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| **Committee:** | Central HDEC |
| **Meeting date:** | 27 September 2022 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 10:30 – 11am | 2022 FULL 13482 | Variability of toe pressures during haemodialysis. | Mrs Rachel Carle | Mrs Helen Walker & Mx Albany Lucas |
| 11.00 – 11.30am (withdrawn by sponsor) | 2022 FULL 13540  (withdrawn by sponsor) | ProtectH2H Study (withdrawn by sponsor) | Dr Mark Wesbter (withdrawn by sponsor) | Ms Sandy Gill & Ms Julie Jones (withdrawn by sponsor) |
| 11.30 – 12.00pm | 2022 FULL 13422 | HZNP-HZN-457-101: A Study to Evaluate Single Ascending Doses of HZN-457 in Healthy Participants | Dr Alexandra Cole | Dr Cordelia Thomas & Ms Patricia Mitchell |
| 12.00 – 12.30pm | 2022 FULL 13543 | The long-term impacts of Covid-19 infection in children | Dr. Julie Bennett | Ms Jessie Lenagh-Glue & Dr Patries Herst |
|  |  | BREAK (30 MINUTES) |  |  |
| 1.00 – 1.30pm | 2022 FULL 13491 | ZB002-01-001: A Study to Evaluate ZB002 in Healthy Participants | Dr Cory Sellwood | Mrs Helen Walker & Ms Julie Jones |
| 1.30 – 2.00pm | 2022 FULL 13456 | 1305-0023 - Fibroneer PF-ILD: A study to find out whether BI 1015550 improves lung function in people with Progressive Fibrosing Interstitial Lung Diseases (PF-ILDs) | Dr Connor O’Dochartaigh | Dr Cordelia Thomas & Mx Albany Lucas |
| 2.00 – 2.30pm | 2022 FULL 13058 | 1305-0014 - Fibroneer IPF: A study to find out whether BI 1015550 improves lung function in people with Idiopathic Pulmonary Fibrosis (IPF) | Dr Connor O’Dochartaigh | Ms Sandy Gill & Dr Patries Herst |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/05/2018 | 22/05/2020 | Present |
| Mrs Sandy Gill | Lay (Consumer/Community perspectives) | 22/05/2020 | 22/05/2023 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Dr Cordelia Thomas | Lay (the Law) | 20/05/2017 | 20/05/2020 | Present |
| Ms Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Ms Julie Jones | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2022 | Present |
| Ms Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 10.00am and welcomed Committee members.

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 23 August 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 13482** |
|  | Title: | Variability of toe pressures during haemodialysis |
|  | Principal Investigator: | Mrs Rachel Carle |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 15 September 2022 |

Rachel Carle 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 two groups the researchers are comparing. The Researcher explained they are diabetics undergoing haemodialysis & non-diabetics undergoing haemodialysis. This allows for direct comparison with a study that was done in Canada.
2. The Committee asked if all participants get the same participant information sheet. The Researcher confirmed that all participants get the same participant information sheet.
3. The Committee asked if the half and half diabetic vs non-diabetic groups are feasible to recruit. The Researcher explained they are optimistic they will be able to recruit 20 in each group.
4. The Committee asked if there are any plans to match non-diabetics to diabetics such as gender, age etc. The Researcher explained once they have enough potential participants for the study, they will look carefully at matching characteristics between groups but they must co-operate with the dialysis team.
5. The Committee asked if the researchers will be putting pre-diabetics into the same group as non-diabetics. The Researcher explained the plan is that pre-diabetics would not be recruited.

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 D22.1 of the application form as a $50 gift voucher as koha is potentially taxable, so make sure that this is an expression of gratitude, not reimbursement for time or effort. The Researcher will need to discuss this with the university and decide how best to proceed.
2. Please include the length of time that a participant cannot have caffeine before the tests.

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

1. Please update the ACC statement, the one submitted is out of date.
2. Please add on page 5 that you will not be able to be identified from reports, presentations, or publications.
3. Please amend page 3 of the PIS: change information to be collected to “reviewed”.
4. Please mention the 15-minute interview earlier in the participant information sheet.
5. Please explain where the money is coming from, as your study has no sponsor listed. If there is the grant from the university, please include this.
6. Please change Māori health support to Māori cultural support
7. Please remove yes/no tick boxes unless truly optional on the consent forms.
8. Please remove the bullet point in the consent form about fitting inclusion criteria: that is something the researcher is responsible for, not the participant.
9. Please note that if the GP needs to be informed, please include this first in the participant information sheets or remove this statement.
10. Please remove from the data management plan the statement: no data will be used for commercial purposes & the mention of under ownership rights that information from the study may lead to the development of a commercial product.

**Decision**

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

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

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| **2** | **Ethics ref:** | **2022 FULL 13422** |
|  | Title: | HZNP-HZN-457-101: A Study to Evaluate Single Ascending Doses of HZN-457 in Healthy Participants |
|  | Principal Investigator: | Dr Alexandra Cole |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 15 September 2022 |

Holly Thirlwall 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 electronic consent and how the process will be done. The Researcher explained that it is not group consenting; it is group explanation of the study. The participants will have opportunities to ask questions one on one before giving consent.
2. The actual consent would be done in the same way they would do it before COVID times. There is an opportunity to discuss the study online and consent online digitally before coming in for the physical screening visit. The Committee asked about what would happen if someone would not have a device available. The Researcher explained that the screening process, discussion of the study will then be done in person if a device cannot be provided, and that consent will be done on paper.
3. The Committee asked about the difference between samples and data that is referred to throughout the study application. The Researcher explained that the samples to be sent overseas are to go to the American labs with de-identified data being sent to LabCorp in Singapore. When the researcher refers to data, they are talking about the data specifically taken from those samples.
4. The Committee asked about future unspecified research. The Researcher explained they will be collecting different information from the samples over time.
5. The Committee asked about Māori consultation and the time frames for completion. The Researcher explained that they will be applying for Māori consultation for the study on the day this meeting was held with the review period being around a week and a half.
6. The Committee asked about the advertising used for this study and the targeting advertisement process/plan. The Researcher explained they always follow the template and the way it differs is the avenue where they advertise through. This is also a phase 1 genetic study, when the study is pushed to phase 3 the advertisements will change and the relationship building with stakeholders, targeted population etc will also see a big change.

**Summary of outstanding ethical issues**

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

1. Please amend the main PIS sections of page 4 and page 6 change “require” to “ask”.
2. Please include the right to access and correct information for participants.
3. Please amend the heading of PIS page 2, the heading should be information and data.
4. Please update DHB information in the contacts section (Waitemata DHB no longer exists)
5. Please amend page 3 of the PIS/withdrawal. Withdrawal should end their involvement immediately. Please include a line of text explaining the process of withdrawal and what is expected to happen to a participant and their samples who wishes to withdraw from the study.
6. Please amend the consent forms, CF currently refers to collecting data but there is no additional collection.
7. Please include where the participants sample, data, information will be sent to.
8. Please double check section 6.3: right to access and change your data, is there in the body of the PIS/CF as on second review by the committee it seems it is missing.

**Decision**

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

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

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| **3** | **Ethics ref:** | **2022 FULL 13543** |
|  | Title: | The long-term impacts of Covid-19 infection in children |
|  | Principal Investigator: | Dr Julie Bennett |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 September 2022 |

Dr Julie Bennet 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 participants are people who have already consented from past studies to be contacted for future research. The Researchers confirmed this.
2. The Committee asked why the Researcher is doing this study and its goals. The Researcher explained that they want to see if vaccination has any effect on long Covid, if children who are vaccinated are less likely to be affected by long Covid symptoms and to identify risk factors associate with worse long Covid symptoms.
3. The Committee asked why the Researcher is asking questions about participant economics in the questionnaire. The Researcher explained that those questions have already been asked in the New Zealand Health Survey and this is explained at the top of the questionnaire. The answers regarding deprivation data from the New Zealand (NZ) Health Survey will be linked to the current study data and will be included in the analysis; this survey will not be asking for this information directly.
4. The Committee asked how the Researchers know the NZ Health Survey data are accurate. The Researchers explained that the health survey is done every year and they will be using data from 2 or 3 years ago and will be used to identify risk factors that can link into longer term effects.
5. The Committee asked if the Researchers will be linking in how many people are in the house as a risk factor. The Researchers explained that they are using this as a risk factor indicator.
6. The Committee asked how the Researchers will avoid stigmatization in reporting about the study in relation to overcrowding of housing, Māori as a risk factor. The Researchers explained that there is no intention of treating Māori as a risk factor. In the context of this study, one determinant of the inequities has got to do with housing. Associating one with ethnicity, housing situation, place in the community is not the intent for this study.
7. The Researchers explained that the intent is to avoid stigmatization at all steps, noting that people may want to live together for cultural reasons and that it is all about long Covid and what resources children are going to need in the future to support them.
8. The Committee asked how the researchers plan to send the letter. The Researcher explained they plan to send the letter by mail to potential participants’ households as they do not have complete email information from the participants from previous studies. If more information is needed the researcher can email the potential participants more information about the study.
9. The Committee asked if more than one child of each household will be taking part in this survey. The Researcher explained it is just one child that is answering the questions even if there are multiple children in the household with the child being randomly selected.
10. The Committee asked how the researchers will know what infection type of Covid the potential participants have had. The Researchers explained that most people in New Zealand have had Omnicom and is what most potential participants are exposed to. They agreed it would be more correct to use the term Covid because they would not be able to rule out infection with other variants.

**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 the following changes to the questionnaire:
   1. Please amend the questionnaire to clarify Q2.b – child’s age group (1-5).
   2. Please amend the questionnaire as it currently does not have text for children under the age of 15.
   3. Please amend the 15+ questionnaire change "name" to "you”.
   4. Please amend the blood sample section of the questionnaire, either remove this question or reword it to clearly state that it is not a part of this study – it is not in the protocol or submission doc but is the last question in the questionnaire.
   5. Please include ER visits into the questionnaire when asking about children seeing their GP or hospitalization.
   6. Please remove the statement that the questionnaire is anonymous, there is data linking occurring with date of births also being recorded. The questionnaire is de-identified.
2. Please amend the wording of "caregiver" to "Parent/Guardian" across study documentation. If a child has no parent/guardian, then it becomes the caregiver. The Committee referred the Researcher to the section 36 of the Care of Children Act.
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 amend the letter of invitation that states currently "Te Whatu Ora (previously the Ministry of Health). It is still the Ministry of Health.
5. Please amend section A8 of your application and change change “Omicrom” to “COVID-19”.

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

1. Please include separate participant information sheets and consent/assent forms for this study for parents, children under 16 and a reconsent for those turning 16 during the study. The participants need to be fully informed of what the study entails, what questions will be asked and what will happen to their data (where it will be stored, future unspecified data, data linkage etc). Please use the HDEC template as a guide.
2. Please include in the PIS/CF’s that when participants fill out the questionnaire that information will be linked to different, previous health studies and who will have access to this data, and how long the data will be stored for.
3. Please include what exactly the data linking is in this study for, what is being linked and if this linking is a requirement for being in the study, please put this at the start of the questionnaire to avoid potential time waste of participants.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

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| **4** | **Ethics ref:** | **2022 FULL 13491** |
|  | Title: | ZB002-01-001: A Study to Evaluate ZB002 in Healthy Participants |
|  | Principal Investigator: | Dr Cory Sellwood |
|  | Sponsor: | PPD, Part of Thermo Fisher Scientific |
|  | Clock Start Date: | 15 September 2022 |

Julia O'Sullivan was present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Committee noted that the table of assessments should be simplified in future applications. This should then be paired with a separate listing of what the assessments are in more detail.
2. The Committee clarified that the MAD arm of the study would be updated with the schedule of assessment etc. as per the results from the SAD arm.
3. The Committee clarified that the future research would not be unspecified and would only concern de-identified data use relating to this study.
4. The Committee clarified that the amount of reimbursement for the SAD study would be determined after the MAD arm of the study has been decided.

**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 statements around blood donation in the exclusion and restrictions require some clarification as currently they repeat information.

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

1. Please change all mention of Canterbury District Health Board (DHB) with the Te Whatu Ora (Canterbury) locality.
2. Please clarify for participants what PPD stands for and who they are.
3. Please clarify the meaning of “significant” in the statements around health conditions that may prohibit someone from being included in the study. Please include a statement concerning that the participants may discuss this with them prior to consent.
4. Please amend “…has smoked 10 cigarettes a day…” to ‘have smoked’ for grammatical correctness.
5. Please amend mention of ‘both’ in regard to the notifiable diseases to state ‘all’ as there are three things listed.

**Decision**

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

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

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| **5** | **Ethics ref:** | **2022 FULL 13456** |
|  | Title: | 1305-0023 - Fibroneer PF-ILD: A study to find out whether BI 1015550 improves lung function in people with Progressive Fibrosing Interstitial Lung Diseases (PF-ILDs) |
|  | Principal Investigator: | Dr Connor O’Dochartaigh |
|  | Sponsor: | Boehringer Ingelheim |
|  | Clock Start Date: | 15 September 2022 |

Sara Homes-Gray was present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Committee clarified that there was no plan for compassionate supply of the drug but there would likely be a follow up open-label extension study.
2. The Committee clarified the process for home-visits. This would be dependent on the sites in the event of another pandemic-type scenario where hospital visits could not occur. Any safety issues would be covered by hospital-specific protocols around home visits.
3. The Committee clarified that an insurance certificate specific to New Zealand would be uploaded.
4. The Committee clarified that there was an error in the PIS/CF and that the questionnaires would be given 3 days prior to or at the study visit.

**Summary of outstanding ethical issues**

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

1. The Committee requested that someone separate from the clinical care of the participants be the person to recruit participants. This is requested in order for the participants to not feel pressured they need to participate to keep their clinician happy.
2. The Committee requested that the sponsor ask the sites whether karakia would be possible.

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

Main PIS/CF:

1. Please clarify for participants a safety plan should any distress be identified in any of the questionnaires. This should highlight any potential follow up, the timeframe for this and the treatment/options that may be provided. The statement noting that the participants will be taken off the medication in the case of suicidality should include a paragraph about what will be done to support them.
2. Please ensure that any option for participants to choose for their General Practitioner to be notified should be clarified. As there is conflicting information as to whether the participants need to have their GP informed to be in the study.
3. Please clarify the placebo procedure as currently it is unclear as to what pills each group will be taking. Consider utilizing an image as well as a better description.
4. Please amend the statements around “avoiding” certain beverages to simply state that only water should be consumed as there is a large list of beverages listed. Please also specify the timeframe of this.
5. Please notify participants that there will be an open label follow on to the study that could provide the drug should the study drug work for them.
6. Please remove the quotation marks around the cultural statement and update said statement with that in the new HDEC PIS template.
7. Please amend mention of the Local Data Protection Authority to instead refer to the Privacy Commissioner.
8. Please change “…justifiable efforts…” where mentioning notification of incidental findings to “…reasonable efforts…”.
9. Please include yes/no boxes should the GP notification aspect be optional.
10. Please amend the first paragraph on page 2 as it is unclear and repetitive.
11. Please amend the statement “…you will be offered standard medical care.” to read “… continue to receive standard medical care”.
12. Please remove redundant repetitions in the section on incidental findings.
13. Please elaborate on the “Routine physical medical exam”.
14. Please amend the ‘benefits’ to state the benefits of the trial or remove this section.
15. Please amend the information surrounding pregnancy and the follow-up should the participant withdraw as this cannot be mandatory.
16. Please clarify for participants the circumstances where home-visits may occur.
17. Please amend reimbursement information to detail what exactly will be reimbursed.
18. Please include a statement in the consent form referring to the ability for partner consent and contact with others where the participant may not be able to be contacted.
19. Please note on page 3 the statement regarding finding out what drug the participant is on should be amended to state “…at the end of the study”.

Optional Future Unspecified Research PIS/CF:

1. Please remove the second agreement/statement regarding the storage of tissue for unspecified use.
2. Please amend the withdrawal statement to note that this is regarding the optional DNA samples.
3. Please amend storage details to state one date. Either 30 years or indefinitely.

Biobanking PIS/CF:

1. Please specify where the samples will be stored.

**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 Cordelia Thomas, Mx Albany Lucas, Dr Patries Herst & Ms Sandy Gill.

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| **6** | **Ethics ref:** | **2022 FULL 13058** |
|  | Title: | 1305-0014 - Fibroneer IPF: A study to find out whether BI 1015550 improves lung function in people with Idiopathic Pulmonary Fibrosis (IPF) |
|  | Principal Investigator: | Dr Connor O’Dochartaigh |
|  | Sponsor: | Boehringer Ingelheim |
|  | Clock Start Date: | 15 September 2022 |

Sara Homes-Gray was present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Committee clarified that there was no plan for compassionate application of the drug but there would likely be a follow up open-label extension study.
2. The Committee clarified the process for home-visits. This would be dependent on the sites in the event of another pandemic-type scenario where hospital visits could not occur.
3. The Committee clarified that an insurance certificate specific to New Zealand would be uploaded.
4. The Committee clarified that there was an error in the PIS/CF and that the questionnaires would be given 3 days prior to or at the study visit.

**Summary of outstanding ethical issues**

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

1. The Committee requested that someone separate from the clinical care of the participants be the person to recruit participants. This is requested in order for the participants to not feel like they need to participate to keep their clinician happy.
2. The Committee requested that the sponsor ask the sites whether karakia would be possible.

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

Main PIS/CF:

1. Please clarify for participants a safety plan should any distress be identified in any of the questionnaires. This should highlight any potential follow up, the timeframe for this and the treatment/options that may be provided. The statement noting that the participants will be taken off of the medication in the case of suicidality should be expanded upon.
2. Please ensure that any option for participants to choose for their General Practitioner to be notified should be clarified. As there is conflicting information as to whether the participants need to have their GP informed to be in the study.
3. Please clarify the placebo procedure as currently it is unclear as to what is expected of participants and what medications they will be taking. Consider utilizing an image or other visual aid as well.
4. Please amend the statements around “avoiding” certain beverages to simply state that only water should be consumed as there is a large list of beverages listed. Please also specify the timeframe of this as well.
5. Please notify participants that there will be an open-label follow on to the study that could provide the drug should the study drug work for them.
6. Please remove the quotation marks around the cultural statement and update said statement with that in the new HDEC PIS template.
7. Please amend mention of the Local Data Protection Authority to instead refer to the Privacy Commissioner.
8. Please change “…justifiable efforts…” where mentioning notification of incidental findings to “…reasonable efforts…”.
9. Please include yes/no boxes should the GP notification aspect be optional.
10. Please amend the first paragraph on page 2 as it is unclear and repetitive.
11. Please amend the statement “…you will be offered standard medical care.” to read “… continue to receive standard medical care”.
12. Please remove redundant repetitions in the section on incidental findings.
13. Please elaborate on the “Routine physical medical exam”.
14. Please amend the ‘benefits’ to state the benefits of the trial or remove this section.
15. Please amend the information surrounding pregnancy and the follow-up should the participant withdraw as this cannot be mandatory.
16. Please clarify for participants the circumstances where home-visits may occur.
17. Please amend reimbursement information to detail what exactly will be reimbursed.
18. Please include a statement in the consent form referring to the ability for partner consent and contact of others where the participant may not be contacted.
19. Please not on page 3 the statement regarding finding out what drug the participant is on should be amended to state “…at the end of the study”.

Optional Future Unspecified Research PIS/CF:

1. Please remove the second agreement/statement regarding the storage of tissue for unspecified use.
2. Please amend the withdrawal statement to note that this is regarding the optional DNA samples.
3. Please amend storage details to state one date. Either 30 years or indefinitely.

Biobanking PIS/CF:

1. Please specify where the samples will be stored.

**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 Cordelia Thomas, Mx Albany Lucas, Dr Patries Herst & Ms Sandy Gill.

## General business

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

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| **Meeting date:** | 25 October 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 3.00PM.