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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 June 2024 |
| **Zoom details:** | https://mohnz.zoom.us/j/96507589841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00 - 12:30pm | 2024 FULL 20185 | BGB-21447 in B-Cell Malignancies | Dr Henry Sze Liang Ngu | Helen / Nicola |
| 12:30 - 1:00pm | 2024 FULL 19019 | Quality of life for children with inherited retinal disease | Dr Sarah Hull | Cordelia / Patricia |
| 1:00 - 1:30pm | 2024 FULL 20208 | The caregiver and parental experience of IFNAR1 deficiency in Aotearoa New Zealand. | Dr Simone Watkins | Sandy / Albany |
| 1:30 - 1:50pm |  | **BREAK (20 mins)** |  |  |
| 1:50 - 2:20pm | 2024 FULL 20472 | 5-FU Holter Study | Dr Nicola Lawrence | Maree / Leesa |
| 2:20 - 2:50pm | 2024 EXP 20133 | Ionised serum calcium and serum potassium as indicators of low phosphate and refeeding syndrome in extremely low birthweight babies. | Dr Barbara Cormack | Helen / Albany |
| 2:50 - 3:20pm | 2024 FULL 20521 | CareSens Air 2 in children and adults with type 1 and type 2 diabetes | Professor Benjamin Wheeler | Cordelia / Patricia |
| 3:20 - 3:40pm |  | **BREAK (20 mins)** |  |  |
| 3:40 - 4:10pm | 2024 FULL 20512 | MK3475A-F65: A Phase 2 study of MK-3475A in participants with rrcHL or rrPMBCL. | Dr Anthony Rahman | Maree / Nicola |
| 4:10 - 4:40pm | 2024 FULL 20549 | A Study evaluating multiple doses of FB102 in people with Coeliac Disease | Dr Nah Yeon (Tina) Baik | Sandy / Leesa |
| 4:40 - 5:10pm | 2024 FULL 16733 | The ANZHIT-2 HAPLO study | Dr Clinton Lewis | Helen / Patricia |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/12/2020 | 22/12/2024 | Present |
| Mrs Sandy Gill | Lay (Consumer/Community perspectives) | 22/05/2020 | 22/05/2023 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Apologies |
| Dr Cordelia Thomas | Lay (the Law) | 22/12/2020 | 22/12/2024 | Present |
| Mrs Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Apologies |
| Mrs Leesa Russell | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Dr Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that apologies had been received from Dr Patries Herst and Ms Jessie Lenagh-Glue.   
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures Dr Nicola Swain, Dr Maree Kirk and Mrs Leesa Russell confirmed their eligibility and were co-opted by the Chair as a 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 28 May 2024 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 20185** |
|  | Title: | A Phase 1/1b Open-Label Dose-Escalation Study of Bcl-2 InhibitorBGB-21447 in Patients With Mature B-Cell Malignancies |
|  | Principal Investigator: | Dr Henry Sze Liang Ngu |
|  | Sponsor: | BeiGene NZ |
|  | Clock Start Date: | 14 June 2024 |

Dr Henry Ngu was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted a statement referring to stopping the study in the commercial interests of the Sponsor and advised a trial may not be terminated solely for commercial reasons in New Zealand.

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 whether participants who did not respond to a lower dose could be offered a higher dose if no other treatment options are available. The Researcher agreed to discuss this with the Sponsor.
2. The Committee encouraged the Researcher to offer participants koha in addition to reimbursement for expenses.
3. The Committee requested that GP notification is a mandatory component of study participation.

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

1. Please include a statement acknowledging that information generated in the study may benefit other people in the future but is unlikely to benefit participants. Please state participation is unlikely to treat the condition beyond a possible extension of life, though this is not guaranteed.
2. Please remove references to cohorts B and C on page 2 as this is not relevant to the study population.
3. Please specify which site (‘the site’) and doctor participants will see.
4. Please correct the typo on number of participants on page 11.
5. Please review the sheet for gendered language. The HDEC template has examples of gender-neutral language that may be adapted.
6. Please include a statement advising participants to keep all study medication away from children.
7. Please state the physical examination involves undressing and state whether the participant can bring a support person.
8. Please amend the statement on informing the participant’s local doctor to state the participant’s GP will be informed.
9. Please add “with your consent” to the sentence on following pregnancy on page 17.
10. Please remove the reference to AIDS when mentioning HIV.
11. Please amend the black box first in human warning to state this specific medication has not been trialled in humans before.
12. Please remove the statement regarding study design and researchers interpreting the results in a fair and appropriate way on page 2.
13. Please remove ‘to the extent allowed by applicable laws and regulations’ and replace it with ‘with your consent’.
14. Please simplify the statement regarding TLS testing to be lay friendly.

**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 Mrs Helen Walker and Associate Professor Nicola Swain.

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| **2** | **Ethics ref:** | **2024 FULL 19019** |
|  | Title: | Paediatric Patient-Reported Outcomes in Inherited Retinal Diseases |
|  | Principal Investigator: | Dr Sarah Hull |
|  | Sponsor: | Te Whatu Ora Te Toka Tumai Auckland |
|  | Clock Start Date: | 14 June 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 Researcher confirmed participants who do not have access to Zoom could attend a face-to-face visit. The Researcher agreed to address parking and travel expenses for these.

Summary of outstanding ethical issues

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

1. The Committee queried if information from parents would be collected. The Researcher confirmed a questionnaire with parents would be done. The Committee noted this was not included in the information sheet. The Committee requested the information sheet is updated to refer to “you and your child” where applicable.
2. The Committee recommended a simple assent form with pictures that children are given in advance so they are not asked to participate on the same day they learn of the study.
3. The Committee requested an update to the protocol to include a safety plan to respond to any participant distress when completing the questionnaires. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7; 11.27).*

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17):*

1. The Committee requested the Researcher adapt the [HDEC Information Sheet template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates). Please include prompts regarding ACC, the right to access and correct information, a Māori cultural statement.
2. Please remove any uses of ‘dependent’ children as this is inconsistent with New Zealand law.
3. Please include information on the PHQ-4. Please explain what it is, what it will ask, that there may be triggering questions and if concerning responses are received what the study’s safety plan is and what will happen (eg a referral). Please state who will be performing the interview and their experience in administering these tools with children and parents.
4. Please specify that the parent may withdraw both their self and/or their child.
5. Please state whether travel / parking expenses will be reimbursed.
6. Please state whether koha will be offered to the child in recognition of their participation and what form the child koha will take.
7. Please amend Māori health support to Māori cultural support.
8. Please specify that assent will be obtained from the child.
9. Please correct the ‘land’ typo in the parental consent form and specify that consent is given for their own participation as well as the child. Please include two signature prompts for this.
10. Please include information in the body of the sheet to describe the clause granting permission for the child’s ophthalmic history to be shared.
11. Please address the discrepancy between length of the forms (one hour in assent form and 30 minutes in the consent form).
12. Please revise the statement ‘no one will be angry or upset’ in the script as this cannot be guaranteed.
13. Please simplify the medical language used in the script to be more child-friendly.
14. Please revise being ‘happy’ to participate to ‘agree’.

**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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| **3** | **Ethics ref:** | **2024 FULL 20208** |
|  | Title: | The caregiver and parental experience of IFNAR1 deficiency in Aotearoa New Zealand. |
|  | Principal Investigator: | Dr Simone Watkins |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 14 June 2024 |

Dr Simone Watkins was not present 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 queried if the $50 koha would be per participant or per family.
2. The Committee recommends revising the information sheet to make it read more welcoming, such as including Pacific greetings in the introduction.
3. The Committee noted some participants may have English as a second language and suggested simplifying the content of the information sheet.
4. The Committee queried if older siblings would be considered caregivers and able to offer their perspective. If this is intended please modify the information sheet to address this possibility.
5. The Committee queried how privacy would be maintained as a family offering information about a rare disease could be identifiable even if no direct identifiers are disclosed.
6. The Committee expressed concern at the potential for the questions to cause whakamā in participants and suggested a revision to make them more user-friendly.
7. The Committee queried how the researcher would accommodate the potential for participants not wanting to contradict a senior member.
8. The Committee queried if the researcher was experienced with Pacific cultural norms and how they would be addressed.
9. The Committee requested an experienced interviewer be onboarded to supervise.
10. The Committee requested the demographics form is uploaded.
11. The Committee requested an update to the protocol to describe the support available for responding to participant distress that may arise during the discussion. This should be provided if participants require it and without them having to ask for it. This could include the researcher providing a follow-up phone call several days later to all participants. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7; 11.27).*
12. The Committee queried how the discussions would be transcribed, who would do it, consent for the transcriber, storage and this detail would need to be included in the study design and data management plan (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7; 12.15a)*.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please include Māori cultural support contact details as participants who identify as both Māori and Pacific may be recruited.
2. Please remove the agree and not agree columns in the consent form for all clauses which are not truly optional. Please keep an option for participants to agree to a summary of results if they choose.

**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 20472** |
|  | Title: | Feasibility study of ambulatory Holter monitoring while receiving infusional fluorouracil (5-FU) chemotherapy |
|  | Principal Investigator: | Dr Nicola Lawrence |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 14 June 2024 |

Ms Jade Scott and Dr Nicola Lawrence 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 PI would be managing the conflict when approaching their own patients for participation in the study. The researcher noted that there would be another physician in the same team who would approach and then there would be a follow-up call with the research nurse over the phone.
2. The Committee clarified the halter monitor is a standard one and that there is unlikely to be any interference with regular activity but that this study is to see if it would be feasible for the participants to wear two devices.
3. The Committee noted that there would be no extra visits as part of the study, and everything would occur during standard of care appointments.

Summary of outstanding ethical issues

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

1. The Committee queried if the participant information sheet could include a picture, the Committee recommended taking a photo of one of the research team wearing one.
2. The Committee queried why koha was not being provided to participants. If possible, within the budget, this should be done.

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

1. Please ensure that participants are made aware whether or not they will be required to remove clothing and that they are permitted a support person.
2. Please remove the contraception statement from the consent form.
3. Please remove the tick-box from the withdrawal statement or amend as necessary.
4. Please include a contact for Māori cultural support, the HDC does not provide this and should not be listed for this.
5. On page 8, please note that any information up to the date of the withdrawal will be used. This should align with the amended consent form.

**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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| **5** | **Ethics ref:** | **2024 EXP 20133** |
|  | Title: | Ionised serum calcium and serum potassium as indicators of low phosphate and refeeding syndrome in extremely low birthweight  babies. |
|  | Principal Investigator: | Dr Barbara Cormack |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 June 2024 |

Dr Barbara Cormack 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 the main aims of the study.
2. The Researcher clarified that the only data included in the AI component of the study would be blood test results.

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 the AI tool in analysing an external dataset to develop a diagnostic tool. The data in New Zealand would be used to validate the tool created. The Committee requested that the use of this data be more clearly defined specifically for use with this tool per the AI form that will be sent to the researcher by the HDEC secretariat. *National Ethical Standards* para *13.4-13.18.*
2. The Committee questioned whether the information sheet and consent forms for the previous study and for the taking of blood etc., are in line with what the data may be used for now. The Committee requires these forms in order to determine if the consent given was broad enough to cover this activity. *National Ethical Standards* para *7.16*
3. The Committee queried the ability to consent the former group who were not consented for future use of this data. The Committee would like a justification for waiver that explicitly states the practical reasons for contact. The Committee suggested that it might be beneficial for a sample of this group to be consulted on their feelings on being reconsented or contacted. The Committee suggested a premature birth group be consulted for this. *National Ethical Standards* para *12.29-12.30*
4. The Committee noted that no response to an email be interpreted as a decline to participation. Cases where the email bounced back would be sufficient for waiver. *National Ethical Standards* para *12.29-12.30*
5. The Committee requested that some Māori and Pasifika consultation occur and be submitted to HDEC. *National Ethical Standards* para *3.7* *&* *12.29c*
6. The Committee requested that the researcher utilize the [HDEC data management template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-tissue-management-template-Nov2022.docx) to ensure that all of the information necessary for the application to be considered is present. *National Ethical Standards* para *12.15a, 14.16 & 14.17*

**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 20521** |
|  | Title: | A Prospective, Single-arm, Open-label, Interventional, Pilot Study to Evaluate the Efficacy and Safety of the Continuous Glucose Monitoring System ‘CareSens Air 2’ in Children and Adult Participants with Type 1 and Type 2 Diabetes |
|  | Principal Investigator: | Dr Ben Wheeler |
|  | Sponsor: | i-SENS, Inc. |
|  | Clock Start Date: | 14 June 2024 |

Dr Ben Wheeler and Ms Alisa Boucsein 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 the exclusion of pregnant people from the study. They also clarified that it is likely that a secondary study will occur in this group.
2. The Committee clarified that any condition with inflammation was being excluded due to the physiological role of glucose in inflammation and that the goal of this study was to test function in a physiologically uncomplicated population.
3. The Committee clarified that the device has no current regulatory approval in New Zealand and will not be available immediately after this study.
4. The Committee clarified that the peer review comments had been taken on board and incorporated into the study. The researcher clarified the comments around study design around the finger pricks and the historical collection of data.

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 there be some planning around participants having a conversation a Aged Care consensual sex and contraception alone with the researchers if anything is disclosed.
2. The Committee noted that the insurance amount is low for this type of study. Please ensure that a minimum of $5 million (NZD) is claimable, the number given for intervention studies is typically around $10 million (NZD). Please note that this is for the event that something unlikely does occur.
3. The Committee requested an adult PISCF as this has not been submitted to the Committee.

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

1. Please review language specifically in relation to the assertion that people with diabetes have high levels of health literacy. Please amend all documents to note that this may not be the case and especially in cases where the recipients of information may be young people/children.
2. Please use the lay title when referring to the study.
3. Please state the value of the prezzy cards.
4. Please frame the participant facing information to make it clear that the children will be directly receiving part of the reimbursement.
5. Please remove mention of the NuvaRing as this form of contraception is not available in New Zealand.
6. Please ensure that the taking of photographs as well as the storage of that data and the privacy of individual participants is clearly explained and documented.
7. Please review and remove gendered language.
8. Please use the standard wording per the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) around accident compensation.
9. Please amend and be consistent with the phrasing used to describe people’s primary care doctor.
10. Please include a cultural statement per the [HDEC template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc)
11. Please be clear that observers may be present for some procedures.

The Committee requested the following changes to the Children’s Participant Information Sheet and Assent Form (PIS/AF):

1. Please include a description that there may be some pain/discomfort and the possibility of numbing the area.
2. Please amend the wording “are you happy to take part” to “do you agree to take part”.
3. Please ensure that the assent form includes that the young person gives their assent to their information going overseas.

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

1. Please remove the wording “you and your child” as no data is being collected from the parents. They are not participants. If this is not the case then you need to amend mention of how the parent is actually participating and what data of theirs will be collected.
2. On page 2 please reword the statement around interstitial fluid to read in lay language as this is quite unclear.
3. Please clarify the period between screening and first visit and whether there may be some variation in the 51-day period.
4. Please clarify the language around how many sensors will be worn at one time.
5. Please clarify the statement around “may not have worn” to clarify what would happen “if they have not worn one”.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).
4. Please provide more detail in study documentation to ensure participant safety if there are potential concerns with their well-being raised as part of this study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4-8.6, 8.9)*
5. Please supply evidence of ACC-equivalent compensation available to all participants in the event of injury during the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Patricia Mitchell and Dr Cordelia Thomas.

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| **7** | **Ethics ref:** | **2024 FULL 20512** |
|  | Title: | A Phase 2 Study to Evaluate the Pharmacokinetics, Efficacy, and Safety of Subcutaneous Pembrolizumab Coformulated With  Hyaluronidase (MK-3475A) in Participants with Relapsed or Refractory Classical Hodgkin Lymphoma (rrcHL) or Relapsed or  Refractory Primary Mediastinal Large B-cell Lymphoma (rrPMBCL) |
|  | Principal Investigator: | Dr Anthony Rahman |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited |
|  | Clock Start Date: | 13 June 2024 |

Dr Anthony Rahman, Kayla Malate, Julia O’Sullivan, Lucy Druzianic, Gill Wyatt, Hamish Prosser, and Kara Bolton were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried 15 years for storage of samples. The Researcher responded that 15 years is good practice internationally for oncology trials.
2. The Researcher confirmed that participants will understand what standard of care is and have it explained by an oncologist before entering the trial.

Summary of outstanding ethical issues

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

1. Please add clarification on page 2 that participants have to be refractory or relapsed.
2. On page 4, please clarify the bottom bullet point regarding ‘the tissue may be completely used and no longer available’ and expand that even if they have had a previous biopsy, they may need another one because the tissue may be completely used.
3. Page 4 states that test results “may” become part of their clinical records, but in New Zealand it will be.
4. Different terminology for doctors across pages 13 to 15. Please use consistent terminology or make it clear what these doctors are as these can be expressions (i.e. usual doctor and family doctor) for the same role.
5. Reproductive risks states there is no issues with semen, but CF asks participants to tell their partner about risks of participation. If there are no risks in semen, please remove that CF item.
6. Please ensure the body of the PIS advises participants that their GP will be notified of participation.

**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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| **8** | **Ethics ref:** | **2024 FULL 20549** |
|  | Title: | A three-part, multi-centre randomised, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics, and immunogenicity of FB102 after single and multiple ascending dose administrations in healthy participants and multiple dose administration in participants with celiac disease. |
|  | Principal Investigator: | Dr Nah Yeon (Tina) Baik |
|  | Sponsor: | Fore Biosciences Australia Pty Ltd |
|  | Clock Start Date: | 13 June 2024 |

Dr Tina Baik, Kshemina Mhaksar, Cheryl Glover, Bev Paperiello, and Thomas Stock 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 queried how they decided on the compensation amount for participants. The Researchers responded that participant burden and previous studies informed the amount. This funding is consistent with other studies. The Committee noted they see a range of participant compensation for studies. Compared to other studies of this nature, this is on the low side for what the study is asking participants to do. In the Committee’s opinion, the endoscopy rate is quite low for an involved procedure that requires time off work and recovery and suggested increasing the amount.

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

1. Please use inclusive and non-gendered language, so amend things like “female who might become pregnant” to just “person who may become pregnant”, etc.
2. There is reference to live vaccine – please clarify that the Covid-19 vaccine is not a live vaccine.
3. Clarify that ‘local doctor’ means GP for more localised context.
4. Ensure acronyms are defined before use such as coeliac (CD), and then use the acronym consistently from there.
5. Please remove the stigmatising mention of AIDs.
6. The Committee noted that the study cannot be stopped only for commercial reasons – the PIS currently states it can be stopped for any reason.
7. Please remove optional tickbox in the CF to ensure mandatory inclusion of data to be retained if participant withdraws after a certain point.

**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 16733** |
|  | Title: | A multi-centre, Australian and New Zealand, phase II exploratory study of amendments to conditioning regimens in haplo-identical  stem cell transplantation – The ANZHIT-2 study |
|  | Principal Investigator: | Dr Clinton Lewis |
|  | Sponsor: | Te Whatu Ora | Te Toka Tumai - Auckland |
|  | Clock Start Date: | 13 June 2024 |

Dr Clinton Lewis and Azmeena Sajid were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried the exclusion of those with HIV. The Researcher responded that there is concern around immune suppression with participation, and the potential for medication interaction.

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 clarified with the Researcher that the surveys used are not offered as part of standard of care (SOC) and are an additional measure for the trial. After discussion, the Committee noted that the routine assessment of survey answers stated by the Researcher is in conflict with the participant information sheet stating that these are not collated until the end and to be sighted by the Sponsor. Given these surveys ask questions surrounding whether a participant is distressed or suicidal, there must be an adequate response in place and timely review of these surveys – all of which should be documented as part of a safety response plan and also clarified to participants of how the study will respond to any distressed identified in participants.
2. The Committee highlighted the following exclusion criteria: "Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule. This condition must be discussed with the patient prior to signing consent and registration in the trial". The Committee requested to please provide examples of this and what is available to ensure someone can participate.
3. The Committee noted a koha would be applicable to this study, and suggested discussing it with the study team if this is something that can be offered.

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

1. The CF states ‘I consent to the future use of any data I provide for research purposes. I understand that before they can use any data I provide, they must seek additional ethics approval.’ This does not have an optional tick/box for it, thus stating it is mandatory, and is not explained in the body of the PIS. Please review and amend.
2. "Vaginal contracepive ring (e.g. NuvaRing®)" not available in NZ - to be removed from PIS. There is an up to date [template for reproductive risks](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) that can be adapted to also avoid gendered language here.
3. Some of the side effects should be defined for lay readability (e.g. stomatitis, febrile neutropenia, oedema etc).
4. Also under side effects, probabilities such as "≥1/100" should read "more than 1 in 100 participants”.
5. GVHD first appears as only an acronym. All acronyms should be defined in full when they first appear.
6. Page 2 states "family donors who have at least 50% (1 in 2 people) identity to patients" – please clarify what this means.
7. Page 2 states "This new study (ANZHIT-2) which you are being invited to participate in the aim to improve the conditioning used in an earlier study by using a new conditioning chemotherapy agent and radiation therapy (total body irradiation/TBI) and determine whether these changes will improve disease free outcome for patients with less side effect" The Committee requested this be rewritten to be a more cohesive sentence.
8. On page 5, "you will be reviewed daily to access your wellbeing" should be "assess"
9. CF needs to specify that participants are consenting for their information for going 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).*
3. Please update the study protocol, taking into account the feedback provided by the Committee*. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please provide more detail in study documentation to ensure participant safety if there are potential concerns with their well-being raised as part of this study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4-8.6, 8.9)*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Mrs Patricia Mitchell.

## General business

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

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| --- | --- |
| **Meeting date:** | 23 July 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 5:10pm.