid identification.
15. On page 11 please include city and country location of all overseas laboratories.
16. Please outline what accommodations are available and what the process is if children become fatigued.
17. Please amend the parent Guardian PIS to use “you” and “your child” where appropriate.

Assent Form

1. Please proofread the assent form.
2. Please simplify for the older children, i.e., removing references to ACC, etc. Please also provide a simplified assent form for younger children, it should be around 1 page. The Committee noted that Starship should have example documents.
3. Please remove the statement “and nobody will be cross with you” as this is not in the control of the researcher.

**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 Patries Herst and Ms Dianne Glenn.

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| **7** | **Ethics ref:** | **2022 FULL 13797** |
|  | Title: | A PHASE II, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, BIOMARKERS, AND EFFICACY OF TOMINERSEN IN INDIVIDUALS WITH PRODROMAL AND EARLY MANIFEST HUNTINGTON’S DISEASE |
|  | Principal Investigator: | Professor Tim Anderson |
|  | Sponsor: | F. Hoffmann-La Roche |
|  | Clock Start Date: | 01 December 2022 |

Laura Paermentier and Steve Duffey 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 queried what follow up is in place regarding participants answering the quality-of-life questionnaires for participants who are suicidal or showing distress. The Researcher advised that the CI would have a conversation with them and will offer referral to psychiatric help or a counsellor. They also noted that they have a social worker who supports participants who can also set up counselling sessions (fully paid).
2. The Researcher clarified there is no planned advertisement material to be developed but will submit to HDEC first if they do.

**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 the following about the Data and Tissue Management Plan:
   1. Under Section 8.5, when discussing future uses of tissue and data, the Committee requested that for future unspecified research where optional additional consent has been provided, to simply refer them to section 8.8 as this is currently dealt with in two places.
   2. In section 12.2.2 where it states “participants may request access to their RBR Genomics sequencing data if permitted by local law”, the Committee requested that the Researcher clarify in the document whether New Zealand law permits it or not. Remove across documentation if New Zealand law does not permit this or say this is permissible if New Zealand law does.

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

Main PIS/CF:

1. The Committee referred the Researcher to the latest [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) that has a more expanded cultural statement around tissue for use.
2. Please amend “Māori health support” to “Māori cultural support”
3. Please proofread for typos and ensure the title is more lay friendly.
4. Please amend phrasing of reimbursement provisions, i.e., “may be reimbursed” should be changed to “will be reimbursed”.
5. Please amend page 8 to tighten up unused space.
6. Please mention on page 16 that karakia will not be available at time of tissue destruction.
7. Under “Are there any risks” near the start, there are no risks discussed and states to look later for information under the Risk section. The Committee queried this layout rationale and asked to merge these.
8. Please amend the font of the risk section to be the same as other fonts in the sheet as this current formatting makes it hard to read.
9. Page 14 states all responses from the mood questionnaires will be confidential. Please clarify that there are situations where this information may need to be shared with appropriate referral services and why.
10. Under the genomic testing section, please make it clear that the mandatory testing is directly related to Huntington diseases or the study drug. If participants want testing for other diseases or broader work, they can go to the RBR for consent.
11. Please specify if whole genome sequencing is performed for the mandatory testing component, and whether there will be risks of full or partial matches across genetics databases.
12. Page 17 states that local law may require that participant study information is given to the participant’s insurance company or employer. Please remove as this is not applicable to New Zealand.
13. Please specify on paragraph 2 and 3 of page 18 whether the study data discussed is identifiable or coded, rather than referring to it as “personal”.
14. In the consent form, ensure the lay summary of results has a YES/NO optional tick box

RBR PIS/CF:

1. Please mention on page 16 that karakia will not be available at time of tissue destruction.
2. It would be useful to say that, when whole genome sequencing is performed, it is unique to a person and therefore identifiable.
3. Please state whether there will be risks of full or partial matches across genetics databases.

Study companion PIS/CF:

1. Please clarify on page 5 that participant may be required to exit the study if a replacement study companion cannot be found.

**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 Mr Barry Taylor and Mr Dominic Fitchett.

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| **8** | **Ethics ref:** | **2022 EXP 13841** |
|  | Title: | Testing a well-being app New Zealand high school students |
|  | Principal Investigator: | Dr Hiran Thabrew |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 01 December 2022 |

Dr Hiran Thabrew 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 that of the developer does not intend to commercialise the app.
2. The Researcher clarified that participants will be provided with a smart phone and internet data for the duration of the study to provide as much practical ability for participation without disadvantaging certain populations or causing undue inducement.
3. The Committee queried whether there was a direct plan for the follow up of identification of signs of emotional distress through the app. The researcher outlined that there would be a research assistant who would be analysing data frequently to ensure that any low scores were raised to the research coordinator for further action to get the participant support.
4. The Researcher clarified that this app was not specifically for the purpose of treating mental health issues and is instead focused on promotion of mental wellbeing.
5. The Researcher clarified that there would be no exclusion of individuals with disabilities.
6. The Committee queried the co-design process of the study and how the development of the app has changed over time with different age groups and with different ethnicities. The Researcher noted that the same groups would be used going forward with consultation as this group was diverse and well versed already in being part of this study.
7. The Committee noted that as there is currently pressure on the healthcare system Aotearoa-wide, and that it may be hard for a General practitioner (GP) follow up to occur if not directly facilitated by the research team. The researcher clarified that the GP would be contacted directly by the research team and follow up would be closely monitored.
8. The Committee queried how the data may be used in the future and in what forms the data may exist in. The Researcher clarified that data will stay on the devices and not be shared elsewhere to ensure privacy. The data would be wiped should the app be deleted.
9. The Committee clarified that the parents do not currently have access to the app as a part of the study. This may be considered in the future but is not currently factored into the protocol.

**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 young people, such as those in this study, may have (and it is probable that a good number will have) capacity to consent for themselves and that this should be considered when recruiting. The Committee recommends that capacity be assessed and, in the circumstances where the young people can consent for themselves, that they be given the opportunity to as per the guidance in the National Ethical Standard para 6.2.
2. The Committee requested that the principal’s role in permitting the study to be conducted in the school be clarified, so as not to be construed as consenting for the children or as a participant themselves. Please more clearly define this and ensure it is addressed in the Participant Information Sheet (PIS) and remove the framing of this as a consent form as it is simply an agreement.
3. The Committee requested that a reconsent form be provided for participants who will turn 16 during the study.
4. The Committee requested that all participant information sheets explain clearly what the study is about.
5. The Committee requested that information that will be presented to children be simple and in paragraphs rather than bullet points.
6. The Committee queried how the Researchers were planning on having the participants not speak to each other during the study. The Researcher planned to some extent to try and manage that risk but recognise that there is little that could be done to completely prevent this “contamination”.
7. The Committee requested a correction in the protocol, there is an error where it states that students from years 9-10 will be participating in the study rather than years 9-11.
8. The Committee requested the following changes to the Data Management Plan (DMP):
   1. Please ensure that the consenting process is properly redefined as discussed with the Committee to incorporate both reconsent and the assessment of capacity to consent in participants under 16 years old.
   2. Please amend the notification of privacy breach where participants are giving their own consent. This may need to factor in severity of potential breaches and should be phrased to first approach the participant for consent to inform their parents. The current wording around informing of parents should still be used where participants have not consented for themselves.

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

Main PIS/CF:

1. Please clearly state where data will be held, for how long, who will have access to the data and for what reasons.
2. Please state who is funding the research.
3. Please state how long the questionnaires will take to complete.
4. Please update the QR codes as these are not currently appropriate for this study and link to an unrelated consent form.
5. Please state if there are restrictions on the use of other mental health apps whilst taking part in the study.
6. Please list other mental health support contacts for young persons.
7. Please include a statement addressing what will happen should a device that has been loaned to a participant is damaged or lost, etc.
8. Please include a section on “what will happen to my information”. This can be simplified for younger participants but should still be included. Please refer to the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc) for guidance.

Parent PIS/CF:

1. Please clarify who is being referred to when mentioning the “school health centre”, specifically who is involved in this centre, as this might be relevant to whānau.
2. Please review the withdrawal request and contact process to ensure it is more lay friendly and clearer for parents.
3. Please amend the storage of data on page 3. This should state the data will be stored for 13 years.
4. This sheet should be specifically for “parent/guardian” and not for ‘parent/caregivers’ as only parents or guardians may legally consent for participants.
5. Please consider softening the language used in this document as currently it reads as quite formal.
6. Please include more information as to the different forms of information that are included in the study and how this will be used and analysed. Please refer to the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc) for guidance.

Assent Form:

1. Please amend mention of the school agreeing to participate as this may pressure children to feel as though they must participate.
2. On page 3, please amend the wording “no one will be upset with you” as this Is not in the control of the Researcher.
3. Please remove the ACC statements from the assent form.

School Principal PIS/CF:

1. Please include a comment that a smartphone will be loaned to a participant if necessary for participation.
2. Please include a brief explanation of the assessment for capacity for consenting.
3. Please amend the data storage period to 13 years.
4. Please rename the consent form to be an agreement.
5. Please consider amending the current language to something more neutral such as “I agree to year 9-11 students at the school being approached to participate.” And “I understand that students will need to provide consent/assent in order to participate and that their parent/whānau/guardian will need to provide signed consent if the student has not consented for themselves.”

**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 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).*
3. Please update the data management plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
4. Please update the participant information sheet and consent forms, 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 Ms Amy Henry and Ms Neta Tomokino.

## General business

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

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| **Meeting date:** | 14 February 2023 |
| **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 3.00pm.