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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 11 October 2022 |
| **Zoom details:** | 96507589841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 10:30 – 11.00am | 2022 AM 4030 | Investigating the high incidence of Māori and Polynesian children with autoimmune neurological disease in New Zealand | Dr Hannah Jones | Dr Devonie Waaka & Mr Anthony Fallon |
| 11.00 – 11.30am | 2022 FULL 12591 | Investigating Autoimmune Encephalitis in New Zealand | Dr Hannah Jones | Ms Neta Tomokino & Ms Joan Pettit |
| 11.30 – 12.00pm | 2022 FULL 13536 | Assessing the effects of LSD micro dosing in people experiencing depression | Associate Professor Suresh Muthukumaraswamy | Mr Dominic Fitchett & Ms Amy Henry |
|  |  | **BREAK (30 MINUTES)** |  |  |
| 12.30 – 1.00pm | 2022 FULL 13560 | RBN-3143-21-001: A Study Assessing RBN-3143 in Healthy Participants and Participants with Moderate-to-Severe Atopic Dermatitis | Principal Investigator Alexandra Cole | Mr Anthony Fallon & Dr Devonie Waaka |
| 1.00 – 1.30pm | 2022 FULL 13579 | 219288 - Phase 3 Study of Bepirovirsen in Nucleos(t)ide Analogue-treated Participants with Chronic Hepatitis B (B-Well 2) | Professor Edward (Ed) Gane | Ms Dianne Glenn & Mr Barry Taylor |
| 1.30 – 2.00pm | 2022 FULL 11763 | USPIO MRI Tracking macrophage scan for brain tumours | Mr Ahmad Taha | Ms Neta Tomokino & Ms Joan Pettit |
|  |  | **BREAK (30 MINUTES)** |  |  |
| 12.30 – 1.00pm | 2022 FULL 13541 | Digital predictors of asthma attacks | Dr Amy Chan | Mr Dominic Fitchett & Ms Amy Henry |
| 1.00 – 1.30pm | 2022 FULL 12865 | ABTECT-2 – ABX464 Treatment Evaluation for ulcerative Colitis Therapy -2 | Dr Vivek Tharayil | Mr Anthony Fallon & Dr Devonie Waaka |
| 1.30 – 2.00pm | 2022 FULL 13343 | Improving Genomic Diagnosis for Tamariki | Professor Stephen Robertson | Ms Dianne Glenn & Mr Barry Taylor |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Devonie Waaka | Non-lay (Intervention studies) | 18/07/2016 | 18/07/2019 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay Intervention/Observational studies) | 28/06/2019 | 28/06/2020 | Apology |
| Mr Dominic Fitchett | Lay (the Law) | 05/07/2019 | 05/07/2022 | Present |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Ascc. Prof Nicola Swain | Non-lay Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Apology |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The Chair opened the meeting at 10.00am and welcomed Committee members, noting that apologies had been received from Associate Professor Mira Harrison-Woolrych and Associate Professor Nicola Swain.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Joan Pettit and Mr Barry Taylor 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 13 September 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 12591** |
|  | Title: | Investigating Autoimmune Encephalitis in New Zealand |
|  | Principal Investigator: | Dr Hannah Jones |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 September 2022 |

Dr Hannah Jones was present via videoconference for discussion of this application.

After discussion with the Researcher, it was agreed that 2022 FULL 12591 be heard prior to 2022 AM 4030, as the principal ethical issue 2022 AM 4030 is the same as 2022 FULL 12591.

**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 peer review recommendations and if they have been incorporated into the protocol. The Researcher explained that they have been incorporated into the protocol.
2. The Committee asked about consent for the retrospective data collection or if the researcher is actually applying for a waiver of consent. The Researcher explained that they would not use tissue samples without the participant’s consent but would consider using the clinical data from medical records if they are unable to contact the participant.
3. The Committee asked about recognizable reporting and the issues that can arise. The Researcher explained that the cohort is large enough now that they believe recognizable reporting will not be an issue.
4. The Committee asked about the postcode question in the participant questionnaire and asked why that was included and if it has anything to do with location data gathering. The Researcher explained that the question allows the research team to understand the socio-economic status of the participant and whānau.

**Summary of outstanding ethical issues**

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

1. The Committee asked what would occur when an adult lacks capacity to consent. The Researcher explained that family and friends would provide assent for the adult. The Committee explained that friends and family cannot give assent or consent for an adult lacking capacity to consent. Proxy consent is possible only for a person with an Enduring Power Of Attorney (EPOA) and only in certain circumstances. The Committee further explained that, due to the nature of the research, the best interest test should not be used when enrolling adults lacking capacity to consent in the healthy control group. However, the best interest test could potentially be used when enrolling adults lacking capacity to consent in the patient cohort on the basis that the research imposes only minimal risk; and has the prospect of providing benefits to the group to which the patient belongs (National Ethical Standards: Research with adults who cannot provide informed consent). Please amend the protocol and informed consent documentation accordingly.
2. The Committee queried how quickly blood samples needed to be collected. The Researcher stated that samples needed to be collected promptly, and that waiting until participants regained capacity to consent would severely limit their utility. The Committee accepted that sample collection was time-critical for some of the assays, however testing of the samples (particularly genetic testing) should not be performed in the absence of consent. The Committee requested the Researcher provide a table for the management / withdrawal of already-collected data and tissue under different consent scenarios. This should include a plan to obtain consent after the participant regains capacity, and processes in place if the participant declines. Please also outline what will happen to samples if the Researcher is unable to reach the participant’s EPOA and capacity to consent is not regained by the participant, i.e., what will happen to data and samples that are collected prior to obtaining informed consent if consent is not later obtained.
3. The Committee asked what tests are being done that could be of clinical significance. The Researcher explained that they believe there are no tests that could be of clinical significance. Please clarify in the protocol and participant information sheet/consent form (PIS/CF) that no unvalidated research test results will be returned to participants, including the genetic tests conducted in the United States
4. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
   1. Please amend page 5 of the DTMP, which states that "All participants will be informed of, and provide consent for, the collection and use of their data and tissue for the purposes of this study." The text should address planned waiver of consent if conditions listed below (item 15) are met.
   2. Please amend pages 8 and 9 of the DTMP and clarify section 8.5. These sections refer to future unspecified use of data and tissue, however there is no mention of unspecified use of tissue in the Participant Information Sheet and Consent Form (PISCF).
   3. Please amend Section 13 of the DTMP to reflect the ability to withdraw data and tissue should a participant withdraw from the study. This should be consistent with the information presented in the requested ‘Informed Consent Scenario’ table.
5. Please ensure the Māori Consultation accountability to whānau statement (Application Form C5) is actioned in the explanations in the study information sheets. Keep consistent and simple. Consider Kaumatua support as part of He Kamaka Waiora if available for whānau.
6. Please amend section C11 of the application for Pasifika Consultation by providing the contact details on PISCF for the Pacific Health team.
7. Please provide a formal justification for the requested waiver of consent, ensuring the conditions listed are addressed. Note that this will apply to collection of data only; no waiver of consent will be approved for use of tissue.The Committee stated generally it could grant a waiver of consent for the retrospective data collection if the following conditions are met:
   1. Attempts to reach the participant to obtain consent were unsuccessful;
   2. The participant would likely provide consent;
   3. It is not possible to get consent due to the age or quantity of the samples, seeking consent would impact on the scientific validity of the study (i.e., for epidemiological studies), or the act of seeking consent could cause undue anxiety or distress to those whose consent was being sought; and
   4. No participant or their family would be disadvantaged by the inclusion of their sample and the public interest in the study outweighs the individual’s right to privacy.

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

All PIS/CF’s:

1. Please include a table containing information about all the research tests that will be conducted, confirming that none are validated or potentially clinically significant.
2. Please include a list of informed consent scenarios for the study, stating in lay language what will happen to a) collected data and b) collected tissue for each scenario.
3. Please ensure simple language is used throughout.
4. Clarify in 'what will this study involve' which parts of the study are mandatory and which are optional. Use of subheadings for each study part would be helpful; each subheading should state whether the part of the study described is for 'all participants' or is 'optional'. Please clearly state whether genetic testing is optional.
5. Please amend the following sentence on page 2 by using lay language: 3(b) “Components of your immune system, for example antibodies, complement and other immune signalling molecules.”
6. Please include on page 3 the Māori cultural tissue 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.”
7. Please remove the following sentence (no genetic testing should be performed in the absence of consent): "We will not perform any exploratory gene testing in individuals who have not provided informed consent. However, if we find a gene is associated with inflammation of the nervous system, we will investigate whether the participant has a change in that specific gene to confirm our findings. This will mitigate the risk of finding an unexpected result that may be important for the participant."
8. Please remove all yes/no options from the consent form unless the clause is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).
9. Please delete repeated consent clauses.
10. Please provide a declaration for the participant’s EPOA to sign if required.
11. On page 8 please amend researcher’s declaration to include reference to best interests of participant (not applicable to PISCF for healthy control group).

Friends and Whānau Information Sheets:

1. Please remove reference to assent from the heading (page 1)
2. Please clarify that the role of friends and whānau is to give an opinion about whether they believe the patient would want to take part in the study, i.e., they are not providing any type of assent or consent for the patient’s participation. Clarify that consent can be provided only by the patient or the patient’s EPOA.
3. Ensure all applicable points raised for ‘Main PISCFs’ above are addressed.
4. Amend declaration to remove reference to assent.

**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 Neta Tomokino and Ms Joan Pettit.

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| **2** | **Ethics ref:** | **2022 AM 4030** |
|  | Title: | Investigating the high incidence of Māori and Polynesian children with autoimmune neurological disease in New Zealand |
|  | Principal Investigator: | Dr Hannah Jones |
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Dr Hannah Jones was present via videoconference for discussion of this amendment.

Following agreement with the Researcher, 2022 AM 4030 was discussed after 2022 FULL 12591, as the same major ethical issue applied to both.

**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**

1. The Committee stated that issues regarding the enrolment of adults lacking capacity to consent, previously discussed in 2022 FULL 12591, applied equally to the current study. Please amend the protocol and informed consent documentation to reflect that friends and whānau cannot provide assent or consent on behalf of the patient, and that proxy consent may be obtained only from an individual with Enduring Power of Attorney (EPOA) for the patient.
2. The Committee accepted that sample collection may be time-critical for some of the assays, however testing of the samples (particularly genetic testing) should not be performed in the absence of consent. The Committee requested the Researcher provide a table for the management / withdrawal of already-collected data and tissue under different consent scenarios. This should include a plan to obtain consent after the participant regains capacity, and processes in place if the participant declines. Please also outline what will happen to samples if the Researcher is unable to reach the participant’s EPOA and capacity to consent is not regained by the participant, i.e., what will happen to data and samples that are collected prior to obtaining informed consent if consent is not later obtained.
3. The Committee requested the Researcher clarify in the protocol and participant information sheet/consent form (PIS/CF) that no unvalidated research test results will be returned to participants, including the genetic tests conducted in the United States.

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

1. Please include a table containing information about all the tests that will be conducted, and which ones are validated and potentially clinically actionable. Make clear that other lab tests are for research purposes only and results will not be returned to participants.
2. For each step, please explain when genetic testing is involved and when it is not.
3. Please include a list of scenarios and the processes that will be followed for each scenario in lay language.
4. Please include a process for the person who will be making the determination of best interest test to discuss with the participant and how they will sign it off to enrol the participant.

The Committee requested the following changes to the Assent Forms:

1. Please remove the age guides (6-11 years and 12-15 years) and use "Information Sheet for Children" and "Information Sheet for Young Children" instead.
2. Please clearly state in the assent forms that the child can say no even if the parent or guardian does give consent.
3. Please use lay language and minimise the content in the short assent form.
4. In the longer assent form, please further explain what a gene is, and that they are shared by blood relatives.
5. In the longer assent form, please include a Māori cultural statement.

**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 Devonie Waaka and Mr Anthony Fallon.

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| **3** | **Ethics ref:** | **2022 FULL 13536** |
|  | Title: | Assessing the effects of LSD micro dosing in people experiencing depression |
|  | Principal Investigator: | Associate Professor Suresh Muthukumaraswamy |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 11 October 2022 |

Associate Professor Suresh Muthukumaraswamy 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 nature of the relationship the Researchers have with MindBio. The Researcher explained that the Health Research Council has funded the trial, that MindBio has funded the university to produce the formulation of LSD, and that MindBio has funded the university to create the study application. The researcher explained that University of Auckland (UoA) will own all intellectual property that comes from the study. MindBio has bought the licensing prior to the trial being conducted. The Committee referenced the MindBio website, which emphasises their involvement in the current study and others currently or previously approved by HDEC. The Committee stated that MindBio stood to benefit significantly from the trial and, as such, commercial compensation in event of study-related injury was appropriate.
2. The Committee asked about the mandatory genetic analysis and the potential breadth of analysis. The Researcher stated they cannot be sure of which genetic tests may be undertaken as others may come to light that they want to test for later, for example that affect interactions between the brain and psychedelics. The Researcher stated that they will not be using this genetic testing for future unspecified research and have made that clear in the Participant Information Sheet (PIS). The Committee stated that as the genetic research was exploratory and not limited to one or two specific assays, it should be optional for participants.
3. The Committee confirmed with the Researcher that this study is being reviewed by SCOTT.
4. The Committee asked how the researchers will be identifying potential participants for this study. The Researcher explained that they have a study database of potential participants and several different advertisement materials that have been submitted. Recruitment will be a mix of using the database and approaching people who have registered interest because of community advertisements.
5. The Committee asked about the questionnaires and if all are intended to be used. The Researcher explained that all questionnaires are to be used and do recognise that there are a large number for participants to complete.
6. The Committee asked about how the drug will be given to the participant and what checks are in place. The Researcher explained that the pharmacists will add the dispensing label and the trial coordinator picks up the packet and checks the identifier and will hand it over to the participant in the facility parking lot. The Committee commented that this may cause issues in terms of chain of custody, dispensing errors, and researcher safety. The Researcher stated that the method of dispensing had worked well in the previous study, and that due to safety concerns, the coordinator will only deliver one packet at a time.
7. The Committee asked about the reference to audio recordings in the data and tissue management plan. The Researcher explained that audio recordings could be shared with researchers overseas who have signed confidentiality forms with the University of Auckland (UoA). The Researcher explained that these audio recordings can be used for a future data set, however in practice the people with access will be the researcher team and the UoA collaborators. The Committee stated that voice is considered a biometric identifier, and that the default position of the HDEC is that identifiable data should not be sent overseas. Please provide a justification for doing so in this case.
8. The Committee asked how and when the whanau interview is being conducted. The Researcher explained that it will not be mentioned at the start of the trial but they will seek consent from the participant before conducting the whanau interview.
9. The Committee asked about device use and if participants without access to a device will be offered one. The Researcher explained that the research team will offer participants devices if they do not have access to one or if they do not want to use their personal device for the trial.

**Summary of outstanding ethical issues**

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

1. Please confirm that participants will be eligible for ACC-equivalent compensation in the event of study-related injury.
2. Please submit a Sponsor certificate of insurance.
3. Please submit confirmation of PI indemnity (MPS Certificate of Membership or equivalent).
4. Please remove all references to “treatment” in the study documents; this study involves an investigational product.
5. The Committee requested the following changes to the study protocol:
   1. The protocol design involves active deception of participants, which is considerably more controversial than withholding information. Provide a scientific and ethical justification for deceiving participants with regard to the active comparator, ensuring all bullet points of National Ethical Standard 7.35 are addressed. Justify not disclosing that the placebo could be one of two different products.
   2. Please amend the protocol to address debriefing participants of the deception, including suitable processes for dealing with complaints in this respect.
   3. Please amend the protocol and Data and Tissue Management Plan (DTMP) to address withdrawal of tissue and data for participants who request this on learning of the deception.
   4. Please include a section into the protocol about audio tonality, stating what audio data is being collected and providing a justification for sharing the audio material with overseas researchers.
   5. Please add to page 59 of C-SSRS that one of the "psychiatric issues" that will trigger study team action is a high suicidality score.

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

1. On page 2 please delete 'any information you give us about yourself will remain private and confidential'.
2. Conflict of interest issues include the University as well as MindBio. Please disclose these more directly.
3. Add cardiac risk to the exclusion items.
4. The statement regarding LSD being a Class A drug and not approved for use in New Zealand is currently on page 15. The Committee requested this be moved to page 2.
5. Please state what genes and DNA are in lay language.
6. Please include exactly what audio recordings are collected, the purpose for this, and access to, uses and retention of the recordings.
7. Please state whether the video screening session of participants is recorded.
8. Please ensure that the consent form statement regarding criminal offences, etc is discussed in the body of the participant information sheet.
9. Please state that participants will take oral liquid containing LSD or placebo and capsules containing active comparator or placebo for every dose. A table would make this easier for participants to follow. The order in which the liquid and capsules are to be taken should also be stated, as should instructions for taking the capsules (with a glass of water, with food, etc).
10. Please remove the black box in the main participant information sheet; it is not needed as this is not a first in human trial.
11. Please clarify what audio data will be sent overseas, to whom and for what purpose. Please also indicate if any other data will be sent with the audio recordings.
12. On page 15, please amend "sorted overseas" to "stored overseas".
13. Please ensure all Participant Information Sheets refer to the correct number of pages.
14. Please amend the section titled "How is the study designed" by breaking component parts up into bulleted sections.
15. Please add information about safety monitoring provided in the protocol to explain risk mitigation.
16. Please include a separate addendum that covers optional genetic research, explaining what the researcher intends to do, for participants to sign if they wish to.

**Decision**

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

1. 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).*
2. please address all outstanding ethical issues, providing the information requested by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Amy Henry and Mr Dominic Fitchett.

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| **4** | **Ethics ref:** | **2022 FULL 13560** |
|  | Title: | RBN-3143-21-001: A Study Assessing RBN-3143 in Healthy Participants and Participants with Moderate-to-Severe Atopic Dermatitis |
|  | Principal Investigator: | Principal Investigator Alexandra Cole |
|  | Sponsor: | Ribon Therapeutics, Inc. |
|  | Clock Start Date: | 29 September 2022 |

Dr Alexandra Cole 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 process in place to monitor and manage disease flares on withdrawal of standard care for participants. The Researcher explained their hope for these participants is that they will no longer be on any medications and so they will not be required to stop medication to enrol in this study. During the study, if a participant experiences exacerbation of their disease, that will be looked at on a case-by-case basis. Participants will receive payment in full if they need to withdraw or are asked to withdraw due to medical issues.
2. The Committee asked if the dosage level will be known by the time participants are consenting into the study. The Researcher explained they do not know currently and are waiting for more checks to be completed before confirming the dosage level.

**Summary of outstanding ethical issues**

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

1. The Committee requested the following changes to the advertisements:
2. Please replace 'new medication' with 'investigational medication' in the radio advertising text for both documents.
3. Please ensure all advertising is withdrawn once enrolment is closed in New Zealand.
4. Please note for informed consent that group information sessions are permitted only for Part A participants.
5. Please amend the Sponsor’s Certificate of Insurance, it currently references 8 'patients'; the application states New Zealand will contribute approximately 20 participants. Please clarify the position and amend if applicable.
6. Please delete references to future use of tissue from Section 8.5 and Section 12.2.2 in the data management plan.

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

1. Please review for typographical errors.
2. Please replace 'respiratory' with 'breathing' (table of assessments)
3. Where multiple blood samples are required over the course of a day, please state the approximate number of sets.
4. On page 7 please delete 'and there will be no cost for you to participate in this study'.
5. On page 9 please provide frequencies for midazolam side effects.
6. Please delete exclusion of injuries caused by midazolam from the compensation section.
7. The drug's efficacy is not an objective of Part A of the trial. Please delete the final two bullet points from Section 7.2.

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

1. Please note that comments for Part A may also be applicable to Part B; review and amend as required.
2. On page 2 please delete the sentence about placebo not being used; it is irrelevant.
3. Please use the wording 'eczema' rather than 'AD’ consistently; currently the terms are used interchangeably.
4. On page 4 please explain what white blood cells and antibodies are / do in lay language.
5. Please explain the skin punch biopsy prior to the table of assessments; the procedure should not be explained in the risk section.
6. Please explain who will do the procedure, whether local anaesthetic is used, what area will be biopsied, how big the biopsy is, whether stitches may be required to close the skin, whether the area is covered for a period post-procedure, approximately how long it will take, and whether any precautions should be taken post biopsy.
7. On page 4 please simplify explanation of questionnaires; technical names are not required.
8. On page 7 please replace 'subjects' with 'participants'.
9. Please amend the risk section as it currently describes procedures - photographs, skin swabs, and skin tape strips (see also above re skin biopsy); it is unclear why these are not described in the 'what will happen during the study' section of the document. The risks section should describe only the risks associated with the procedures.
10. The sentence “You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study’s scientific integrity" is not applicable to open-label studies, please delete.

**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 Devonie Waaka and Mr Anthony Fallon.

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| **5** | **Ethics ref:** | **2022 FULL 13579** |
|  | Title: | 219288 - Phase 3 Study of Bepirovirsen in Nucleos(t)ide Analogue-treated Participants with Chronic Hepatitis B (B-Well 2) |
|  | Principal Investigator: | Professor Edward (Ed) Gane |
|  | Sponsor: | GSK |
|  | Clock Start Date: | 29 September 2022 |

Professor Edward 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 whether the study will target recruitment from Māori and Pasifika populations. The Researcher explained that Māori, Pasifika and Asian populations make up 90% of the clinic’s patients.
2. The Committee asked how long after the trial drug is deemed successful will it be available for participants. The Researcher explained that the drug is currently in Phase 3 and will need further approval and funding hopefully in the next 5 years.
3. The Committee asked about the participants’ treatments and how long some participants have been treated. The Researcher explained that it is usually many months, some even years now, and the participants are very familiar with their conditions and would understand the medical terms used in the information sheets.

**Summary of outstanding ethical issues**

1. The Participant Information Sheet and Consent Forms (PISCF) reference the potential for home visits by the research team. If this is planned, please provide a home visit safety protocol to address researcher safety and tikanga.

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

Main PIS/CF:

1. On page 1 and 3 please replace 'new medicine' with 'investigational medicine'.
2. Please reduce the header for all PISCF’s.
3. Please use the lay title (not the formal title) as the main title.
4. On page 1 please replace the IEC statement with HDEC's PISCF template statement.
5. On page 2 of the restart PISCF please remove repetition, i.e. “You will continue to be followed closely for both good and bad effects of the study treatment”
6. On page 3 please give approximate number of New Zealand participants.
7. On page 5 onwards please delete teaspoon and cup references for blood volumes.
8. On page 8 and 9 please move all information and consent regarding optional future research to addendum.
9. On page 8 please clarify that the optional future research will not involve any genetic research.
10. Please change race to ethnicity on page 5 and ensure ethnicity data is collected that it is relevant to New Zealand.
11. Please include (if there are any) what the reproductive risks are for male participants.
12. Please list which contraception cannot be used if participating in this trial.
13. On page 1, 4 and 10 please delete repetition regarding signing the consent form and being given a copy.
14. On page 4 and 10 please delete repetition regarding participation in other studies.
15. On page 11 and 12 please delete vaccine from the discussion of study drug risks and costs.
16. On page 12 please remove brackets from [for male participants] in reproductive risk section.
17. On page 9 and 14 please move information about mandatory samples to one place.
18. On page 14 please delete information regarding optional genetic research; discussed in separate PIS/CF.
19. On page 15 please un-bold bulk of bolded text.
20. On page 15 please include statement that karakia not available at time of tissue destruction.
21. On page 15 please delete reference to health insurance number.
22. Please address risk of confidentiality breach and of sending data overseas (data section).
23. On page 21 please delete 'The injury was caused by belantamab mafodotin, daratumumab, bortezomib, or dexamethasone.'
24. On page 23 please delete 'Complaints Contact Person'.
25. Please add statement regarding GP notification of significant abnormal results in the consent form.
26. Please add statement regarding reproductive risks and responsibilities in the consent form.

Genetic PIS/CF:

1. Please address risk of potential matches across genetic databases, if applicable.
2. Please note that the consent form appears to give consent for related research only, while unrelated research is referenced in the body of the PIS. Clarify what is intended and amend as applicable.
3. Please un-bold ACC statement. Note that it is sufficient to reference main PISCF if preferred.
4. On page 3 please include statement that karakia will be not available at time of tissue destruction.
5. On page 7 please explain or delete reference to sponsor not accepting the claim if “injury caused by belantamab, mafodotin, daratumumab, bortezomib, or dexamethasone.”
6. Please remove non catholic institution option.

**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 Dianne Glenn and Mr Barry Taylor.

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| **6** | **Ethics ref:** | **2022 FULL 11763** |
|  | Title: | USPIO MRI Tracking macrophage scan for brain tumours |
|  | Principal Investigator: | Mr Ahmad Taha |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 September 2022 |

PI was not available to join the meeting.

**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. Please note that the SCOTT approval uploaded relates to the previous study. Clarify whether the current SCOTT review is full or administrative.
2. Please clarify how the study design meets the description of parallel design (it is single arm).
3. Please specify in the eligibility criteria that all participants are willing and able to give informed consent.
4. Please note while study methodology is clearer in the Participant Information Sheet and Consent Form (PISF/CF), it is extremely limited in the protocol. Provide more detailed methodology with schedule of assessments (screening window; timing of enrolment / blood sampling / infusion and scan / tumour sampling / discharge from study).
5. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
6. The responses provided are contradictory, particularly regarding identifiable v de-identified v anonymous data and tissue. Please review thoroughly and amend to clearly reflect what is intended.
7. Please review Section 8.5 (future use of tissue) which is inconsistent with the application form.
8. Genetic incidental findings are referenced in Section 12.1, while the application form states no genetic analysis will be undertaken. Please clarify what is intended and amend documentation accordingly.

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

1. Please review for typographical errors.
2. Please take care not to over-promise benefit ('the extra scan will give investigators extra information').
3. Please amend the use of tissue, it requires better description (e.g., study-specific blood tests)
4. Please describe in lay language what genes, are and the breadth of the intended analyses.
5. Please discuss return of results from validated tests with regards to the scan and genetic analyses performed on the tumour, including potential significance to blood relatives if applicable.
6. Please remove the statement that a participant will leave the study if they experience an AE.
7. Please state whether the iron infusion and associated monitoring and/or scan results will be retained in the clinical record.
8. Please state that the participant's GP or treating specialist will be informed of clinically significant results.
9. On page 5 please delete statement regarding restricted access while on-study.
10. On page 7 please delete optional tick box regarding GP notification of significant abnormal results.
11. 'I consent to any remaining tissue(s) to be used in future aspects of the study' has not been introduced in the body of the PIS. Please amend body of PISCF accordingly.
12. On page 2 please state the risks of genetic analysis.
13. Please state the known risks of Ferumoxytol.
14. Please amend page 4 and clarify if future use of data includes tissue samples.
15. Please amend page 4 and state that data may be sent overseas, and the risks associated with this.
16. Please remove the tick box for the participant's GP being informed of any significant abnormality.
17. Please remove the tick box for the Ethics committee reviewing the data from the consent form.

**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 Joan Pettit and Ms Neta Tomokino.

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| **7** | **Ethics ref:** | **2022 FULL 13541** |
|  | Title: | Digital predictors of asthma attacks |
|  | Principal Investigator: | Dr Amy Chan |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 September 2022 |

Dr Amy Chan 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 recruitment and if the Researchers are part of the clinical team. The Researcher explained that the researchers are separate from the clinical team at Auckland hospital.
2. The Committee asked if the researchers will be screening the participant notes and information. The Researcher explained that they will get a daily list of people who have been admitted that have asthma, that will then be given to the researchers who will then review those patients if it fits the recruitment criteria.
3. The Committee asked about the approach to potential participants and the process. The Researcher explained that the initial approach will be through a member of the research team and using posters around the emergency department/hospital explaining the study and giving potential participants the opportunity to join the study. Research assistant may also approach a potential participant. The Researcher continued to explain in the future they will use a leaflet containing a bit of information about the study and emphasise that potential participants can refuse participation in the study.
4. The Committee asked about consent for those under 17 years and asked why the parent/guardian consents for them. The Committee explained that persons aged 16 and over consent for themselves and persons under 16 given they are capable to, should be given the option to consent for themselves. The Researcher asked if they should submit a separate form for these age groups. The Committee explained that if the persons have capacity to consent, they should understand what is in the adult Participant Information Sheet and Consent Form (PIS/CF), therefore not needing to submit another, separate PIS/CF.
5. The Committee asked if the $10 for data cover is realistic for participants and will it be topped up if the data runs out. The Researcher explained that the $10 was determined by a previous pilot study and that $10 is just a baseline, the research team will cover all data costs.
6. The Committee asked about data management policy and if participants’ local data information and tracking can be turned off during the study. The Researcher explained that the location data will be required during the study as they want to link the data to the pollen and air pollution data. The Researcher further explained that location data does not need to be turned on for all devices used in the study, if they have the location data of one device to link the data together.
7. The Committee asked about the use of artificial intelligence (AI) and the AI expertise within the research team. The Researcher explained that the team has a history of using AI and machine learning in previous studies and that this study is a collaborative approach.
8. The Committee asked about what would happen if a participant lost one or more devices. The Researcher explained that the first device would be covered by the research team, however if the device was to be lost multiple times the participant would not get a replacement device and would not be able to contribute anymore data to the study, emphasising that the research team will not charge the participant for losing any device.
9. The Committee asked about the questionnaires and if the sheets will be modified so that the questionnaire carries participant ID only. The Researcher confirmed this.

**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, as the study was recruiting children, koha should not be a focus in initial recruitment for the study,
2. Please make the koha appropriate for the age group of those who consented, such as small gift/book/money for a child who consented as they are the participant.
3. 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.
4. Please refer to the National Ethical Standards regarding AI, and ensure applicable Standards are addressed in the data management plan.
5. Please explain which device will be enabled with location data tracking and ensure the device that is tracking data of participants is the device that offers the most data protection for participants.
6. The Committee noted that home visits are being conducted as part of this study. Please ensure there is a researcher safety plan for entering homes.

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

1. Please include photographs of study devices to accompany explanations.
2. Please make it clear to participants that their data will be used by the commercial companies that are making the devices for this study.
3. Please include a QR code in the information sheet that sends participants to a list of hyperlinks for the privacy policies of the device companies, to avoid participants typing in entire websites directly.
4. Please include in the body of the information sheet that there will be a small koha for participation.
5. Please explicitly state that the study will use AI to achieve its aims, explain what AI is in lay language, and address AI-specific risks (e.g. increased risk of re-identification).
6. Please provide information regarding GPS and whether exact location is recorded; this may be sufficient to identify participants when combined with other data.
7. Please clarify whether data obtained by the smart devices is owned by the devices or the research team, and whether the researchers have any control over data collected on the devices.
8. It is stated participants will be directed to a link to view peer-reviewed journal articles to view study results; these mean little to lay people. Please ensure all participants are provided with the option of receiving a simple lay summary of study results.
9. Please use the HDEC PISCF template ethics approval statement.

Consent Forms:

1. Please review the consent form for new information that is not a consent clause and delete or move to the body of the PIS.
2. Please clarify who the clinical supports are in the clause 'I am aware of the clinical supports available for me to access should my asthma worsen...'. If this reflects usual health care providers and is not provided by the research team, state this explicitly.

Assent Forms:

1. Please review title; suggest using the term 'teenager' or 'young person' rather than 'child'.
2. Please state how long doing the activities will take and how often they need to be done.
3. Please state that GPS will be enabled (many teenagers have strong views regarding GPS on personal devices)
4. Please make it clear that the devices need to be returned at the end of the study in good condition.
5. Please state that the participant can pull out of the study at any time, without having to give a reason.
6. Please state that the adolescent's wishes take precedence over the parent/guardians.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Ms Amy Henry.

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| **8** | **Ethics ref:** | **2022 FULL 12865** |
|  | Title: | ABTECT-2 – ABX464 Treatment Evaluation for ulcerative Colitis Therapy -2 |
|  | Principal Investigator: | Dr Vivek Tharayil |
|  | Sponsor: | Abivax |
|  | Clock Start Date: | 29 September 2022 |

Sandra Hargrove 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 what will happen if a participant has a decline in health and has been removed from the study, and if there will be any follow up and support for the participant. The Researcher could not answer this question but assured the committee that there will be support in place for these participants that may have a decline in health.
2. The Committee asked about the reasoning for saying there will not be ongoing access available for participants. The Researcher explained that they are preparing an application that will be seen at the next HDEC meeting for a follow-on maintenance study which will be for responders and non-responders to ABX464, and participants will be invited to enrol in that study for 1 year. A long-term safety study has also been mentioned, however the researcher did not have details on the study design to hand. The researcher confirmed that there are plans in place to have open label access.

**Summary of outstanding ethical issues**

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

1. Where an investigator also provides specialist clinical care to a potential participant, please ensure the participant speaks with a member of the research team not involved in clinical care at some point during the recruitment process. This mitigates perceived pressure to participate due to the existing doctor-patient relationship.

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

Main PIS/CF:

1. Please review for typographical errors and formatting inconsistencies.
2. Please review for repeated information and delete (throughout document).
3. Please use subheadings to separate procedures (blood samples, stool samples, colonoscopy etc) and ensure adequate white space between sections.
4. Please state approximately how long it will take to complete questionnaires and diary entries.
5. Please clarify whether participants need to provide personal email addresses for the eDiary - and if so, who has access to them. State also whether the information provided by the participant is linked to their email address (i.e. is potentially identifiable).
6. On page 4 please state whether the colonoscopy requires a separate clinic visit, where the procedure will be performed, and the visit duration.
7. On page 4 and 5 please fill in the blanks (XX) for screening and treatment visit durations.
8. Please note that when discussing the maintenance study, clarify whether the participant continues with the same Rx allocation, or whether all participants receive active drug.
9. Please move 'If you cannot follow these restrictions, you should not be in this research project' above the COVID 19 information'. Currently it appears that ticking 'no' will result in study exclusion.
10. On page 17 please note that if it is not optional for participant's data to be used for future related and/or unrelated research, delete 'if you agree'. If it is optional, add an optional tick box to the applicable clause on the consent page.
11. On page 1 please amend by dropping the following sentence to a new paragraph to give it more prominence: “Obefazimod is the experimental study drug that is being tested in this study.” (it’s currently placed at the end of the introductory paragraph and is easily missed).
12. On page 9 please include that karakia will not be available at time of tissue destruction.
13. Please reconcile information about the procedure performed at Week 8; page 4 states sigmoidoscopy at week 8, yet page 5 states ‘colonoscopy or sigmoidoscopy’.
14. Please amend page 3 to clarify the difference between a colonoscopy and sigmoidoscopy. These procedures should be explained in lay terms if possible.
15. Page 3 is missing start of the following sentence in second last paragraph: “lining of your sigmoid colon and rectum (the lowest parts of the colon).” Please amend.
16. Please state that ongoing access to the study drug will be available to participants through extension studies.
17. Please delete optional tick boxes from the consent page; both are mandatory components of study participation.

Echo PISCF:

1. Please clarify that the echo involves gel being applied to the chest and a probe being moved across the skin.
2. Please state where the echo will be performed and by whom.
3. Please explain 'pseudonymised' in lay language.
4. Please amend the text in 'what will happen to the result of this sub study', as it is contradictory.
5. Please clarify whether ECG Readings should instead reference echo results; ECGs are not mentioned in this PISCF.
6. Please remove optional tick boxes for mandatory consent clauses.
7. Please clarify what 'I agree that I may also be contacted later(s) for my permission in connection with this sub-study' and amend the clause accordingly.

Pregnancy PISCF:

1. This document is to be submitted for HDEC approval only in the event of a participant or partner pregnancy. Note that it has not been reviewed as part of the current submission.

**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 Devonie Waaka and Mr Anthony Fallon.

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| **9** | **Ethics ref:** | **2022 FULL 13343** |
|  | Title: | Improving Genomic Diagnosis for Tamariki |
|  | Principal Investigator: | Professor Stephen Robertson |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 29 September 2022 |

Professor Stephen Robertson 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 recruitment and how potential participants will be approached. The Researcher explained that potential participants will be identified/referred by their clinician, the Researchers then contact the participant and ask if they feel comfortable having a conversation about the Researcher’s study and if they would like to be included.
2. The Committee asked if the genomic data will be submitted accompanied by clinical data. The Researcher explained that the genomic data can be submitted with the clinical data, the purpose being that the Researchers can look for a relationship between the two so clinicians can make data for their own patients.
3. The Committee asked if there are enough database protections of participants’ data and avoid misuse of data. The Researcher explained that while there will not be a declaration of ethnicity in the data, there is also no monitoring, and no approval procedure for someone who performs an analysis and wishes to present it in literature. There are no feedback mechanisms and is a one-step acceptance terms and conditions, thus any breach would be retrospective in nature.
4. The Committee asked if the Kinghorn Centre for Clinical Genomics and if the Garvin Centre are the same. The Researcher explained that one is embedded in another, so they are the same.
5. The Committee asked why participants cannot withdraw their data as stated on page 5 of the participant information sheet. The Researcher explained that the participants can withdraw and take back their data anytime they want and this clause in the information sheet that states otherwise may be a typo and will be amended.
6. The Committee asked if the documents will be presented in Māori or will there be interpreters available for the participants. The Researcher explained that the Māori documents and consent forms have never been used by previous participants, however the researchers can still happily supply them if needed.
7. The Committee asked about assent forms, why one was not submitted, and if the Researcher is willing to create one. The Researcher explained that they are able to create and submit assent forms, however it is unlikely that participants will have capacity to understand the assent forms.

**Summary of outstanding ethical issues**

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

1. In the Data Management Plan (DTMP) please amend wording of "anonymised" information and insert an explanation as to what this is.
2. On page 3 of the DTMP please remove instructions to researchers.
3. The Committee requested an appropriate koha is provided for participants.

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

1. Please state clearly that genes are shared with blood relatives.
2. Please remove references to the Decipher Databank from the main PISCF and include in a separate information sheet or addendum. The addendum should address what data will sent, the name and location of the databank, who will have access to the data, and what data will be used for. Please clearly state any additional risks associated with entry of data into the databank. Please clarify that data will be submitted to the databank only in the event of a genetic diagnosis being made.
3. On page 2 please clarify who would collect the blood sample (if required) and whether this would necessitate an additional clinic visit.
4. On page 3 please take care not to overstate benefit and make it clear that a genetic diagnosis is not guaranteed.
5. On page 5 please address rights to withdraw or access databank information.
6. On page 5 please address inconsistent information provided regarding withdrawal of collected data.
7. Please include contact details for Māori cultural support.
8. Please separate the statement regarding rights of access to information from Databank information.
9. Please separate the statement regarding return of results from the Databank information.
10. Please provide more detail about the blood sample that will be taken if there is not enough sample left from the previous testing. This should include how much blood will be taken, and where will the family go to have a sample taken, etc.
11. Please consider including a statement of the possible risks for siblings or wider family members of the child participant, the availability of genetic counselling, etc.
12. Please amend page 2/4, data should be stored for at least 10 years after participants turn 16 years of age.
13. Please state on page 2/3 that samples will be disposed of with karakia (not just in the Consent Form).
14. Please include on page 3 that any study expenses should be reimbursed (travel costs for additional blood sampling, etc).

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Barry Taylor and Ms Dianne Glenn.

## General business

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

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| --- | --- |
| **Meeting date:** | 08 November 2022 |
| **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 4.00pm.