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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 15 October 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12.00-12.30pm | 2024 FULL 21158 | 206867: A study to compare the effects of FF/UMEC/VI with FF/VI in 12–17 year-olds with asthma | Dr Paul Hamilton | Mr Jonathan Darby & Dr Andrea Forde |
| 12.30-1.00pm | 2024 FULL 21078 | A Study to Investigate Efficacy and Safety of Sonrotoclax Plus Zanubrutinib Compared With Placebo Plus Zanubrutinib in Adult Patients With Relapsed/Refractory Mantle Cell Lymphoma. | Dr Marie Hughes | Ms Maakere Marr & Dr Sotera Catapang |
| 1.00-1.30pm | 2024 FULL 21279 | GuiDIng energy provision using indiREct CalorimeTry - DIRECT trial | Ms Varsha Asrani | Ms Catherine Garvey & Ms Jade Scott |
| 1.30-2.00pm | 2024 FULL 21395 | Quality of life for children with retinal dystrophy | Dr Sarah Hull | Mr Jonathan Darby & Dr Kate Parker |
| 2.00-2.300m |  | *Break 30 minutes* |  |  |
| 2.30-3.00pm | 2024 FULL 21354 | MK-4482-023: A Phase 3 Study of MK-4482 in Non-Hospitalised Adults With COVID-19 at High Risk for Disease Progression | Dr Claire Thurlow | Mr Jonathan Darby & Dr Sotera Catapang |
| 3.00-3.30pm | 2024 FULL 19391 | Whiria te hohenga - Supportive cancer care - a feasibility study | Ms Jeannine Stairmand | Ms Catherine Garvey & Dr Andrea Forde |
| 3.30-4.00pm | 2024 FULL 21128 | AROINHBE-1001: A Study To Evaluate ARO-INHBE in Adult Volunteers with Obesity With and Without Type 2 Diabetes. | Dr Rinki Murphy | Ms Maakere Marr & Ms Jade Scott |
| 4.00-4.30pm | 2024 FULL 21027 | ITL-2002-CL-301: A Phase 3 Study to Evaluate NTLA-2002 in Participants With Hereditary Angioedema (HAE) | Dr Hilary Longhurst | Ms Catherine Garvey & Dr Kate Parker |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Kate Parker | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey | Lay (the Law) (Chair) | 19/03/2019 | 19/08/2024 | Present |
| Dr Sotera Catapang | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |

## Welcome

The Chair opened the meeting at 11.30am and welcomed Committee members, noting that no apologies have been received.  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Maakere Marr 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 21158** |
|  | Title: | 206867: A study to compare the effects of FF/UMEC/VI  with FF/VI in 12–17-year-olds with asthma |
|  | Principal Investigator: | Dr Paul Hamilton |
|  | Sponsor: | GlaxoSmithKline Research & Development Limited |
|  | Clock Start Date: | 3 October 2024 |

Dr Paul Hamilton and Ms Angela Chelet 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 Andrea Forde declared a potential conflict of interest and the Committee decided to continue with them included in the discussion.

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 three products were approved for use in New Zealand both separately, or combined as a double, but the triple combination was not yet approved for use together in New Zealand.
2. The Committee clarified that the comparator would also be a new combination for the participants. The participants would be moved to the comparator during the run-in but that would be equivalent to their Standard of Care (SoC). If there was an increase in symptoms (or other issues with the comparator) during this time, there would be reconsideration of progression to randomisation for those participants.
3. The Committee clarified that there would be no continued access to the study intervention or the comparator once the study had concluded, even if it is beneficial. Please raise this with the sponsor. The Committee noted that the comparator is fully funded and that the researchers may recommend to their usual doctor that this is prescribed (if the participant benefits).
4. The Committee noted that as the individual medicines are approved in New Zealand, SCOTT may not review this. If they do not the researchers must provide other independent peer review.

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 simplification of the language used in the Participant Diary as it requires high health literacy that is not appropriate for this age group.
2. The Committee requested clarification as to where the data will be stored that is collected using the AiCure application.
3. The Committee noted in B21.1 of the submission that a conflict of interest had been noted for the clinicians who may be the participants primary clinician as well as the study doctor, please clarify how this will be mitigated and what steps will be taken to address this in the study where practicable.
4. The Committee queried why the data would be kept for 30 years. Please clarify why this may be kept for this long and why this is necessary.
5. The Committee requested that the Participant information sheets (PIS) be retitled. Please also rename the assent form to remove the age range. This can be used as appropriate based on the literacy and competency of the person assenting/consenting. This must be appropriate to the New Zealand context and the age of consent being 16 years old; and please ensure that it is clear that a parent or guardian may consent not any “other relation” as presently worded.
6. The Committee requested clarification as to whether the reimbursement for travel would only be through a third-party vendor or if there would be provision of a direct stipend. Please clearly document this in all relevant study documentation.
7. The Committee noted that the insurance certificate expires before the date of expected closure.
8. The Committee requested reasoning be provided as for why people under 16 would not be assessed for competency to consent utilising a Gillick competency assessment. This should be the standard approach as it is quite likely that some people under 16 with experience of brittle asthma would be capable of consenting.
9. The Committee requested information on the data privacy of the company providing the application and requested clear assurance around the transfer of data to third parties. The Committee is concerned that there is not enough information in the PIS or Data and Tissue Management Plan (DTMP) about the use of data by the application specifically, concerning the protection and linking of data within apps on the same device.
10. The Committee queried how the management of additional samples being taken will be handled and requested that this be documented in the protocol.

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

1. Please remove reference to tube-tying and hysterectomy on page 15 as this is highly unlikely to be a relevant contraceptive measure in this age group.
2. Please include information as to why bloods are being taken, as currently there is only mention of pregnancy testing. If this is specifically for the PK subset, please state this.
3. Please clarify the participant numbers so that this is consistent with adverts and the PISs.
4. Please clarify which samples are being sent to Singapore, i.e. if this is for the PK sampling only, please state this. Please clarify where testing for pregnancy will be done.
5. Please note that the $10NZD amount per month will not be sufficient for the upload of daily video data through the application. Please specify why the transfer of this data is explained clearly and this component of the study is well described in the PISCFs.

**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 Andrea Forde and Mr Jonathan Darby.

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| **2** | **Ethics ref:** | **2024 FULL 21078** |
|  | Title: | A Study to Investigate Efficacy and Safety of Sonrotoclax Plus Zanubrutinib Compared With Placebo Plus Zanubrutinib in Adult Patients With Relapsed/Refractory Mantle Cell Lymphoma. |
|  | Principal Investigator: | Dr Marie Hughes |
|  | Sponsor: | Beigene NZ Unlimited |
|  | Clock Start Date: | 3 October 2024 |

Dr Marie Hughes, several members of the research team and sponsor representatives 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 how the relapse participants were identified in clinic and how they would then be recruited.
2. The Committee clarified how missed doses would be recorded and managed.
3. The Committee clarified how ongoing access to the study intervention would be provided as indicated in the submission.
4. The Committee clarified that the researchers would have research nurses or other study staff who was not the PI to have separate conversations about participation to prevent any conflict or feelings of coercion.

Summary of outstanding ethical issues

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

1. The Committee requested that other policies relevant to data governance be included or appended to the data and tissue management plan.
2. The Committee requested that the participants be provided the contact details for the study co-ordinator and/or a study nurse so they can independently discuss the study.
3. The Committee queried if the sponsor would be considering licensure in New Zealand following this trial.
4. The Committee queried whether pregnant women would be excluded from treatment. The researcher noted that it would depend on the trimester. The Committee noted that the absolute exclusion of pregnant women in a trial for therapies for malignancy is not appropriate and that it should be addressed as a case-by-case approach.

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

1. Please shorten if possible for readability.
2. Please amend mentions of “infant” in the sections talking about pregnancy to instead read “outcome of the pregnancy”.
3. Please remove the tick-box from the notification of general practitioners point in the consent form. This is mandatory.
4. Please amend the statement around approval by the HDEC to note that HDEC only approves the ethical aspect of the study.
5. Please take out wording like "treatment", "study treatment" and "your disease" replace with "study; dosing; study plan; study dosing" or similar. In the case of “your disease”, consider referring to this in another way.
6. Please remove all measurements of blood as written in teaspoons and replace with millilitres.
7. Please amend the statement on page 26 to refer to “Māori” instead of “their people”.
8. Please amend the statement on page 30 concerning Māori data sovereignty to replace “Māori people” with “for Māori”.
9. Please amend the consent forms to include the words “and cultural support” after “whānau/family”.
10. Please review for repetitious sections within the PISs such as listing of information that is then within tables.
11. Please clarify how participants will be reimbursed and for what.
12. Please remove “also called the AIDs virus” from the Main PIS as this wording is stigmatising.
13. Please be clear that the participants may experience a deterioration of their condition as well as potential benefit or plateau.
14. Where referring to side effects please amend to “adverse events” particularly when referring to Covid-19.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Sotera Catapang and Ms Maakere Marr.

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| **3** | **Ethics ref:** | **2024 FULL 21279** |
|  | Title: | GuiDIng energy provision using indiREct CalorimeTry - DIRECT trial |
|  | Principal Investigator: | Ms Varsha Asrani |
|  | Sponsor: | Te Whatu Ora |
|  | Clock Start Date: | 3 October 2024 |

Ms Varsha Asrani 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 suggested that the researcher contact the research office within the researcher’s institution for guidance on how to sufficiently respond to the Committee’s requests and for help with what is required for a research project.
2. The Committee queried whether the pilot study could be conducted in patients who are able to consent. The researcher explained that this is not the case because of dietary differences between ICU, and other wards.
3. The Committee noted that the study is not using Kaupapa Māori methodology and that this was not accurately answered in the submission form.
4. The Committee noted that ethnicity data *must* be collected.

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 researcher signed as sponsor and that this is incorrect, the signatory for Te Whatu Ora should be the research office. Please contact the internal research team to obtain this.
2. The Committee noted that no data and tissue management plan or participant information sheets had been provided to the Committee for review. Please refer to the HDEC templates for guidance on what is required of these documents. *(National Ethical Standards for Health and Disability Research and Quality Improvement* para *9.71 & 9.8)*
3. A PIS for participants to give consent to continue in the study must be provided, to cover ongoing data collection and/or use of collected data in this research. *(National Ethical Standards* para *7.70, 7.18 & 7.20-7.21)*
4. The Committee requested that the PIS provided for family members or interested parties explains the study, best interests, and that they are being asked to consider participation from the participant’s perspective (not themselves to give consent to participation). (*National Ethical Standards* para *7.70, 7.18 & 7.20-7.21)*
5. The Committee noted that the reasoning for considering that participation may meet the best interests test needs to be detailed, as well as the process for determining this and that the application is not currently consistent with the law and HDC Code of Rights 7 (4) in its current state. (*National Ethical Standards* para *7.70)*
6. The Committee queried the timing and intention of the acceptability survey for participants and requested it be clearly explained how this is done once participants are conscious.
7. The Committee noted that the peer review did not address the recruitment of non-consenting participants and requested that the researcher specifically obtain review from someone with experience in ICU non-consented research. (*Health and Disability Ethics Committee Standard Operating Procedure* para *10 & 11.)*
8. The Committee queried who would be consulted when reviewing whether to enrol participants on a best interest basis. The researcher noted that the treating intensivist would be consulted as to whether this would be in the best interest of the participants. Please detail this clearly in the protocol. (*National Ethical Standards* para *7.70, 9.71 & 9.8)*
9. The Committee requested that the process of consultation with family and whānau and interested parties be protocolised. *(National Ethical Standards* para *7.70, 9.71 & 9.8)*
10. The Committee requested clarification as to how each group of randomised participants would be handled in equipoise. This needs to be clearly documented and articulated in the Protocol. *(National Ethical Standards* para *7.70, 9.71 & 9.8)*

**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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| **4** | **Ethics ref:** | **2024 FULL 21395** |
|  | Title: | Quality of life for children with retinal dystrophy |
|  | Principal Investigator: | Dr Sarah Hull |
|  | Sponsor: | University of Auckland and Greenlane Clinical Centre |
|  | Clock Start Date: | 3 October 2024 |

Dr Sarah Hull 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 an application pending for funding for the application. If that is not successful, the researcher intends to seek funding elsewhere.
2. The Committee clarified the database being utilised for recruitment was already consented specifically for this type of use.
3. The Committee clarified that there was no conflict of interest for the peer reviewers.

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 researcher has signed for the sponsor. This is incorrect and must be signed off by the internal research team at the University of Auckland. Please approach the research office within the institution for this function.
2. The Committee queried if it would be at all possible for the researcher to utilise supported decision making and permit those with some developmental delay to participate (currently excluded from participation) with parent/guardian assistance.
3. The Committee requested that the researcher place a scale below each question in the survey.
4. The Committee queried if there would be the opportunity for people to read and consider the participant information sheet (PIS) and the researcher noted that this would be possible. The Committee suggested having someone associated to the study contact the potential participants and provide PISs prior to coming into the site.
5. The Committee queried the availability of the free counselling, who would be providing this and how and requested that this be detailed clearly in the PISs and the protocol and it should be discussed in concert with the participants to ensure that the onus is not placed entirely on the participants should support be required.
6. The Committee requested that specifics about where the data would be sent be included in the data management plan and PISs.
7. The Committee queried whether there had been validation of the survey in adults with both RD and hearing impairment. The researcher responded that the survey had not been validated in adults with both visual and hearing impairments. The researcher advised that it would be unlikely that there would be child participants with both significant hearing and visual impairment. This may need to be addressed in the Protocol.
8. The Committee requested a clear measurable outcome for the study be identified in the protocol.
9. The Committee requested the following changes to the Data Management Plan (DMP):
   1. Please note that the source documents need to be kept for 10 years after the youngest participant turns 16. Please amend this in the DMP.
   2. Please include all data policies that are being followed as links in this document.
   3. Please correctly state the sponsor of the study.
   4. Please clarify data is being sent overseas and ensure this is explored and clarified further within the Māori Data Sovereignty section.
   5. Please include more information around the data governance including if there is a steering Committee and the security of the information and how this will be managed onshore and overseas.
   6. Please specify who (person/institution) data will be shared with in Toronto.

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

Adult PIS/CF:

1. Please outline a safety plan should there be responses given that indicate psychological distress as part of the study.
2. Please be clear where funding is coming from.
3. Please be clear that there may be the possibility to do the interview online.
4. Please be clear where data will be sent and what protections are in place.
5. Please note that the formatting disappears on page 4.
6. Please be clear who the data will be shared with in Canada.
7. Please clarify that data sent overseas will be deidentified.

Young Person PIS/CF:

1. Please be clear what the koha will be and for how much.
2. Please simplify the PIS for younger children (specifically for around 6-year-olds). It may be better to have two documents one for children with a lower level of comprehension and one for a higher level. The younger one should include more pictures.

**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).*

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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| **5** | **Ethics ref:** | **2024 FULL 21354** |
|  | Title: | MK-4482-023: A Phase 3 Study of MK-4482 in Non-Hospitalised Adults With COVID-19 at High Risk for Disease Progression |
|  | Principal Investigator: | Dr Claire Thurlow |
|  | Sponsor: | Merck, Sharp and Dohme |
|  | Clock Start Date: | 3 October 2024 |

Dr Claire Thurlow, Ms Julia Bitzer and Ms Angela Chelet 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 the availability of the study intervention in New Zealand. The researcher clarified that there is limited availability for use in hospitals but in the community it is incredibly hard to access. The Researcher clarified that the only way the participants would otherwise gain access would be if they were hospitalised.
2. The Committee clarified that if participants are hospitalised, they would potentially be able to continue on the study and if they required further treatment in the hospital there would be no issues with ongoing participation, but communication between research and clinical staff will be necessary. Participants may be withdrawn if they required further other treatment or it would be unsafe for them to continue in the study. The Researcher clarified that the study dosing occurs over a course of 5 days and will not impact on participants receiving acute care.
3. The Committee clarified that for participants who are potentially eligible and enrolled prospectively, where some time has elapsed before they test positive for COVID-19, they will have a further discussion to confirm eligibility and ensure informed consent.
4. The Committee requested clarification around recruiting participants through General Practice. The Researcher noted that they would not be reimbursing GPs for referrals and as such the participant would not be reimbursed the fee for the GP consultation, during which the possibility of study recruitment was raised.

Summary of outstanding ethical issues

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

1. The Committee requested that if there are home visits that a researcher safety plan be provided for review.
2. The Committee queried the routine exclusion of pregnant people, with a pre-existing risk factor, who are at an significantly increased risk of adverse outcomes from Covid infection,. Please clarify this with the sponsor. The duration of the pregnancy is not an adequate reason unless there is significant scientific proof that this is a valid exclusion.
3. The Committee noted that the application may not be reviewed by SCOTT as this intervention is approved. If this is not to occur, then the researcher would require further peer review.
4. Please include in the adverts that the application has been approved by Northern A HDEC.

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

1. Please remove the tick-box from the statement in the consent form relating to notification of the participants general practitioner, this should be mandatory.
2. Please provide a safety plan for follow-up of responses to the questionnaires including how clinicians may be alerted to scores that could indicate concern.
3. Please clarify what specifically is meant by “Items of small value might be provided”. If this is a study device, please be clear around this. If this refers to reimbursement, please be clear about this.
4. Please clarify if transport will be covered and how.
5. Please include how many blood tests will need to be undertaken as part of the pharmacokinetic testing.
6. Please clarify if influenza infection will also be followed-up as per the protocol.

**Decision**

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

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

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

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| **6** | **Ethics ref:** | **2024 FULL 19391** |
|  | Title: | Whiria te hohenga - Supportive cancer care - a feasibility study |
|  | Principal Investigator: | Ms Jeannine Stairmand |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 3 October 2024 |

Ms Jeanine Stairmand 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 the researcher would be training kaiāwhina staff and that the reimbursement would be provided to their employer. Participation of staff occurs during work hours.
2. The Committee clarified that kaiāwhina would be approached directly to participate, rather than asking the employer for a staff-wide approach.
3. The Committee clarified that information and feedback would not be collected from any Rongoā Māori practitioners. The researcher clarified that this was more to facilitate connections for people to these services rather than collecting information about this.
4. The Committee clarified that the study is entirely funded by the Cancer Society.
5. The Committee clarified it would likely not be possible for the kaiāwhina/navigators to be gender-matched to the cancer patients, but if this is possible, please include this in the protocol and the participant information sheet (PIS).

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 suggested utilising the [HDEC data management plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) to ensure that all the aspects required for data and privacy of those participants is accounted for.
2. The Committee requested a researcher safety plan for home visits. It would be appropriate for this to be the provider’s pre-existing plan around this.

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

1. Please clarify that there are limits around confidentiality and privacy with participation and recordings for any focus groups.
2. Please clarify if the audio-recording taken as part of the staff working with cancer patients will be mandatory, and why the sessions are recorded. Specifically, refer to the usefulness of this in determining the feasibility of the tool and what privacy can be assured etc. Please state if participants can ask for this to be turned off at any time for their comfort or any other reason.
3. Please review for the few typos in the document.
4. Please clarify when referring to the HDEC approval that the HDECs only approve the ethical aspects of the study.

**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 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).*

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| **7** | **Ethics ref:** | **2024 FULL 21128** |
|  | Title: | AROINHBE-1001: A Study To Evaluate ARO-INHBE in Adult Volunteers with Obesity With and Without Type 2 Diabetes. |
|  | Principal Investigator: | Dr Rinki Murphy |
|  | Sponsor: | Arrowhead Pharmaceuticals, Inc. |
|  | Clock Start Date: | 3 October 2024 |

Miss Kayla Malate, Miss Julia O’Sullivan, Miss Lucy Druzianic and Dr Rinki Murphy were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee noted that the headlines provided for the advertisements are misleading as the study is not intended to help participants to lose weight.
2. The Committee requested justification from the sponsor as to why there is no intention to purposefully recruit from populations who are significantly more likely to suffer obesity and Type 2 diabetes such as Māori and Pasifika.
3. The Committee requested that the adverts specifically note that there is to be no change in the participant’s diet and exercise as part of the study.
4. The Committee queried potential for ongoing access.
5. The Committee requested clarification around the routine exclusion of people with previous HIV, Hepatitis B and C. The researcher noted that liver damage or liver enzyme issues may have issues with the safety of the medicine and impact study analysis. The Committee requested clarification around the use of previous HIV, or Hepatitis B and C infection as a marker of potential liver damage that might raise safety issues and also interfere with PK analysis. Please note that this being a routine exclusion is not appropriate.
6. The Committee requested provision of follow up with the Sponsor for future licensure and availability in New Zealand.
7. The Committee requested that the DSMC be independent.
8. In the data and tissue management plan, please list the NZCR data governance oversight policies and not just the Te Whatu Ora policies. Sites may add their own as required.

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

Main PIS/CF:

1. Please note that General Practitioner notification should be mandatory.
2. Please be clear that HDECs only approve the ethical aspects of the study.
3. Please use consistent terminology for the study intervention.
4. Please be clear what medications are currently approved for use in New Zealand for weight loss.
5. Please provide an approximate time for the unit visits after the 2-day stay.
6. Please correct te reo spelling to include tohutō (macrons) and remove them where incorrect. Where in doubt please refer to the Māori dictionary online to guide you in this.
7. Please state the number of New Zealand participants.
8. Please be clear what reimbursement will occur when.
9. Please be clear what will be covered in terms of travel and when and how this may be managed.
10. Where you first refer to the reserve participants, please make it clear that they will also be reimbursed.
11. Please be clear that the mode of function of the investigational medicine is to reduce appetite.
12. Please provide side effects from the sub-cutaneous injections.
13. Please clarify that barrier contraceptives are only required in combination with other “effective” modes of contraception and not with ‘highly effective‘ modes of contraception.
14. Please clarify in the “tests and procedures” that the study visit activities occur in the in-person stay.

Part 2 PIS/CF:

1. Please include in the back-box how this is the first time these interventions have been used in conjunction.
2. Please correct “treatment of obesity” to “potential therapeutic benefit to obesity” or similar, avoiding the use of ‘treatment’.
3. Please use the full term for Glycogen-like-protein 1 the first time it appears and then use the abbreviation from that point on.
4. Please clarify what the meal provisions may be or the expectations around meals and what may be provided and why and when.
5. Please amend wording in the visit schedule from clinic visit to clinic stay for the inpatient part of the study
6. Please be clear what reimbursement will occur and when.
7. Please be clear what will be covered in terms of travel, and when and how this may be managed.
8. Please be clear that withdrawal from tirzepatide does not necessitate withdrawal from receiving AROINHBE/ the entire study.
9. Please be clear that the mode of function of the investigational medicine is to reduce appetite.
10. Please provide side effects from the sub-cutaneous injections.
11. Please clarify that barrier contraceptives are only required with other “effective” modes of contraception.
12. Please clarify in the “tests and procedures” that the study visits activities occur in the in-person stay.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Maakere Marr and Ms Jade Scott and Dr Andrea Forde.

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| **8** | **Ethics ref:** | **2024 FULL 21027** |
|  | Title: | ITL-2002-CL-301: A Phase 3 Study to Evaluate NTLA-2002 in Participants With Hereditary Angioedema (HAE) |
|  | Principal Investigator: | Dr Hilary Longhurst |
|  | Sponsor: | Intellia Therapeutics Inc. |
|  | Clock Start Date: | 3 October 2024 |

Dr Hilary Longhurst, Ms Kayla Malate, Ms Julie O’Sullivan and Ms Lucy Druzianic were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the GTAC review had been submitted and no response had yet been obtained from that Committee.
2. The Committee clarified that there is some flexibility for recruitment even in cases where initially potential participants with mental illness etc., may be ordinarily excluded in the study.
3. The Committee clarified the blinding process.

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 protocolised clarification as to the review time and follow up for questionnaires particularly in cases where there may be the possibility for the questionnaires to be triggering or should the participants report mental distress that needs follow up.
2. The Committee queried why the 15-year follow up had not yet been included in the study protocol. It is not currently aligned with the consent form which requests consent to follow up for 15 years. If the follow up is involved, then there must be clear language in the PISCF to explain this.
3. The Committee requested that the data retention period be consistent between the Data and Tissue Management Plan (DTMP) and the Participant Information Sheets and Consent Forms (PISCFs).

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

1. Please note that General Practitioner notification should be mandatory.
2. Please clarify how the smartphone is provided, the length of provision, how it will be provided and under what circumstances. Please also specify if data will be provided if the application requires networking.
3. Please clarify that medication can be provided to treat acute symptoms.
4. Please remove mention of comparison of the study intervention to a Standard of Care treatment when explaining a phase 3 trial as this is not the case here.
5. Please clarify that off-target editing occurred in dog ovaries, and although there was no germline editing, participants should be advised of this.
6. Please clarify that gender-matched clinicians and a chaperone may be requested for genitourinary examinations.

**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:** | 19 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 4:30pm.