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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 8 October 2024 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 10.30am-11.00am | 2024 FULL 20736 | Tune-401-001: A Study to Evaluate Tune-401 in Single Ascending Doses and an Expansion Dose in Participants with Chronic Hepatitis B (CHB) Infection. | Prof. Ed Gane | Dr Patries Herst & Mr Dominic Fitchett |
| 11.00am-11:30am | 2024 FULL 20918 | ABI-1179-101: A Study to Evaluate ABI-1179-101 in Healthy Participants and in Participants with HSV-2 Infection and Recurrent Genital Herpes | Prof. Ed Gane | Dr Kate Parker & Ms Neta Tomokino |
| 11.30am- 12.00pm | 2024 EXP 20969 | Enhancing Patient Stratification and Prognosis using Cardiac CT | Dr. Jichao Zhao | Dr Nicola Swain & Ms Dianne Glenn |
| 12.00pm-12.30pm | 2024 FULL 20497 | Digital Twins for the management of chronic disease - Pilot Study | Prof Merryn Tawhai | Dr Amy Henry & Dr Maree Kirk |
| 12.30pm-1.00pm | 2024 FULL 19645 | Co-designing digital solutions for dementia | Dr Gonzalo Maso Talou | Dr Nicola Swain & Mr Jonathan Darby |
| 1.00pm-1.30pm |  | **Break 30 minutes** |  |  |
| 1.30pm-2.00pm | 2024 FULL 21118 | Assessment of the usability of a mobile dermatology app | Hon. Prof. Amanda Oakley | Dr Patries Herst & Mr Dominic Fitchett |
| 2.00pm-2.30pm | 2024 FULL 21164 | XPF-010-304- An Open-label Study of XEN1101 in Epilepsy | Dr Beatriz Romero Ferrando (not in attendance) | Dr Kate Parker & Dr Maree Kirk |
| 2.30pm-3.00pm | 2024 FULL 21275 | BG-C477-101: A first-in-human Study of BG-C477, an antibody-drug conjugate, in Patients with Selected Advanced Solid Tumours | Dr Sanjeev Deva | Dr Amy Henry & Ms Dianne Glenn |
| 3.00pm-3.30pm | 2024 FULL 21067 | Capstan Medical TMVR Study: FIH | Professor Mark Webster | Dr Kate Parker & Mr Jonathan Darby |
| 3.30pm-4.00pm | 2024 FULL 20757 | Photobiomodulation for chronic fatigue. | Prof Dirk de Ridder | Dr Amy Henry & Ms Neta Tomokino |

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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 | Apologies |
| Mr Dominic Fitchett | Lay (the Law) (Chair) | 05/07/2019 | 05/07/2022 | Present |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Ascc. Prof Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| 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 | Apologies |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Mr Jonathan Darby | Lay (Law and Ethical Reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Dr Kate Parker | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |

## Welcome

The Chair opened the meeting at 10am and welcomed Committee members, noting that apologies had been received from Dr Devonie Waaka and Ms Neta Tomokino.  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mr Jonathan Darby, Dr Kate Parker and Dr Patries Herst confirmed their eligibility and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 20736** |
|  | Title: | Tune-401-001: A Study to Evaluate Tune-401 in Single Ascending Doses and an Expansion Dose in Participants with Chronic Hepatitis B (CHB) Infection. |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | Tune Therapeutics, Inc. |
|  | Clock Start Date: | 26 September 2024 |

Dr Ed Gane, Ms Lucy Druzianic, Ms Julia O’Sullivan, Ms Kayla Malate, Dr Derek Jantz, Dr Heidi Zhang and Mr Stanley Yune 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 function and longevity of the study medicine, specifically discussing the animal study population, any potential off-target concerns for the DNA methylation, duration time of the methylation in the body and the selection of the period of protected sex for those taking part.
2. The Committee noted that the selection of E12 on the submission was incorrectly filled in and confirmed with the researcher that there would be ACC-equivalent compensation.
3. The Committee clarified that the opportunity for a second dose as noted in the study documentation was specifically to address the possibility that one dose would not quite be enough to be therapeutic. The researcher noted that a second dose would likely be well-tolerated.

Summary of outstanding ethical issues

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

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

1. Please include information on page 21 specific to the possibility and reasoning for the second dose should the first prove to be sub-therapeutic.

**Decision**

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

* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| **2** | **Ethics ref:** | **REFERENCE** |
|  | Title: | ABI-1179-101: A Study to Evaluate ABI-1179-101 in Healthy Participants and in Participants with HSV-2 Infection and Recurrent Genital Herpes |
|  | Principal Investigator: | Prof. Ed Gane |
|  | Sponsor: | Assembly Biosciences, Inc. |
|  | Clock Start Date: | 26 September 2024 |

Dr Ed Gane, Ms Lucy Druzianic, Ms Julia O’Sullivan, Ms Kayla Malate 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 age ranges on the different arms of the study.
2. The Committee clarified the eConsenting for the healthy patients.
3. The Committee noted the responses to C5 and C10 and requested clarification on how the possibility for stigma would be addressed. The researcher responded, satisfactorily, as to how this would be managed.
4. The Committee clarified the reasoning for Hepatitis A testing.

Summary of outstanding ethical issues

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

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

1. Please clarify what a “high fat breakfast entails” and how quickly it needs to be ingested.
2. If the sponsor has not committed to the Medicines New Zealand guidelines, then please remove this paragraph.
3. Please remove or amend the note relating to stopping long-term medications such as anti-depressants. This should also be amended in the advertising material
4. Please clarify the process for the eConsenting group sessions.
5. Please consider having a lay title or include a sentence explaining the origin of the title as presented in the PISCF.
6. Please include another sentence, on page 2, to further clarify the cohorts and how one of them will not be conducted.
7. Please include the exclusion criteria points in red in the table.
8. Please reduce jargon where possible.

**Decision**

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

* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| **3** | **Ethics ref:** | **2024 EXP 20969** |
|  | Title: | Enhancing Patient Stratification and Prognosis using Cardiac CT |
|  | Principal Investigator: | Dr. Jichao Zhao |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 26 September 2024 |

Dr Jichao Zhou 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 there would be any additional costs relating to the study and the researcher noted that the research visits would be done during the patient’s standard of care visits to the clinic so there would be no costs associated to this study.
2. The Committee clarified that the wearable device was a patch for the ECG not a watch.

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 use of 300 retrospective and 100 prospective patients. The researcher noted that this was based on advice given by clinicians in this field. The Committee noted that to use the 300 retrospective files, the researcher would need to present a request for a waiver of consent per the [National Ethical Standards relating to waivers of consent](https://neac.health.govt.nz/national-ethical-standards/part-two/12-health-data) para *12.28-12.30* and aspart of this to justify why consent could not be gained and what consultation had been undertaken to determine that a waiver would be acceptable to the affected communities..
2. The Committee requested that the protocol be reviewed to remove references to MRI scan data that are remaining from the previous protocol.
3. The Committee queried why the study included so many more participants data than the power analysis indicated was needed. Please clarify why 400 records are needed.
4. The Committee noted that the data management plan (DMP) talked about access to identifiable data by a number of parties that should not have access to the research data in an identifiable form. This would all be largely available in the clinical record, please amend this to be less inclusive as most of the people listed as having access would not be accessing the data from the study.
5. The Committee queried why the DMP included mention of clinically actionable incidental findings. If this could happen then this will need to be addressed in the waiver request as if there is a potential to find something it needs to be stated how the correct people will be identified and notified of this finding. If this is not possible then remove from the DMP.
6. The Committee noted that there was intention to collect ethnicity data, but queried whether there would be enough data in the set to be able to account for the differences specifically for Māori and Pasifika peoples. This is specifically of interest as AI models do not represent these ethnicities well and for this research to be scientifically valid in New Zealand it must serve these groups. Please consult and consider collaborating with patient groups or a Māori scientist. Please clarify in your reply what ethnicity reporting of your data might be possible.

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

1. Please disclose that the data collected will be aggregated with the retrospective dataset.
2. Please state clearly that participant data will be used to create an artificial intelligence (AI) model.
3. Please clarify if there is any commercial application for the model that will be created by the study.
4. Please insert the request for an interpreter right at the beginning of the PIS.
5. On page 6, there is a section about future use for research. If there will be future research, then this needs to have an explicit additional bullet point in the consent form asking if participants agree to this.
6. On page 2 please correct the statement including mention of the district health boards, as these no longer exist.
7. Please remove and replace the 0800 4 ETHIC number from the document with the general Ministry of Health number (0800 400 569).

**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 update the data 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).
5. Please provide a formal request for a waiver of consent for the secondary use of data without consent per the requirements set in the National Ethical Standards for Health and Disability Research and Quality Improvement (para 12.28-12.30)

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Nicola Swain and Ms Dianne Glenn.

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| **4** | **Ethics ref:** | **2024 FULL 20497** |
|  | Title: | Digital Twins for the management of chronic disease - Pilot Study |
|  | Principal Investigator: | Prof. Merryn Tawhai |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 26 September 2024 |

Dr Meryn Tawhai and other members of the research 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 that there would be no medication dosing advice to participants using this application. The researcher noted that the system would be providing more lifestyle-based compliance feedback rather than numerical data. The aim being specifically to improve the health literacy of the individuals using the application.
2. The Committee clarified that there may be therapeutic benefit from the study.

Summary of outstanding ethical issues

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

1. The Committee requested a plan around hyperglycaemia as well as the existing one for hypoglycaemia and information for the participants in the Participant Information Sheet and Consent Form (PISCF) as well as clear protocolisation of what would happen around this. Even if there is no plan around the latter condition it would be advisable to address this in the PISCF to prevent misunderstanding regarding lack of alerts.
2. The Committee requested a statement in the Data Management Plan concerning the data from the wearable device, including where it would be sent, who would have access to it and if it would be sold to third-parties. If there are data privacy statements from the manufacturers or developers of the device, please include links to these.
3. The Committee noted that the level of cultural sensitivity was quite poor in the submission form. The Committee requested that in future you address these questions with consultation of Pasifika and Māori in mind.
4. The Committee noted that the PISCFs do not contain any information about the randomisation that will have occurred prior to the forms being given to each group of participants. Please explain this in each version being used.
5. The Committee noted that health data must be kept for 10 years, not 6.
6. The Committee requested that the research office at the university be contacted and sign off the submission as the sponsor.

The Committee requested the following changes to the Participant Information Sheets and Consent Forms (PIS/CFs):

All:

1. Please summarise the data management process to clarify the movement and handling of data so that it is easy to understand for participants.
2. Please clarify how participants will be alerted to medical events. Please also specify whether clinicians would be contacting participants and how should there be an alert.
3. Please clarify how often people would be contacted for check-ins and by who.
4. Please clarify if the information provided by the AI would be reinforced by anyone else, otherwise simply state that information will only be provided and reinforced through the AI.
5. Please clarify if the smartwatch will need to be returned at the end of the study and if it would be an option to keep the device if they are finding benefit.
6. Please clarify the payment schedule and the amounts listed to be consistent where mentioned.
7. Please clarify if the eDiary will be collected or if there would be an option for this to be kept by the participants.
8. Please amend “equal and diverse” recruitment. It is not necessary to include the recruitment approach in the PISCF.
9. Please remove mention of prioritising Māori per the Treaty requirements. Te Tiriti o Waitangi contains nothing about prioritising Māori and is therefore not being correctly referenced. Again, recruitment strategy should not be included in the PISCF.
10. Please review for jargon. If abbreviations are used, they must first be fully written before then being used in an abbreviated form.
11. Please amend the use of the word “cab” to say “taxi” or “Uber” as would be more appropriate in the New Zealand context.
12. Where stating, “Participants will interact with the device at home…” please specify how frequently the participants should be doing specifically in terms of using the device, what might happen if they are away from home and how frequently they would be required to interact.
13. Please include a plan for follow up of potential signs of distress if they are indicated by the questionnaires being used in the study and please inform participants how often and by who these results will be assessed.
14. Please include page numbers, version numbers and a date in the footer.
15. Please explain what “health literacy” means.
16. Please amend the paragraph “anonymisation and pseudo-anonymisation of data, restricted access…. and at rest.” as it makes no sense and is overly complicated
17. Please inform the participants whether the data will be used to train the AI and how long their data may be kept and used for this purpose.
18. Please inform participants what happens if a device is broken or lost etc., and what will happen in these circumstances.

Control PIS/CF:

1. Please amend the references to AI goal setting as per page 2 as this group will not be given the AI.

**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 Amy Henry and Dr Maree Kirk.

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| **5** | **Ethics ref:** | **2024 FULL 19645** |
|  | Title: | Co-designing digital solutions for dementia |
|  | Principal Investigator: | Dr Gonzalo Maso Talou |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 26 September 2024 |

A sub-investigator from the study team 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 noted that there was not enough detail in the study protocol. Please refer to the NEAC standards chapter 9 for more guidance on what is expected. *(National Ethical Standards for Health and Disability Research and Quality Improvement* para *9.7, 9.7a & 9.8*.)
2. The Committee noted that the advertisements must comply with the [HDEC advertising guidance](https://ethics.health.govt.nz/guides-templates-and-forms/advertising-guidelines-for-clinical-research) and include the dates of the actual study and the approval number for the application as the current ones appear to be copies from another study in another country.
3. The Committee noted that the Data Management Plan (DMP) contained a section on Future Unspecified use of Data for Research (FUR). If this is not occurring, then remove it from the DMP. *(National Ethical Standards* para *12.15.)*
4. The Committee noted that the DMP is labelled as the protocol. Please amend this.
5. The Committee noted that the protocol must include all relevant information as to what will happen to the speech data. The DMP must also include this information including who will handle the date, what form it will be stored in, who will have access, how it will be transcribed and what analysis will be conducted etc., on this data. A lay version of this must also be included in the Participant Information Sheet. *(National Ethical Standards* para *12.15, 7.15, 9.7, 9.7a & 9.8*.)
6. The Committee queried whether the linguistic data would be used for clinical intervention. The researcher noted that the tool would be used to ascertain information about cognitive decline and for ongoing monitoring. Please include this in the Participant Information Sheet. *(National Ethical Standards* para *7.15.)*
7. The Committee noted that the researcher indicated in the submission form that the research will not be using AI but confirmed in the meeting that they do not know if they will be using AI as the model has not yet been created. If AI is used this will require additional review and the Committee requested that the researcher use and refer to the HDEC [Health data and new technologies supplementary form.](https://ethics.health.govt.nz/guides-templates-and-forms/health-data-and-new-technologies-supplementary-form)
8. The Committee noted that the researchers did not understand what Kaupapa Māori methodology was and that this approach is strictly referring to the study being conducted by Māori, with Māori, for Māori. This is not the case. The researcher has conducted and is collaborating with Māori but this is consultation and co-design, not Kaupapa methodology.
9. The Committee requested that the researcher include only people in the study who already have a dementia diagnosis and detail recruitment process in the protocol. *(National Ethical Standards* para *9.7)*
10. The Committee requested a clear protocolised plan for researcher safety for home visits.
11. The Committee requested that the research office at the university be contacted and sign off/authorize the submission as the sponsor.
12. The Committee noted that health data must be kept for 10 years, not 6. This should be written in the protocol and DMP. (*National Ethical Standards* para *9.7a.)*
13. The Committee requested an easy-read version of the PIS, given the target population of this research will have dementia. Otherwise, reasoning must be provided to prove how the current PIS has been made easy to read for people in the early stages of cognitive decline. (*National Ethical Standards* para *7.15.)*
14. The Committee requested a full description of the co-design process and what is meant by this in terms of the protocol. This should be detailed in the protocol and may require further amendment to the DMP. *(National Ethical Standards* para *9.7a.)*
15. The Committee requested that the protocol include information and literature acknowledgement around working with vulnerable populations and people with early stages of cognitive decline and particularly how AI may impact these groups differently. *(National Ethical Standards* para *9.7a & 13.1-13.5)*

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

1. Please do not refer to the koha of $30 to be for time as this will has tax implications. Please also clarify that this is additional to reimbursement for travel to the site.
2. Please include the contacts required for advocacy, HDECs and cultural support per the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc), please note this will require the researchers to find someone who can provide Māori cultural support.
3. Please provide a contact for the research team that participants would contact in the event they have questions.
4. Please remove the time limit on the ethics approval. There is no limit on this for HDECs, so long as annual progress reports are submitted yearly.
5. Please include that the recordings will be deleted once they have been coded (if this is the case).

**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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| **6** | **Ethics ref:** | **2024 FULL 21118** |
|  | Title: | Assessment of the usability of a mobile dermatology app |
|  | Principal Investigator: | Hon. Prof. Amanda Oakley |
|  | Sponsor: | Te Whatu Ora |
|  | Clock Start Date: | 26 September 2024 |

Professor Amanda Oakley 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 and confirmed with the Researcher the sponsor of the study is Te Whatu Ora.
2. It was clarified that participants get no diagnosis information back from the app, just the dermatologist outcome.
3. The Researcher confirmed AIP will only receive summary study data, not raw study data, and information collected as part of the study will not be used on an ongoing basis by AIP to help train their AI.

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 study reads as if the dermatologists are also participants as they are filling in surveys about the platform’s usability. This group will require a brief participant information sheet/consent form (PIS/CF) as they are participants.
2. The Committee requested to upload the five-question survey and the survey to get the opinions of the patient-participants surrounding information given.
3. The Committee stated more information around data management is required than what is available in the submitted data management plan to satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) was encouraged to see what information is currently missing.
4. The Committee requested confirmation that the concerns raised by the Peer Reviewer were addressed.
5. The Committee noted that the application form says the study is using Kaupapa Māori methodology but it’s not, and to be mindful of this for future submissions.
6. Application form states posters or pamphlets will be put in waiting room. Any advertisement such as posters or pamphlets must be provided before use or confirm not being used.
7. The Committee noted that some language used towards participants was not entirely appropriate. Items of concern include referring to Pacific people broadly as having “a lack of interest in self-care” or generalising that they are shy. There are also constant references to patient where it should be participant.

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

1. Please remove mention of koha for time, just for participation.
2. Please amend “skin problem” to “skin issue”.
3. The Committee suggested to rephrase the statement around identifiable images that “we will take care that the photograph does not have identifiable features” rather than the implication it’s the participant’s responsibility.
4. References to participant as “the patient” but then also “you”. This should be consistent and refer directly to the participant.
5. Statements like “we think the app is convenient and secure and improves…” etc., should remain neutral given the point of the study is to evaluate this.
6. Flow of study procedures is not clear such as when they may see a doctor, a flow chart would help aid understanding.
7. PIS refers to AIP as the Sponsor. Please remove this but refer to AIP as appropriate when relevant.
8. On page 7 statement “after you have been assigned a code, anonymising your information, you will not be able to access, withdraw or request changes to this information” – the Committee noted that this makes it de-identified, not anonymised. In addition, this should be reviewed and corrected for what can happen to this information.
9. Remove references to notifying GP or usual doctor of participation as that is not occurring for this study.
10. Please state they will be approached by a student.
11. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).

**Decision**

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

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

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

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| **7** | **Ethics ref:** | **2024 FULL 21164** |
|  | Title: | XPF-010-304- An Open-label Study of XEN1101 in Epilepsy |
|  | Principal Investigator: | Dr Beatriz Romero Ferrando |
|  | Sponsor: | Worldwide Clinical Trials Pty Ltd (on behalf of Xenon Pharmaceuticals, Inc.) |
|  | Clock Start Date: | 26 September 2024 |

Ms Kate Ives 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, while the application stated this is a healthy volunteer trial, this is actually not and will involve patients.
2. The Committee clarified that this study is a carry-on open-label trial from another that has been reviewed by another HDEC. This study will have about 4 participants in the primary site and around 4 participants from another site that is looking to join the study. Please include this once the site has joined the trial.
3. The Committee clarified that while the box indicating there is no ACC-equivalent compensation had been ticked in the submission that there was in fact appropriate insurance organised for the study.

Summary of outstanding ethical issues

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

1. The Committee noted that the pregnant partner information sheet has not been reviewed and should be submitted to be added to the list of approved study documents if and only where a participant’s partner becomes pregnant during the study (as an amendment).
2. The Committee clarified the process for dealing with concerns raised around mental distress identified through the use of the study questionnaires. Please detail this plan in the Protocol and the Participant information Sheets (PIS). Please ensure that the team that may support this plan is made aware of these plans.
3. The Committee requested that the general practitioners (GPs) of the participants are notified of use of the study intervention and that this is mandatory as part of participation specifically as the drugs may increase the potential for suicidal ideation. Please also remove the tick box option for this in the consent forms.
4. The Committee queried whether the sponsor had committed to the Medicines NZ Guidelines as indicated in the PIS. Please remove this if they have not committed to these guidelines.
5. The Committee noted that it is a requirement for NZ Ethnicity data to be collected. Please do so at a site level.
6. The Committee queried whether there may be compassionate provision of the study intervention should the study drug be effective. Please clarify this with the sponsor. Detail whether or not this may happen in the PIS.
7. The Committee suggested rewording the language in the compensation section of this application to be clear to participants that there are no guarantees as to compensation provided should a fall occur etc., which could be likely with a change in epilepsy medication. Please have the Sponsor and the insurer agree to a change in the wording that makes this abundantly clear.
8. The Committee requested protocol and territory specific insurance certificates for this study.

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

1. Please include in the statement on page 9 around contacting the study doctor should they experience feelings of distress to include that they may be contacted if distress is indicated in their questionnaires. You can also add in here the plan required above.
2. Please quantify what is considered harmful use of drugs and alcohol where mentioned.
3. Please be specific around what is meant by “enough sleep”.
4. Please clarify where stating “You will be asked not to drive until you are used to the medication” how long this may be and for whom this is relevant (people moving from placebo).
5. Please include that a karakia will not be available at the time of tissue disposal in the section “What will happen to my blood”.
6. Please remove all reference to measurements of blood in teaspoons and just list the amounts in millilitres.
7. Please be clear how reimbursement will be provided and how much. Please remove reference to “negotiating” this with the study doctor.
8. Please clarify if the participants would be permitted to keep a copy of the back-up diaries.
9. Please clarify the need for in-person visits, the number of visits, and whether there may be a possibility for some to be carried out over the phone.
10. Please update the reproductive risks section to the wording included in the [HDEC template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc)
11. Please clarify the time period within which the eDiary must be filled in post-seizure.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Kate Parker and Dr Maree Kirk.

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| **8** | **Ethics ref:** | **2024 FULL 21275** |
|  | Title: | BG-C477-101: A first-in-human Study of BG-C477, an antibody-drug conjugate, in Patients with Selected Advanced Solid Tumours |
|  | Principal Investigator: | Dr Sanjeev Deva |
|  | Sponsor: | BeiGene NZ Unlimited |
|  | Clock Start Date: | 29 September 2024 |

Dr Sanjeev Deva and several 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 when the optional collection and storage information sheet would be provided and consented to in the study timeline.

Summary of outstanding ethical issues

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

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

1. Please avoid the use of the word “treatment”, please use “study drug” or “study intervention” instead.
2. Please refrain from the use of the word “time” when referring to reimbursement as this may have tax implications.
3. Please clarify how reimbursement will be handled and how the participants may receive this and what amount may be provided.
4. Please include the number of New Zealand participants as well as the number of international participants.
5. Please be clear as to whether or not genetic testing will occur rather than stating that it “may”.
6. Please clarify what genetic testing may target. If this is whole genomic testing or simply a look at specific genes relating to this disease, then state that. There is no need to specify every gene but please specify the types of things that will be under study and why.
7. Please specify the city and country that samples will be stored in.
8. Please remove the tick-box for General Practitioner notification as this should be mandatory.

**Main PIS**

1. Please include the option for an interpreter at the top of this document.
2. Under “reproductive risks” please include the public funding for storage of sperm and eggs.
3. Please provide details or a link for the Medicines NZ Guidelines.
4. Please clarify what “genes” are in lay terms and any risks associated with this.
5. Please note where “if local law allows” is mentioned please simply specify whether this is allowed per local law.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| **9** | **Ethics ref:** | **2024 FULL 21067** |
|  | Title: | Capstan Medical TMVR Study: FIH |
|  | Principal Investigator: | Prof. Mark Webster |
|  | Sponsor: | Capstan Medical |
|  | Clock Start Date: | 26 September 2024 |

Professor Mark Webster, and several members of the sponsor 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 process and timeline of testing the device in non-human animal trials and the period which the device is tested.
2. The Committee queried how necessary the annual in person check-up is if it is optional. The researchers noted that it is not specifically mandated and there would be very little in terms of blood testing that would be relevant to collect at that time point. The researcher noted there was a wish to balance burden whilst also ensuring that people were followed up on.
3. The Committee clarified that there would be a pause between each device procedure. The researcher noted that this wait would be for 24 hours.

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 protocol and territory specific insurance certificate.
2. The Committee queried how long the images are held by the sponsor. The researcher noted that they would be kept for 7 years. The Committee noted that this must be at least 10 years but no more than 20 by the sponsor. Please include this in the protocol and data and tissue management plan.

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

1. Please be clear that there is bovine material in the study device.
2. Please provide a better description of the device in lay terms and please provide a diagram or photograph if possible, such as the one in the protocol.
3. Please separate the risks by risks associated with the device and risks associated with the procedure. Please simplify this list to remove unnecessary items and items that are repeated. Please quantify these in numbers out of 100 or 1000 etc., for lay reading and order them in most likely to least.
4. Please include possible benefits to the study under the relevant section.
5. Please specify an amount provided for reimbursement rather than requesting receipts (e.g. a stipend).
6. Please remove the statement concerning the Medicines New Zealand Guidelines as this is a device study and the guidelines do not pertain to it.
7. Please specify that blood analysis will occur in New Zealand, not overseas.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Kate Parker and Mr Jonathan Darby.

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| **10** | **Ethics ref:** | **2024 FULL 20757** |
|  | Title: | Photobiomodulation for chronic fatigue. |
|  | Principal Investigator: | Prof. Dirk de Ridder |
|  | Sponsor: | The University of Otago |
|  | Clock Start Date: | 26 September 2024 |

Dr Divya Adhia and another member of the research team 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.

Dr Nicola Swain declared a potential conflict of interest and the Committee decided to include them in the conversation.

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 amount reimbursed was sufficient to cover participants’ costs.
2. The Committee clarified that the General Practitioner (GP) details would be collected after consenting and then the researcher would ensure that they were informed of trial participation and be contacted in the event of incidental findings.
3. The Researcher clarified what the Case Report Forms were.
4. The Committee queried whether the Māori support noted in the information sheet was able to conduct the support and advice as required. The researcher clarified that this was the case and reassured the Committee that this person was sufficiently experienced and available for the purpose of the study.
5. The Committee clarified the use of the term “chronic fatigue” per the fact it is more commonly used by lay people. Anyone with symptoms of fatigue may benefit so the researchers will include the wide group covered by this largely non-clinical terminology.

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 social media advert (if differing from the provided document) and the radio script that would be run for review.
2. The Committee noted that “encouraging” the participants to give a reason for withdrawal should be removed from the protocol. There should be no compulsion to provide this when withdrawing from the study and this directly contradicts the Participant Information Sheet (PIS).

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

1. Please include the description of “photobiomodulation” earlier in the PIS for ease of reading.
2. Please clarify the request to refrain from consumption of alcohol, caffeinated beverages and the use of tobacco is for the sake of the data not because there would be any side effects caused by this.
3. Please explain how the intervention may work in lay terms and state what it is proven to improve the symptoms of.
4. Please clarify how many visits are required and how long the visits will be.
5. Please remove the statement “the brain is considered the soul in Māori and Pasifika cultures”.
6. Please clarify how screening for cognitive disorders over email or the phone would be accurate. If this will not be done, please remove this from the PIS.
7. Please note that not receiving a benefit is not a risk. Please remove this from the risks section.
8. Please include that the driving service “Driving Miss Daisy” will be provided for use if required.

**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 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).*

## General business

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

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| **Meeting date:** | 12 November 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 4pm.