|  |  |
| --- | --- |
| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 04 April 2024 |
| **Zoom details:** | https://mohnz.zoom.us/j/96507589841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12:30 - 1:00pm | 2024 FULL 19771 | A Phase 1 Study of BGB-B2033, Alone or in Combination With Tislelizumab, in Participants With Advanced or Metastatic Solid Tumors | Prof Ed Gane  | Jonathan / Sotera |
| 1:00 - 1:30pm | 2024 FULL 13562 | The BEAD Study | Dr. Lynn Sadler | Catherine / Andrea |
| 1:30 - 2:00pm | 2024 FULL 19553 | Validation of a mental wellbeing scale for young people with chronic stomach symptoms | Dr Stefan Calder | Jonathan / Derek |
| 2:00 - 2:30pm | 2024 FULL 20067 | A clinical trial of gene-modified immune cells to treat lymphomas that have not responded to or have come back after chemotherapy (ENABLE-2) | Dr. Philip George | Catherine / Derek |
|  |  | **BREAK 30 MINUTES** |  |  |
| 3:00 - 3:30pm | 2024 FULL 19940 | DBQ103CT: Safety, pharmacokinetics, immunogenicity, & biological effects of DONQ52 in celiac disease patients with gluten challenge | Dr Dean Quinn | Jonathan / Andrea |
| 3:30 - 4:00pm | 2024 FULL 19923 | WHIRI TB: Towards tuberculosis elimination for Māori | Professor Philip Hill | Catherine / Jade |
| 4:00 - 4:30pm | 2024 FULL 20128 | Measuring vaccine induced protection against tuberculosis in blood | Dr Gergely Toldi | Catherine / Jonathan |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mr Derek Chang  | Non-lay (Intervention studies)  | 08/07/2022 | 08/07/2025 | Present  |
| Dr Kate Parker  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Apologies |
| Dr Andrea Forde | Non-lay (Intervention studies)  | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey  | Lay (the Law) (Chair) | 19/03/2019  | 19/03/2022  | 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 |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Dr Kate Parker.

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 19 March 2024 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1**   | **Ethics ref:**   | **2024 FULL 19771** |
|   | Title:  | A Phase 1 Study of BGB-B2033, Alone or in Combination With Tislelizumab, in Participants With Advanced or Metastatic Solid Tumors |
|   | Principal Investigator:  | Professor Ed Gane |
|   | Sponsor:  | BeiGene NZ Unlimited |
|   | Clock Start Date:  | 04 April 2024 |

Professor Ed Gane was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee asked about trial registration and if it is still pending. The Researchers will confirm registration.
2. The Committee asked about potential participant numbers and enrollment. The Researchers explained that there will be limited eligible participants given the first line treatment is unfunded in New Zealand. Around 100 patients are being treated a year across New Zealand, and of those 100 15-20 percent will be considered for this study.

Summary of outstanding ethical issues

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

1. Please add all laboratory locations to the DTMP.
2. Please add relevant organisation data and tissue management policies to the DTMP.
3. Please ensure sections B1 and D4 are consistent in terms of the potential provision of non-research clinical care to participants by investigators.
4. Please amend section D9 of the application form to ensure it reflects that participants will have all the information necessary to make an informed decision prior to consenting.

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

1. On page 2 please ensure that a full explanation is given before using acronyms.
2. On page 5, in the table of examinations, tests, or procedures please rephrase “Your study doctor will ask to perform antidrug antibody (ADA) tests…” to “will ask you to provide blood samples for ADA testing…”
3. On page 8 please ensure this reflects that the investigator is responsible for informing a GP.
4. On page 2, section 2: BGB-B2033 +/- tislelizumab. Please add a statement referring to current marketing approvals for tislelizumab in New Zealand and overseas.
5. On page 11 “These side effects could be similar to tislelizumab (see section 10.2.1)” There is no section 10.2.1, please amend.
6. On page 18, “Your GP [will / may] be notified of your participation”. Please amend to “Your GP will…”
7. Please check for spelling errors and grammar errors.
8. Please indicate the time-points per day for PK determination.
9. For the examination treatment and procedures section, please include a table.
10. Please ensure that the NZ sponsor, Beigene Unlimited is reflected in the PIS.

**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 Sotera Catapang and Mr Jonathan Darby.

|  |  |  |
| --- | --- | --- |
| **2**   | **Ethics ref:**   | **2024 FULL 13562** |
|   | Title:  | The BEAD Study |
|   | Principal Investigator:  | Dr. Lynn Sadler |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 16 March 2024 |

Dr Jordan Wimsett and Dr Lynn Sadler 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 discussed the progress of the feasibility study, noting that this main study is substantially unchanged. The researchers explained the feasibility findings and that participants’ data remains blinded to the Researchers and therefore can be included in the main study.
2. The Committee asked about the material gathered from the interviews of participants and if that material has been written up and prepared. The Researchers explained that the plan is for an interim analysis and are currently writing an abstract for a conference and plans to publish.
3. The Committee asked about the reference to data sharing with a study in the UK involving use of the fetal pillow. The Researchers explained the study in the UK is yet to gain approval and any data sharing will be addressed by way of amendment.
4. The Committee discussed the observational research that has been conducted with the study device and the Researcher explained that Dr Sadler has published a retrospective study on the use of the device prior to the feasibility study and will provide this.
5. The Committee asked about the communication of results. The Researcher explained since the start of the feasibility study, the medical device company has retracted the paper supporting the use of the device and has re-done all the promotional material. The Researchers will not share the participant data with the device company and the device company is not involved in the design of the study or the data collection. The Researchers will be publishing the paper and may tell the device company the findings if needed but at present have no plans to do so.
6. The Committee asked about communication of the study findings to MedSafe and the researchers advised of communications to date and acknowledged the importance of communicating information about the research to MedSafe.
7. The Committee asked about the Researchers’ response to the peer reviewer’s comment on the use of the device suggesting that the device only be used in the context of the proposed study. The Researcher explained that the device is licensed in NZ and is used by individual clinicians based on individual clinical judgment and preference.

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 existing peer review is for the feasibility study. The researchers advised the Committee that the published paper, referenced in this application as being published since the feasibility application, was a retrospective study. The Committee requested a copy of this paper and the associated peer reviews, editorial comments, letters to the editor etc.
2. The Committee recommended any advice or changes made to the study due to the feedback of other clinicians regarding recruitment that this is submitted to HDEC through an amendment. The Committee requested the upload of additional peer review coming in because of the funding process.
3. The Committee also discussed the collection of data from clinicians involved in the research and advised that any changes resulting from this will need to be submitted as an amendment if there is any change to recruitment process.
4. The Committee noted that once the feasibility study is complete the recruitment materials such as the posters and video will need to be revised and submitted as an amendment.
5. Please upload the IDMC charter.
6. Please upload the survey information.
7. In the data management plan please remove references to participants aged under 16.

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

1. Please review the Consent Form for clinicians to ensure it is suited to that participant group and review for errors.
2. Please note that HDEC approval is for the ethical aspects of a study and HDECs do not provide locality approval.

**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 Andrea Forde and Ms Catherine Garvey.

|  |  |  |
| --- | --- | --- |
| **3**   | **Ethics ref:**   | **2024 FULL 19553** |
|   | Title:  | Validation of a mental wellbeing scale for young people with chronic stomach symptoms |
|   | Principal Investigator:  | Dr Stefan Calder |
|   | Sponsor:  | New Zealand Health Research Council Programme Grant |
|   | Clock Start Date:  | 04 April 2024 |

Dr Stefan Calder was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee asked if the measures in place to assess capacity to provide informed consent are adequate given the somewhat sensitive nature of the questions related to mental health. The Researchers explained the measures in place.
2. The Committee asked about the exclusion criteria highlighting the self-induced vomiting or eating disorder exclusion criteria keeping in mind the high prevalence of youth eating disorder in primary and secondary mental health and some misleading information on social media regarding eating disorder and Disordered Eating Behaviours. The Researchers explained that is it a global online survey and they are reliant on self-report.
3. The Committee asked about potential psychological risks as, while the application states that there are no anticipated risks, there is acknowledgment of potential emotional discomfort from answering psychometric questions. The Researchers explained that none of the psychometric tools being used are diagnostic tools but are utilized to assess the participants to give an indication how they are feeling. Providing reference to appropriate mental health resources in the participant facing information was discussed and agreed.

Summary of outstanding ethical issues

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

1. Please remove details of the AHREC and include the HDEC contact details.
2. Ethics approval is not time bound, please amend the wording to the following: ethical aspects of the study have been approved by Northern A HDEC.
3. Please amend the invitation email to replace with "If you, or if you are a parent, your child...".
4. Please include some wording around the young person involving their parents if they wish.
5. Following the advice, If any of the questions make you feel upset or you would like to contact someone to talk about your mental health further, please talk to your family or friends, or contact your general health practitioner, a psychologist, or a support service/ free support line in your country, please delete "or you would like to contact someone to talk about your mental health further" to impress the need for them to speak up.
6. Please include information to explain where the data will be stored and for how long.
7. In the data management plan please add pertinent UoA governance documents e.g., Research Data Management Policy, Code of Conduct for Research, Data Governance Policy etc.
8. Please amend the application from section A.4.

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

1. Please add a version number/date to the participant information sheet and protocol.
2. Please provides links to resources for participants where possible.

**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).*

|  |  |  |
| --- | --- | --- |
| **4**  | **Ethics ref:**   | **2024 FULL 20067** |
|   | Title:  | A clinical trial of gene-modified immune cells to treat lymphomas that have not responded to or have come back after chemotherapy (ENABLE-2) |
|   | Principal Investigator:  | Dr. Philip George |
|   | Sponsor:  | Malaghan Institute of Medical Research |
|   | Clock Start Date:  | 04 April 2024 |

Brittany Lavender, Patries Herst and Dr Weinkove was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee asked about the submission to GTAC. The Committee also asked about EPA approval. The Researchers explained that the study was submitted to GTAC the same day as the submission to HDEC, and that the Researchers have approval from EPA in relation to the transport of the modified cells. The researchers agreed to provide copies of the GTAC and EPA approvals/recommendations. The Committee asked about how long the manufacturing process will take and if any variations with this. e The Researchers explained the manufacture takes 11 days however there is variation based on several factors. The Committee acknowledged this and requested that this be explained to participants.
2. The Committee asked about the possibility of participants receiving a second administration of CAR-T cells, as referenced in the Protocol. The Researchers explained that it is very unlikely to occur for example in the instance of a manufacturing failure/problem. This will be clarified for participants.
3. The Committee asked about the recruitment process and if the participants were recruited in Wellington or more widely. The Researchers confirmed that participants could be recruited nationally, with travel and accommodation assistance accordingly. The Committee questioned whether this study was commercially sponsored as the sponsor includes a commercial arm, and the intention is to commercialise the product and manufacturing process if successful. The Committee acknowledged the provision for cover in the Protocol, noting the need for this to be no-fault. The Researchers acknowledged uncertainty and noted their intention to discuss the issue with ACC.
4. The Committee asked if participants should be vaccine boosted before coming into the study. The Researcher explained that most of the participants will have recently had chemotherapy and the contraindication for live viral vaccines is due to this the earlier chemotherapy. The researchers acknowledged that the need for vaccine boosters is of ongoing international interest.

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 note that GTAC approval is imperative and notice of the details of GTAC approval are informative for HDEC approval in particular with regard to participant facing documentation. The Committee requested that the GTAC decision be provided. Pending consultation with ACC this study will be treated as commercially sponsored so please ensure that the Protocol (section 16.6) reflects no-fault compensation and that this is reflected in the PIS.
2. The Committee stated more information around data management is required 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 is not mandatory but is encouraged to be adapted or used as a guide/starting point.
3. Section B12 of the application refers to GTAC as Medsafe, please amend.
4. Please submit the EPA approval documentation.

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

1. In the main participant information sheet please amend the advocacy email and correct the HDEC phone contact number.
2. Please include how long the manufacturing process will take and the potential variation with this.
3. For the tissue bank, please clarify and include what data is retained and if this is identifiable.
4. Please amend the barrier contraception section “to avoid damage from secreted chemotherapy” to exclude reference to a diaphragm.
5. For the questionnaires HDEC suggest including Whānau and/or friends into who participants may want to talk to in case of distress.
6. Please amend the Costs and Financial Support section: it will be beneficial to provide more info regarding the process for accessing financial assistance (travel and accommodation expenses under the National Travel Assistance (NTA), including eligibility criteria and how to apply.
7. On page 19: "Due to the possible risk of ICANS, you must not drive or operate heavy machinery for at least 8 weeks after receiving WZTL-002 CAR T-cell therapy. " The reasons for the driving restrictions are not clearly articulated here, please amend.

**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 Ms Catherine Garvey and Mr Derek Chang.

|  |  |  |
| --- | --- | --- |
| **5**   | **Ethics ref:**   | **2024 FULL 19940** |
|   | Title:  | DBQ103CT: Safety, pharmacokinetics, immunogenicity, & biological effects of DONQ52 in celiac disease patients with gluten challenge |
|   | Principal Investigator:  | Dr Dean Quinn |
|   | Sponsor:  | Chugai Pharmaceutical Co., Ltd |
|   | Clock Start Date:  | 04 April 2024 |

Prof Richard Stubbs 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 inclusion of Pfizer in the submission. The researchers indicated that this was an error.
2. The Committee queried the exclusion of vaccination with inactivated influenza vaccine. The researchers clarified that this was appropriate for an early stage interventional 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. Please amend section C18.2: all participants have the right to a support person.
2. Because it's an intervention study, it's routine to advise GPs please include this.
3. Please list the local data governance policies.
4. In relation to pre-screening using the third party Evrima, please ensure that participants are advised of who has access to their data. Please also ensure that this is included in the data management plan. Please also state what happens to identifiable data that is collected from screen failures, and please include this in the data management plan.
5. Please amend the advertising to ensure that it reflects that the study involves only a potential new treatment. Please also review the email recruitment materials and content which is currently not acceptable for use.
6. Please include details of the global sponsor.
7. The Committee stated more information around data management is required than what is available in the study documentation 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/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.
8. Please amend the pregnancy and lactation section. There is reference to egg donation being prohibited but no reference to sperm donation being prohibited The Committee noted that the IB references the absence of reproductive or developmental toxicology studies. The committee considered that male participants also have a responsibility to avoid conception.
9. Please revise wording on collection of data about the event of pregnancy and infant by seeking further consent from the participants.

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

1. On page 4 please remove the reference to the ‘unborn’ baby’ Please amend the wording and include the section regarding the risks to the pregnancy.
2. Please amend the units used as measurements of alcohol consumption The Committee queried the precision of the measurements and suggested that rounding be considered.
3. Please remove the wording in the emails to a GP which refers to; “We do this, in part, by integrating with existing clinical management systems to identify suitable patients for active clinical trials that could positively reshape their healthcare journey.”
4. Please note that HDEC only approve ethical aspects of the study.
5. Please provide a clean version of the protocol.
6. Please amend the exclusion criteria by providing more detail upfront for participants.
7. Please review page 6 of the PISCF, heading “What Study Treatment will I be taking?” The following text does not answer this question.
8. Please include how much participants will be paid.
9. Please ensure that participants are fully informed of data collected when using the eDiary prior to use and ensure that identifiable data is not collected by third parties. Please clarify whether a paper diary is available.
10. Please review all advertising against the HDEC advertising guidelines.
11. Please remove all references to Pfizer.
12. The Committee queried the Quality of Life questionnaires referenced in the PISCF and requested that they be uploaded for review.
13. Please amend the Study treatment period: In the first paragraph it says that on day 9 participants will be at the study site for 6 hours in the next paragraph that changes to 7 hours.
14. The Committee requested the inclusion of a cultural tissue statement to the PIS. The Committee recommended the following statement: *“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
15. "For Male Participants: Male participants and their partners are not required to use any form of contraception.” Please clarify and amend the wording. HDEC recommend contraception be used for both male and females’ participants.

**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 Mr Jonathan Darby and Dr Andrea Forde.

|  |  |  |
| --- | --- | --- |
| **6**   | **Ethics ref:**   | **2024 FULL 19923** |
|   | Title:  | WHIRI TB: Towards tuberculosis elimination for Māori |
|   | Principal Investigator:  | Professor Philip Hill |
|   | Sponsor:  | New Zealand Health Research Council & Te Niwha |
|   | Clock Start Date:  | 04 April 2024 |

Ms Sue McAllister and Prof Philip Hill 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 Committee commended the researchers for the changes made to the study.

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

Summary of outstanding ethical issues

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

1. Please add the location and likely time for the focus groups.
2. Please add additional organisational policies in the data management plan (UoA, TWO).
3. Please amend the safety plan as allowing 3 hours following the scheduled end of a visit before contact is made is too long. HDEC suggest if there is no contact within 30 minutes of the scheduled end, escalate to next step.
4. Please include more details about Prof Nina Scott and the potential conflict of interest with Māori consultation.

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

1. In the participant information sheet for situational analysis HDEC suggest letting the participant know that the researcher will be coming to the participants home and how they will arrange the time/location to be convenient for the participant.
2. Please adjust the assent forms. The language used is too technical, please consider simple pictures, for example, lungs/coughing.
3. Please amend the participant information sheet (7-11yrs) by adding what the blood sample is testing for. HDEC suggest adding some pictures.
4. Please amend the Health Professional participant information sheet by including a sentence regarding no cost to participant/will not be reimbursed for your time.
5. Please include who has approved the study, please note that HDEC only approve the ethical aspects of the study.
6. Please include if there are provisions in place to address barriers to participation, such as transportation or childcare issues.
7. Please include the mental health support resources that are available for participants, particularly considering the potential stigma associated with TB.

**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).*

|  |  |  |
| --- | --- | --- |
| **7**   | **Ethics ref:**   | **2024 FULL 20128** |
|   | Title:  | Measuring vaccine induced protection against tuberculosis in blood |
|   | Principal Investigator:  | Dr Gergely Toldi |
|   | Sponsor:  |   |
|   | Clock Start Date:  | 04 April 2024 |

Dr Gergely Toldi was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee asked about the appointments with participants, who will be talking to the participants and the time frames. The Researcher’ will be meeting with the participants and taking the blood samples and will provide advice or answer any questions the participants have during the 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. Please add Dr Toldis contact information on the advertising.
2. Please amend 20 drops of blood, into mLs.
3. Please upload a copy of the peer review on letterhead and dated for clarification.

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

1. There is a possibility that participants data may be sent overseas. Please add the statement from the HDEC PISCF template: “Your [coded / identifiable / anonymised] information may be sent overseas. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders."
2. Please amend the baby consent form by changing statements from “my information”/”my samples” to “my baby’s information” and “my baby’s samples” etc.
3. Please remove reference to teaspoons.
4. Please include who has approved the study, please note HDEC only approve the ethical aspects of the study.
5. Please include that when participants attend the appointment for the follow up blood samples, they are free to ask for advice/questions/progress about their baby/infant.

**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).*

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 21 May 2024 |
| **Zoom details:** | TBD |

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.