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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 18 May 2021 |
| **Meeting venue:** | Via Zoom: https://mohnz.zoom.us/j/96507589841 Meeting ID: 965 0758 9841 |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.15pm | Confirmation of minutes of meeting of 20 April 2021 |
| 1.30pm | New applications (see over for details) |
| 1.30-1.55pm  1.55-2.20pm  2.20-2.45pm  2.45-3.10pm  3.10-3.20pm  3.20-3.45pm  3.45-4.10pm  4.10-4.35pm  4.35-5.00pm | i 21/NTA/65  ii 21/NTA/69  iii 21/NTA/70  iv 21/NTA/67  Break  v 21/NTA/68  vi 21/NTA/71  vii 21/NTA/73  viii 21/NTA/77 |
| 5.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |  |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Present |  |
| Mrs Kate O'Connor | Lay (consumer/community perspectives) | 29/01/2020 | 29/01/2021 | Apologies |  |
| Mrs Helen Walker |  |  |  | Present |  |
| Dr Kate Parker | Non-lay (observational studies) | 11/02/2020 | 11/02/2023 | Present |  |
| Ms Rochelle Style | Lay (ethical/moral reasoning) | 14/06/2017 | 14/06/2020 | Present |  |
| Ms Catherine Garvey | Lay (the law) | 19/03/2019 | 19/03/2022 | Present |  |
| Dr Sotera Catapang | Non-lay (observational studies) | 11/02/2020 | 11/02/2023 | Present |  |
| Dr Michael Meyer | Non-lay (health/disability service provision) | 11/02/2020 | 11/02/2023 | Absent |  |

## Welcome

The Chair opened the meeting at 1.00pm and welcomed Committee members, noting that apologies had been received from Mrs Kate O’Connor and Dr Michael Meyer

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mrs Helen Walker confirmed their eligibility, and was co-opted to be acting Chair 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 20 April 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **21/NTA/65** |  |
|  | Title: | LIBerate-HeFH |  |
|  | Principal Investigator: | Professor Russell Scott |  |
|  | Sponsor: | Clinical and Regulatory Services (CARSL) Consultin |  |
|  | Clock Start Date: | 29 April 2021 |  |

Joanna Young, Jane Kerr, Virginia Grayling, Prasanna Karunasekera. and Professor Russell Scott were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study aims to evaluate the long-term efficacy and safety of LIB003 in Heterozygous Familial Hypercholesterolemia patients on Stable Lipid-Lowering Therapy requiring additional low-density lipoprotein cholesterol reduction (LIBerate-HeFH). A randomized, double-blind, placebo-controlled phase 3 global study with 36 New Zealand participants.

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 researchers have submitted three parallel studies investigating the same compound (sellanderline protein) for review at this meeting; LIBerate-HeFH (21/NTA/65), LIBerate-CVD (21/NTA/69), LIBerate-HR (21/NTA/70).
2. The Committee advised that they will be reviewing all the studies together as one due to the similarity of information, stating specifically if any comments relate only to a particular study.
3. The Committee asked what the total number of New Zealand participants across the three studies is. The Researcher advised that it will be approximately 90.
4. The Committee noted the response to application question about benefit to Māori (P.4.1) and asked if there are any statistics on the familial gene presence in Māori. The Researcher advised that the prevalence is slightly less in Māori. The Committee recommended including any statistics of the prevalence of a disease in Māori (or an explanation if unknown) when answering P.4.1. for any future applications.
5. The Committee noted that these studies are global multi-site studies and that data from New Zealand will be shared with the other sites.
6. The Committee queried how Researchers choose which participants are enrolled in the cardiovascular disease study (005) versus the high-risk of cardiovascular disease study (006). The Researcher advised that the studies are essentially the same and only participants with a history of a cardiovascular event (e.g. heart attack, stroke) can be enrolled in the cardiovascular disease study (005).
7. The Committee queried why there are two separate studies for cardiovascular disease when the inclusion criteria is the same for both studies. The Researcher advised the Sponsor is interested in two outcomes; the use of the drug in secondary prevention (those who have had a cardiovascular event) and the primary prevention of an event in those at high risk. She added that those who have not had an event will not be enrolled in cardiovascular disease (005) study.
8. The Committee noted that the participants being recruited will already be aware that they have this genetic condition and therefore will not be discovering for the first time during this study that they have the condition.
9. The Committee queried how participants are recruited into these studies. The Researcher advised that they have two avenues for recruiting participants. The first is a large research database of people who have agreed to be contacted about further studies. The second is through their hospital colleagues who refer patients to them who meet the criteria and are interested in the study.
10. The Committee noted that there was no update on the status of the SCOTT application for this study.
11. The Committee agreed that the Pregnancy and COVID-19 participant information sheet and consent forms (PIS/CF) are to only be reviewed by the HDEC if either of the situations arise. This will ensure that the HDEC have the most up-to-date and relevant information when reviewing the documents. If either of the instances arise, please submit documentation as an amendment via the post approval pathway.
12. The Committee recommend the Researchers consider the following points if they do end up submitting COVID-19 documentation to HDEC:
    1. Please ensure that all relevant risks are covered in the PIS/CF for procedures at home (e.g. procedures completed at home would likely carry more risk than if they were performed in a clinic).
    2. Please ensure the Main PIS/CF is added as an addendum to the COVID-19 PIS/CF so that participants have access to all the information in one place.
    3. Please add relevant ‘what happens to my data/samples’ sections that detail who the third party health provider is for the home visits and how the participants personal health data will be handled by this provider (home visit nurses). Please also ensure that these nurses are trained about relevant issues and to ensure they understand the privacy and confidentiality obligations.
    4. Please ensure a safety plan is provided that mitigates risks to participants and researchers conducting home visits *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25, 11.62).*

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 advised that the Sponsor’s indemnity insurance certificate states an aggregate limit of $5m which is not adequate for the three studies, The Committee requested that the Researcher obtains an increased insurance limit from the Sponsor that is sufficient to cover the number of participants (either for individual studies or cover for the three studies together).
2. The Committee requested that the insurance includes the New Zealand body as it currently only names the overseas Sponsor.
3. The Committee noted that there is an inconsistency between the protocol and the PIS/CF for cardiovascular disease (005) study about whether genetic testing will occur in this study. The Researcher advised that she does not believe it is not necessary for the 005 study and will confirm this with the sponsor.
4. The Committee noted that the study documentation mentioned terminating the study for commercial reasons and informed the researcher that in New Zealand you cannot terminate a therapeutic study for commercial reasons only. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.37).*
5. The Committee requested that the study protocols and PIS/CFs are updated with drug information since October 2020, including those studies currently in the United States, Norway, Israel, South Africa, Turkey, and India. The Researcher confirmed that they will update the PIS/CFs using the latest investigator’s brochure.
6. The Committee advised that on page 8 of the high risk/cholesterol study (006) PIS/CF, it implies that participants will not know the outcome of their DNZ testing for HeFH and queried why not. The Researcher advised that all participants are tested as part of the clinic process and any positive result is discussed with the participant if they choose to know the results.

Data & Tissue Management Plan (DTMP)

1. The Committee advised that the data and tissue management plan (DTMP) appears to be missing some key information (e.g. how data will be shared with the other study sites and how the data will be protected). The Committee requested that the DTMP is tailored to ensure it is study specific. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15 and 14.17).*
2. The Committee advised that it is a requirement in New Zealand to collect ethnicity data. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.10).*
3. The Committee noted that there is inconsistency between the PIS/CF and the DTMP which states that data/tissue collected prior to the participant’s withdrawal will continue to be analysed whereas the PIS/CFs make this optional and that participants can choose to withdraw their samples. The Committee advised that it is up to the Researchers which option they choose but either way participants need to be informed and the DTMP and PIS/CF must be consistent.
4. The Committee advised that the DTMP has inconsistent statements about whether there will be data and tissue for future unspecified research (FUR) (section 8.5 versus section 12.2) and advised that a standalone PIS/CF for FUR is required if this is an option. The Researcher confirmed that there will not be any option for FUR and will amend the DTMP accordingly.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. The Committee advised that there are discrepancies between the three study PIS/CFs about how many previous studies have been undertaken with the study drug. Please review/revise all PIS/CFs to ensure the information is both consistent and up to date.
2. The Committee requested that, in the interests of full disclosure, the PIS/CFs state that the drug is made in Chinese hamster ovaries.
3. The Committee noted the statements in the cardiovascular disease (005) PIS/CF that two participants developed a temporary antibody response without any evidence of impact on how well the study drug worked, or association with injection site reactions. Please include this information in the other PIS/CFs.
4. Please make it clearer in all the PIS/CFs that each study visit (after the screening) will require blood samples and therefore fasting the night before is required.
5. Please change the consent for GP notification on all the PIS/CFs from optional to mandatory.
6. Please ensure the information in the PIS/CFs where genetic testing is being done complies with ethical standards as the current description does not (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.27-14.34a, and 14.35 – 14.41).*
7. Please ensure the ‘What happens to my information’ and ‘What happens to my samples’ sections are reconciled with the DTMP and relevant information provided.
8. Please revise page 8 of the high risk/cholesterol (006) PIS/CF to clearly explain that participants can be notified of their result of the DNA testing for HeFH.
9. Please state the correct HDEC (Northern A).
10. Please amend the statement about stopping the study for commercial reasons as per the Committee’s earlier point.
11. The Committee recommended removing abstinence as a recommended method of contraception. Please adapt to your study, the standard statements for contraception in the PIS/CF template on the [HDEC website](https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates).

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Kate Parker and Ms Rochelle Style.

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| **2** | **Ethics ref:** | **21/NTA/69** |  |
|  | Title: | LIBerate-CVD |  |
|  | Principal Investigator: | Dr Jane Kerr |  |
|  | Sponsor: | Clinical and Regulatory Services (CARSL) Consultin |  |
|  | Clock Start Date: | 06 May 2021 |  |

Joanna Young, Jane Kerr, Virginia Grayling, Prasanna Karunasekera. and Professor Russell Scott were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study aims to evaluate the long-term efficacy and safety of LIB003 in patients with cardiovascular disease on stable lipid-lowering therapy requiring additional low-density lipoprotein cholesterol reduction (005). A randomized, double-blind, placebo-controlled phase 3 global study with 35 New Zealand participants.

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 researchers have submitted three parallel studies investigating the same compound (sellanderline protein) for review at this meeting; LIBerate-HeFH (21/NTA/65), LIBerate-CVD (21/NTA/69), LIBerate-HR (21/NTA/70).
2. The Committee advised that they will be reviewing all the studies together as one due to the similarity of information, stating specifically if any comments relate only to a particular study.
3. The Committee asked what the total number of New Zealand participants across the three studies is. The Researcher advised that it will be approximately 90.
4. The Committee noted the response to application question about benefit to Māori (P.4.1) and asked if there are any statistics on the familial gene presence in Māori. The Researcher advised that the prevalence is slightly less in Māori. The Committee recommended including any statistics of the prevalence of a disease in Māori (or an explanation if unknown) when answering P.4.1. for any future applications.
5. The Committee noted that these studies are global multi-site studies and that data from New Zealand will be shared with the other sites.
6. The Committee queried how Researchers choose which participants are enrolled in the cardiovascular disease study (005) versus the high-risk of cardiovascular disease study (006). The Researcher advised that the studies are essentially the same and only participants with a history of a cardiovascular event (e.g. heart attack, stroke) can be enrolled in the cardiovascular disease study (005).
7. The Committee queried why there are two separate studies for cardiovascular disease when the inclusion criteria is the same for both studies. The Researcher advised the Sponsor is interested in two outcomes; the use of the drug in secondary prevention (those who have had a cardiovascular event) and the primary prevention of an event in those at high risk. She added that those who have not had an event will not be enrolled in cardiovascular disease (005) study.
8. The Committee noted that the participants being recruited will already be aware that they have this genetic condition and therefore will not be discovering for the first time during this study that they have the condition.
9. The Committee queried how participants are recruited into these studies. The Researcher advised that they have two avenues for recruiting participants. The first is a large research database of people who have agreed to be contacted about further studies. The second is through their hospital colleagues who refer patients to them who meet the criteria and are interested in the study.
10. The Committee noted that there was no update on the status of the SCOTT application for this study.
11. The Committee agreed that the Pregnancy and COVID-19 participant information sheet and consent forms (PIS/CF) are to only be reviewed by the HDEC if either of the situations arise. This will ensure that the HDEC have the most up-to-date and relevant information when reviewing the documents. If either of the instances arise, please submit documentation as an amendment via the post approval pathway.
12. The Committee recommend the Researchers consider the following points if they do end up submitting COVID-19 documentation to HDEC:
    1. Please ensure that all relevant risks are covered in the PIS/CF for procedures at home (e.g. procedures completed at home would likely carry more risk than if they were performed in a clinic).
    2. Please ensure the Main PIS/CF is added as an addendum to the COVID-19 PIS/CF so that participants have access to all the information in one place.
    3. Please add relevant ‘what happens to my data/samples’ sections that detail who the third party health provider is for the home visits and how the participants personal health data will be handled by this provider (home visit nurses). Please also ensure that these nurses are trained about relevant issues and to ensure they understand the privacy and confidentiality obligations.
    4. Please ensure a safety plan is provided that mitigates risks to participants and researchers conducting home visits *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25, 11.62).*

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 advised that the Sponsor’s indemnity insurance certificate states an aggregate limit of $5m which is not adequate for the three studies, The Committee requested that the Researcher obtains an increased insurance limit from the Sponsor that is sufficient to cover the number of participants (either for individual studies or cover for the three studies together).
2. The Committee requested that the insurance includes the New Zealand body as it currently only names the overseas Sponsor.
3. The Committee noted that there is an inconsistency between the protocol and the PIS/CF for cardiovascular disease (005) study about whether genetic testing will occur in this study. The Researcher advised that she does not believe it is not necessary for the 005 study and will confirm this with the sponsor.
4. The Committee noted that the study documentation mentioned terminating the study for commercial reasons and informed the researcher that in New Zealand you cannot terminate a therapeutic study for commercial reasons only. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.37).*
5. The Committee requested that the study protocols and PIS/CFs are updated with drug information since October 2020, including those studies currently in the United States, Norway, Israel, South Africa, Turkey, and India. The Researcher confirmed that they will update the PIS/CFs using the latest investigator’s brochure.
6. The Committee advised that on page 8 of the high risk/cholesterol study (006) PIS/CF, it implies that participants will not know the outcome of their DNZ testing for HeFH and queried why not. The Researcher advised that all participants are tested as part of the clinic process and any positive result is discussed with the participant if they choose to know the results.

Data & Tissue Management Plan (DTMP)

1. The Committee advised that the data and tissue management plan (DTMP) appears to be missing some key information (e.g. how data will be shared with the other study sites and how the data will be protected). The Committee requested that the DTMP is tailored to ensure it is study specific. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15 and 14.17).*
2. The Committee advised that it is a requirement in New Zealand to collect ethnicity data. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.10).*
3. The Committee noted that there is inconsistency between the PIS/CF and the DTMP which states that data/tissue collected prior to the participant’s withdrawal will continue to be analysed whereas the PIS/CFs make this optional and that participants can choose to withdraw their samples. The Committee advised that it is up to the Researchers which option they choose but either way participants need to be informed and the DTMP and PIS/CF must be consistent.
4. The Committee advised that the DTMP has inconsistent statements about whether there will be data and tissue for future unspecified research (FUR) (section 8.5 versus section 12.2) and advised that a standalone PIS/CF for FUR is required if this is an option. The Researcher confirmed that there will not be any option for FUR and will amend the DTMP accordingly.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. The Committee advised that there are discrepancies between the three study PIS/CFs about how many previous studies have been undertaken with the study drug. Please review/revise all PIS/CFs to ensure the information is both consistent and up to date.
2. The Committee requested that, in the interests of full disclosure, the PIS/CFs state that the drug is made in Chinese hamster ovaries.
3. The Committee noted the statements in the cardiovascular disease (005) PIS/CF that two participants developed a temporary antibody response without any evidence of impact on how well the study drug worked, or association with injection site reactions. Please include this information in the other PIS/CFs.
4. Please make it clearer in all the PIS/CFs that each study visit (after the screening) will require blood samples and therefore fasting the night before is required.
5. Please change the consent for GP notification on all the PIS/CFs from optional to mandatory.
6. As previously noted, please address whether genetic testing will be done in this study and, if so, please ensure the information in the PIS/CFs where genetic testing is being done complies with ethical standards as the current description does not. Please note in particular, that on page 9 of the CVD PIS, the Māori tissue statement refers to genetic testing. If there is no such testing in this study, that reference must be removed. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.27-14.34a, and 14.35 – 14.41).*
7. Please ensure the ‘What happens to my information’ and ‘What happens to my samples’ sections are reconciled with the DTMP and relevant information provided.
8. Please revise page 8 of the high risk/cholesterol (006) PIS/CF to clearly explain that participants can be notified of their result of the DNA testing for HeFH.
9. Please state the correct HDEC (Northern A).
10. Please amend the statement about stopping the study for commercial reasons as per the Committees earlier point.
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Decision

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* Please address all outstanding ethical issues, providing the information requested by the Committee.
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After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Kate Parker and Ms Rochelle Style.

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| **3** | **Ethics ref:** | **21/NTA/70** |  |
|  | Title: | LIBerate-HR |  |
|  | Principal Investigator: | Dr Jane Kerr |  |
|  | Sponsor: | Clinical and Regulatory Services (CARSL) Consultin |  |
|  | Clock Start Date: | 06 May 2021 |  |

Joanna Young, Jane Kerr, Virginia Grayling, Prasanna Karunasekera. and Professor Russell Scott were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study aims to evaluate the long-term efficacy and safety of LIB003 in patients with cardiovascular disease, or at high risk for cardiovascular disease, on stable lipid-lowering therapy requiring additional low-density lipoprotein cholesterol reduction (006). A randomized, double-blind, placebo-controlled phase 3 global study with 40 New Zealand participants.

Summary of resolved ethical issues

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

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2. The Committee advised that they will be reviewing all the studies together as one due to the similarity of information, stating specifically if any comments relate only to a particular study.
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2. The Committee requested that, in the interests of full disclosure, the PIS/CFs state that the drug is made in Chinese hamster ovaries.
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5. Please change the consent for GP notification on all the PIS/CFs from optional to mandatory.
6. Please ensure the information in the PIS/CFs where genetic testing is being done complies with ethical standards as the current description does not (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.27-14.34a, and 14.35 – 14.41).*
7. Please ensure the ‘What happens to my information’ and ‘What happens to my samples’ sections are reconciled with the DTMP and relevant information provided.
8. Please revise page 8 of the high risk/cholesterol (006) PIS/CF to clearly explain that participants can be notified of their result of the DNA testing for HeFH.
9. Please state the correct HDEC (Northern A).
10. Please amend the statement about stopping the study for commercial reasons as per the Committees earlier point.
11. The Committee recommended removing abstinence as a recommended method of contraception. Please adapt to your study, the standard statements for contraception in the PIS/CF template on the [HDEC website](https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates).

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Kate Parker and Ms Rochelle Style.

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| **4** | **Ethics ref:** | **21/NTA/67** |  |
|  | Title: | EQ121-010: A Phase 1 Study to Evaluate the Safety and Pharmacokinetics of EQ121 in Healthy Adults and Patients with Rheumatoid Arthritis |  |
|  | Principal Investigator: | Dr Chris Wynne |  |
|  | Sponsor: | Novotech (New Zealand) Limited |  |
|  | Clock Start Date: | 06 May 2021 |  |

Dr Chris Wynne and Courtney Rowse were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a Phase 1 study consisting of two sub-studies: Sub-study 1 is a randomised, double-blind, placebo-controlled, dose-escalation study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of EQ121 following oral single (Part 1) and multiple (Part 2) ascending dose administration in healthy subjects. Sub-study 2 is a randomised, double-blind study to evaluate the safety, tolerability and pharmacokinetics of EQ121 following multiple dose administration in adults with rheumatoid arthritis who are on a stable oral methotrexate regimen.

Summary of resolved ethical issues

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

1. The Committee noted that this application is for the second sub-study of the Phase 1 study. The first part of the study is currently being undertaken in Australia with healthy volunteer participants. The sub-study will be undertaken in New Zealand after the first part is complete. The sub-study participants are patients with rheumatoid arthritis.
2. The Committee noted that participants will stay for seven nights as part of the study. The Committee queried whether this was a standard timeframe for Phase 1 studies and for ensuring participants’ safety. The researchers confirmed this and highlighted that the patient participants are different from participants who are healthy volunteers. The researchers acknowledged that patient participants with rheumatoid arthritis often have already taken time off from work due to trouble with their symptoms. The researchers assured the Committee that the patient participants’ stay is for observation and guaranteed dosing.
3. The Committee noted that the Participant Information Sheet was good overall. However, the Committee requested confirmation of whether it is correct that the bloods will be destroyed one year following completion of the study. The researchers confirmed this.
4. The Committee queried whether participants will be vaccinated against COVID-19 before the study, or if this was a complete exclusion criterion. The researchers advised that participants will need to be immunised, highlighting the greater importance of this in an immunocompromise population, over carrying out a Phase 1 study.
5. The Committee queried whether the researchers considered that $5 million was sufficient cover for participants. The researchers stated that they considered this sufficient.

Summary of outstanding ethical issues

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

1. The Committee asked whether there have been any safety signals for the first part of the study that is underway in Australia. The researchers confirmed that to date there have been no safety signals. Further, they will not commence the sub-study in New Zealand until there has been a safety review of the participants in the first part of the study. The safety review results will be available within 90 days. Please provide information from the safety review as soon as this is available, with an updated Participant Information Sheet if there is new relevant information based on the safety data from the first part of the study.
2. The Committee requested that the researchers have certainty around notifiable diseases as active acute Hepatitis B and C are both notifiable as per the Schedule of Notifiable Diseases in the Health Act 1956. Please update the documentation accordingly.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please remove all patient identifiers from the questionnaires.
2. Please remove ‘abstinence’ as a recommended method of contraception from the Participant Information Sheet in accordance with [HDEC’s reproductive risks template](https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates).

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee
* Please submit the results of the first part of the study to the Committee
* 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).*

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| **5** | **Ethics ref:** | **21/NTA/68** |  |
|  | Title: | UNITE Project |  |
|  | Principal Investigator: | Dr Katie Douglas |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 04 May 2021 |  |

Dr Katie Douglas and Professor Joseph Boden were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The aim of the study is to examine cognitive, functional, psychological and biological factors related to subjective cognitive impairment in two groups of individuals exposed to the 2011 Canterbury Earthquake sequence: those reporting the highest levels of subjective cognitive impairment and those reporting the lowest levels of subjective cognitive impairment. This will determine what factors relate most strongly to perceived cognitive difficulties, which will in turn be used to develop treatments for this population. The study will investigate rates of, and factors contributing to, perceived cognitive difficulties in a large population exposed to multiple stressors and is important for the population of Canterbury, and populations affected by natural and man-made disasters worldwide.

Summary of resolved ethical issues

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

1. The Committee noted that the application relates to the earlier parent study, which was approved separately by the Southern HDEC (16/STH/188/AM07). That approval covers the recruitment and screening used for this study. The Committee noted it did not have access to all material in relation to the parent study and the DNA collection aspect of the study.
2. The Committee requested clarification about the purpose of the screening for enrolment into this study. The researchers advised that it is a dual purpose and is of interest to the parent study as well as this study. The researchers also confirmed that when participants are consented to undertake the assessment during the parent study, they will know about the dual purpose in that the results of their assessment in the parent study may lead them to being contacted about this study.
3. The Committee requested an update in terms of recruitment and screening for this study. The researchers advised that they have not commenced recruitment and screening yet. The questionnaire is currently being adapted for online presentation and should be rolled out by the end of May 2021.
4. The Committee queried whether participants would be aware that the researchers are looking for those with the lowest and highest perception of cognitive difficulties, and that they will be stratified into separate groups. The researchers confirmed that under their pre-amendment approval from the Southern HDEC, they are now explicitly telling participants.
5. The Committee asked whether participants can receive their individual results from the parent study and this study. The researchers confirmed that participants could do so on request.
6. The Committee queried whether there are any concerns about what the assessment results might show and if there is a management plan if any issues are discovered. The researchers advised that the participants are screened on a subjective cognitive function questionnaire. Accordingly, it is the participant’s own view of how they perceive their cognitive function. The researchers clarified that they will not proceed with a participant who self-reports their cognitive functioning has impairments and they will be excluded.
7. The Committee queried whether a half-day was enough time in which to complete 12 objective cognitive function tests plus nine questionnaires, and whether there was a risk of increasing participants’ stress in the process of collecting this data. The researchers confirmed they would be using a cognitive testing battery that they have trialled in previous studies. The tests take approximately 1.5 hours or less to complete. The questionnaires are also relatively short. People with severe mood disorders have completed the tests and questionnaires in the time allocated. The researchers do not see how participants for this study (who are generally a healthy sample of participants) will have difficulty. The researchers also stated that there will usually be someone in the room with each participant, or checking in to see how they are doing, while completing the tests and questionnaires. If a participant becomes distressed there are clinicians in the research team who can be contacted to assist.
8. The Committee queried whether there is an IQ test to determine cognitive capability of the participants. The Committee noted that having an IQ of less than 80 is in the exclusion criteria. The researchers advised that when the participants were children, they completed IQ tests, so they have historic IQ scores across the cohort. The researchers confirmed that having an IQ over 80 is within the inclusion criteria.
9. The Committee queried whether there is a possible risk of stigmatisation for participants in terms of their mental health. The Committee also requested confirmation that the research nurse would be carrying out the tests and questionnaires. The researchers advised that the research nurses are well-trained and are qualified for this study as they work in several other studies in the department on mental health. The research nurses are qualified to assess mental health symptoms in this study sample. If there is any ambiguity about a participant’s mental health symptoms, the research nurses can also discuss with a psychiatrist.
10. The Committee requested clarification about how participants will be consented from the parent study into this study. The Committee also requested assurance that health information for this study has not been previously gathered for the purpose of this study (apart from the previously obtained IQ scores). The researchers clarified that after the parent study is complete, they would identify the participants they want to contact for this study. The researchers will initially contact the participants by phone to inform them about the study and ask if they are interested in taking part. The researchers will later provide an information sheet and complete screening questions. The initial phone call does not involve screening questions. The Committee recommended that the researchers exercise caution when undertaking the screening questions and ensure that participants have consented before asking questions that disclose health information.

Summary of outstanding ethical issues

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

1. The Committee noted that once participants are in the study, they will also undergo several objective assessments that go beyond their perception of their cognitive function. This includes physical assessments and blood samples. The Committee noted that it was not clear in the Participant Information Sheet, Protocol, or other documentation about what is needed for this study. The Committee requested that the researchers clearly explain in the Participant Information Sheet what they will be doing, what they will need from participants, and what they want to obtain for their other studies, including the parent study. Please also put more information in the Protocol and Participant Information Sheet about blood samples, noting that these samples will be obtained for other reasons, not just cognitive function.
2. The Committee requested further clarification about the Participant Information Sheet as it is unclear how the DNA collection is relevant to this study. The researchers clarified that DNA is not required for the purposes of this study, but is to be requested of participants for the purposes of the parent study and DNA stored in the Gene Structure and Function Lab under approval from Southern HDEC. The DNA originally collected from the study cohort was from when they were 28 years old. The DNA stock is now old, has run low, and outlived its utility. The researchers advised that they intend to have participants return in order to obtain a new sample of the material if they consent to this. The Committee noted that this is an opportunistic way of obtaining DNA and recommended that the researchers create a separate information sheet in accordance with current NEAC standards which clearly addresses what the researchers are doing with the samples, who is going to have access, how they will be stored and used, and what will be done with the data. Please also make it clear that this is optional for participants.
3. The Committee noted that the Participant Information Sheet, Protocol, and other documentation lack specific information about what data the researchers are going to have that is identifiable, what is to be de-identified, what will be stored, and who is going to have access to the data and use it. Please submit a data management plan which includes any relevant data being linked from the parent study and other studies . Please refer to the [HDEC templates](https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans) and [current National Ethical Standards](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health) which specifically relate to data linking. Please adapt these documents to specifically match the study.
4. The Committee noted that for the blood samples and biobank (Gene Structure and Function Laboratory, Department of Pathology, University of Otago, Christchurch), more information is required about consenting for future use of samples in a biobank. The Committee requested that the researchers ensure they include the information required in accordance with the current NEAC standards to be assured that participants have the right information about the biobank and requested that a Tissue Management Plan be submitted. This plan can be combined with the data management plan – please refer to the [HDEC templates](https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans) and [current National Ethical Standards](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health).
5. The Committee requested the creation of a separate information sheet for future unspecified research on tissue.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please clearly state that the researchers might be exploring other causes of trauma for participants given that these will not be restricted to the 2011 Canterbury Earthquake.
2. Please clearly state that any abnormal results for participants will be sent to their respective general practitioners.
3. Please remove all references to ‘anonymous files’ in the Participant Information Sheet, given that none of the files will be anonymous.
4. Please provide a Māori tissue statement for tissue that will be obtained for this study. It may be helpful to refer to the [HDEC template](https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates) for this.
5. Please include an ACC compensation statement.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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).*
* Please provide a Data Tissue Management Plan to ensure the safety and integrity of participant data and tissue. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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

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| **6** | **Ethics ref:** | **21/NTA/71** |  |
|  | Title: | Sensory neuropathy, ultrasound and RFC1 testing |  |
|  | Principal Investigator: | Dr Richard Roxburgh |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 06 May 2021 |  |

Dr Richard Roxburgh, Dr Anthony Garvey and Miriam Rodrigues were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study looks at patients referred for nerve conduction studies who have been found to have a sensory neuropathy. Participants will be studied in detail to look at specific changes to their nerve conduction studies, including ultrasound of the nerves, formal vestibular testing and autonomic function testing. Their DNA will be screened first for the RFC1 mutation and those that are negative will have genetic testing for a panel of neuropathy genes. All participants will be consented by a qualified genetic counsellor and given options of receiving the results of their genetic testing or not. Study samples will be retained (in keeping with standard lab practice) for up to 20 years. Participants will be given an option to make their genetic samples and clinical information available for future unspecified research.

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 researchers are accessing identifiable health information without consent for the purpose of pre-screening. After discussion, the Committee were satisfied that a technical waiver of consent to access this information is warranted

Summary of outstanding ethical issues

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

1. The Committee queried if the potential cohort will already have a diagnosis or this gene test already performed. The researcher stated they will not and will likely be diagnosing some people through this study. The Committee requested that it is clearly explained to participants that this is going to be diagnosed through a gene test and other diagnostic tests and that is part of the purpose of the study.
2. The Committee stated that the protocol and participant information sheet need information about genetics, tissue, return of results, incidental components, where labs are and some further detail and transparency about the biobank and how the study interacts with it. Further, the Committee recommended a localised Data and Tissue Management Plan (DTMP) for this study to ensure it is clear what the New Zealand protocols are. Use of the [HDEC template](https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans) is not mandatory but is encouraged to be adapted or used as a guide.
3. The Committee noted that the future unspecified use component is sensible, however, more needs to be documented as to whether RFC1 negative people are consenting into the biobank or another future use. If this is the case, a separate optional participant information sheet will need to be used.
4. The Committee asked the researcher to clarify the recruitment process. The researcher responded that people are identified from Neurology Department notes and by the time they are contacted, clinicians know they have a sensory neuropathy. A genetic counsellor will contact them, and they will be recruited through that process. The Committee asked for an initial letter to be sent to them first about the study before they are approached so it may not be cold-calling for some potential participants.
5. The Committee stated that Māori responsiveness is light in the application overall and to please consider the [guidance provided by HDEC on their website](https://ethics.health.govt.nz/guides-templates-forms-0/cultural-questions-hdec-application-guidance) when responding to ethical issues raised.
6. As per National Standard 15.19, certain information held by biobanks should be publicly available. The Committee noted the link provided in documentation linked to an international website and did not provide sufficient information for transparency.
7. Please upload evidence of indemnity held by the investigators/CI..

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

1. The Committee noted that the information sheet is hard to follow and lacks important detail (some of which is included in the protocol but not in the PIS) and recommended the Researcher adapt the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-feb-2020-270220.doc) In particular, use of the template to help with structure, readability, and for appropriate genetic warnings with sending samples overseas.
2. Please include a lay-friendly title for the study
3. Please amend to comply with the genetic and genomic research standards: Standards 14.27 – 14.41 including, non-exhaustively, explaining upfront that a genetic test is being performed, outlining what the genetic testing involves (explaining it isn’t a whole genomic analysis), explaining that the sample is going to Perth and that the genetic test report will be kept on the person’s clinical record.
4. Please include a further explanation of RFC1 such as what it is and what the acronym stands for.
5. Please clarify the length of visits, whether there are multiple visits, and that testing is done at different sites.
6. The Committee noted the claims of assuring participants that blood samples and information will only be used in neurological disease studies approved by an ethics committee and, as noted, requires clarification whether RFC1 negative people are consenting into the biobank or another future use and, if that is the case, requires a separate optional participant information sheet. The Committee requested a statement clarifying that if these studies are overseas, there is a chance for no New Zealand representation and cultural considerations may not be undertaken.
7. Please amend the Māori cultural statement which is incomplete (page 5)
8. Please ensure nothing new is mentioned in the consent form that isn’t already raised in the main body of the information sheet first. Please review.
9. Retention of data on withdrawal is inconsistent with statements made in the PIS - please amend for consistency
10. Genetics Tissue FUR consent form - this CF is insufficient and lacks clarity in terms of the use of blood and then the use of DNA and other requirements for consenting to genetic research – please refer to the NEAC Standards.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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 & 15.8-15.10).*
* Please supply a data and tissue management plan to ensure the safety and integrity of participant data and tissue *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15 & 14.17).*
* Please provide a separate optional participant information sheet for biobanking and tissue FUR.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Dr Karen Bartholomew

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| **7** | **Ethics ref:** | **21/NTA/73** |  |
|  | Title: | A Study for Participants with Moderate to Severe Chronic Obstructive Pulmonary Disease and Chronic Bronchitis (FRONTIER 4) |  |
|  | Principal Investigator: | Dr Dean Quinn |  |
|  | Sponsor: | AstraZeneca |  |
|  | Clock Start Date: | 06 May 2021 |  |

The researcher was not present via videoconference for discussion of this application which was brought forward from the scheduled time because the Committee had been advised that there would be no attendance by the researcher. The Committee concluded during that discussion to give provisional approval to the application on the basis that some outstanding ethical issues required further input.

It subsequently transpired that the researcher was available for discussion but, after communications with him, he was satisfied with the decision to provisionally approve the study.

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 Study

1. A randomized, double-blind, placebo-controlled. proof-of-concept study to assess the efficacy, safety and tolerability of MEDI3506, administered subcutaneously every 4 weeks for 7 doses. Participants are with moderate to severe COPD receiving standard of care as maintenance therapy. Consists of three periods: screening, intervention, and follow-up

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 there is use of a participant training quiz and documentation which includes a patient guide, a patient pamphlet and training story video. The Committee noted that the pamphlet and guide don’t contain all the information required in a participant information sheet (PIS), especially anything about data use and cannot be used in place of a PIS. The Committee further noted to ensure that this number of documents and different media formats do not clutter or confuse the informed consent process.
2. Two devices are being used in this study (excluding the electronic diary) – (1) the cough monitor & (2) an AM3 asthma device to make PEF Measurements which also pairs with another device. The Committee stated there is insufficient information about the AM3 device and how it works. With the cough monitor, participants are warned that conversations will be picked up by the monitor but the only information that will be used for the study from the recording is the number of coughs and when they were. The cough monitor vendor is based in America and the cough monitor sends the data there (protocol section 8.1.4). There is insufficient detail about how this works in data management terms and nothing in the Data and Tissue Management Plan (DTMP). Similarly, with the AM3, the Committee queried what device is it pairing with. The Committee stated that clarity around data collection, use, transfer and storage for the AM3 and cough measurement devices is required in the PIS, protocol and DTMP.
3. The Committee noted the form for withdrawal and stated that in New Zealand withdrawal does not have to be in writing. Further, there is no PIS which accompanies the withdrawal form that outlines the follow-up options although the main PIS makes it clear that withdrawal can be verbal, in writing, or via email and explains the efforts that will be made to contact those lost to follow-up and continued use of/access to their records but isn’t mandatory here. This information should also be included in the withdrawal form as participants should not be expected to remember the contents of the PIS further into their participation.
4. The Committee asked for clarification whether the sub-study involving use of CT imaging (mentioned in one of the patient pamphlets) is being conducted in New Zealand.
5. The Committee stated that the pregnancy PISs are not reviewed as part of this application and should be submitted in the event of a pregnancy as an amendment to ensure it is fit for the context of the pregnancy if it occurs.
6. Section 9.1 DTMP refers to the possible need for remote monitoring in which case the site will share participant data using RealTime CTMS. The Committee queried if this is identifiable data.
7. While it states on page 3 of the Genetic Sub-study that you may share (summary) results with health insurance companies but not individual results, the Committee noted that given the possible combination of information from other datasets and if a person is an outlier, it may be possible to identify them and this sharing is not stated in the main PIS. The Tissue FUR PIS specifically states: “In particular, it will not be used to make decisions about future services available to you, such as insurance” and there is nothing about sharing with health insurance companies in the DTMP. Please amend all relevant documentation for clarity and consistency.

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

All:

1. Please add the Sponsor details to all information sheets
2. Please review all sheets for typos.

Main PIS/CF:

1. The Committee noted that COVID-19 is a notifiable disease. If any testing is done to determine a positive case, please amend to state this is notifiable.
2. On page 5 please ensure “race” is replaced with “ethnicity”.
3. On pages 11-12, mandatory components and optional components are mixed up, please clarify
4. On page 14, please use the [template](https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates) wording for contraception as abstinence is not an accepted method.
5. On page 18, the Committee noted it is confusing to have all of the data future unspecified research in this main PIS when it says it’s optional and will be in a separate PIS/CF. Please remove the extra paragraphs and simply state there is optional data FUR in a separate PIS/CF.
6. On page 18 there is no reference to anonymised data being made available to other researchers, as described in Section 8.5 DTMP.
7. Participants should also be informed that anonymised data and tissue are unable to be accessed, corrected, or withdrawn; and that return of individual results will not be possible as per page 7 of the DTMP
8. Please remove databank information on page 20 from the main PIS as this is only relevant to the optional study.
9. Please make it clear on page 21 that the study cannot be stopped for commercial reasons.

Optional Tissue Future Unspecified Research (FUR) PIS/CF:

1. Use of data is not sufficiently clear and only suggests that coded data will be used. However, it is not mentioned that identifiable data won’t be used, and what kind of coded data will be used.
2. There’s insufficient identification of the risks of participating in FUR. Please expand on these.
3. A compensation clause is missing, please amend to include.
4. The Committee noted that in addition to the above stated sections, this information sheet requires all sections as a standalone form as some participants may have lost the main PIS and should not be required to refer back to it. Please include all relevant sections from the main PIS into this PIS.
5. The Committee noted references to databases on page 3 but none are named. The Committee queried if Astra Zeneca have a databank. If so, this should be named and it could be noted that other databases cannot be identified at this time.
6. Please give details of databases that the data might be deposited into (note that the genetic FUR PIS refers to the UK Biobank)
7. On Page 2, please amend the following statement so as not to over-promise there will always be due recognition of Māori culture especially given there may be no New Zealand representation on overseas ethics committees deciding on future research. Please include all relevant overseas warning statements from the NEAC Standards (eg, Standards 12.14 – 12.17): *“There will be due recognition of the indigenous culture of Māori as the tangata whenua (indigenous people) practices and beliefs of an ethnic and/or religious nature will be fully respected. Research will be undertaken in a culturally sensitive and appropriate manner.”*
8. The Committee noted on page 3 that the following statement is incomplete and over-states what health authorities think – please amend: *“Health authorities as well as pharmaceutical companies believe that access to clinical studies data advances clinical science and medical knowledge and is in the best interest of patients and public health, provided that patient privacy is protected.”*
9. The Committee queried if all researchers, including external ones, take all of the data protection steps outlined (including all doing a DPIA). Please amend as appropriate on page 3.
10. Please explain fully the following statement on page 3: *“Your data will then be transferred to several data experts to be verified and for results to be calculated”*
11. The scope of the FUR suggests it’s beyond the current research study (page 1) and also appears to include research on any health problems but the Consent Form has two separate sections which splits out the scope of the FUR to be (1) on the same subject as FRONTIER 4 and (2) unlimited scope of FUR. Neither section is optional. Please amend for consistency and clearly outline what is optional.
12. Please ensure further consistency between the PIS and CF e.g. in relation to withdrawal from the study, the CF has the participant agree that the information collected up to the point when withdraw may continue to be used BUT the PIS says the opposite (that coded data will be destroyed (unless part of analyses))

Optional Genetic Sub-Study PIS/CF:

1. Refer to comments made about other information sheets and amend this PIS as relevant, especially the notes concerning missing sections.
2. Page 2 does not explain what kind of genetic testing will be done. Please amend.
3. It is not sufficient to include a hyperlink to Astra-Zenaca’s personal data retention policy especially since New Zealand isn’t listed as a country and falls under the ‘rest of the world’ option.
4. Please don’t refer to the main PIS throughout this PIS as it cannot be relied on that participants would have retained the main PIS. Please amend so that all relevant aspects of the main PIS are included in this PIS.
5. On page 3, please amend the following statement so as not to over-promise there will always be due recognition of Māori culture especially given there may be no New Zealand representation on overseas ethics committees deciding on future research. Please include all relevant overseas warning statements from the NEAC Standards (eg, Standards 12.14 – 12.17): *“There will be due recognition of the indigenous culture of Māori as the tangata whenua (indigenous people) practices and beliefs of an ethnic and/or religious nature will be fully respected. Research will be undertaken in a culturally sensitive and appropriate manner.”*
6. Please refer to comments made about the other CFs and amend relevant sections that apply to this CF.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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 & 7.58*).
* Please update the data and tissue management plan to ensure the safety and integrity of participant data *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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

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| **8** | **Ethics ref:** | **21/NTA/77** |  |
|  | Title: | The Healthy New Zealand Foods Pilot Study |  |
|  | Principal Investigator: | Professor Jeremy Krebs |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 06 May 2021 |  |

Professor Jeremy Krebs and Meika Foster were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The High Value Nutrition (HVN) National Science Challenge works with scientists and businesses to add nutritional value to fresh and processed food products for the benefit of consumers whether in New Zealand or elsewhere in the world. The current proposal describes a pilot study that will be used to finalise the study design, power calculations, and final methodology of the main intervention study, He Rourou Whai Painga.

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 protocol mentions a DEXA scan, but this is not in the participant information sheet. The researcher clarified that this is not going to be part of this study but will be asking if participants are prepared to do one for the purpose of the main study.

Summary of outstanding ethical issues

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

1. The Committee queried if the 30 Māori cases will just be index or if whānau will be included in that number also. The researcher clarified that if there is another adult in the household, they can become part of the 30 index cases, but otherwise other members of the household are included in the research but not as the 30 cases. The Committee noted this needs to be clearer in the participant information sheet as well as outlining what varying degrees of participation there are (i.e. questionnaires only but no blood samples)
2. The Committee asked the researcher for their intention with children participation and blood tests. The researcher responded that the overarching research question and principle behind the main part of the research is that they want to modify the diet to a more healthy dietary pattern of the index person, but realise that as part of their whānau, if they intervene at a whānau level, the researchers will hopefully improve nutrition of the whole whānau. Because it is known there are intergenerational effects on nutrition and health outcomes, there is a high probability that other household members will be at risk of cardiometabolic disease if the index participant has had this risk identified. There is currently no literature at this stage as to whether the primary outcome measure applies to children, but the purpose is to get an understanding and help plan the main study. The questionnaires will not apply to all children due to age and comprehension. The Committee stated more information is needed in the protocol on the involvement of children in this study and how this is being age tailored. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
3. The current assent form is not fit for purpose and age specific ones are required along with parental consent. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.22.d, 6.27 & 7.16).* The [HDEC templates](https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates) are available to be adapted.
4. The Committee queried how the recruitment of Māori participants through the Kokiri Marae partnerships works. The researcher responded that Kokiri have partnered with University of Otago for research and have their own methods of recruitment which they defer to. The Committee requested that more detail in documentation about their recruitment process is required.
5. The Committee queried if the Māori wellbeing questionnaire is exclusive to those recruited through Kokiri marae or if that is open to all Māori participants. The researchers confirmed this is available for all Māori participants regardless of how they are recruited. The Committee requested this questionnaire is uploaded for the Committee to review.
6. The Committee queried if there was mandatory biobanking as the standard blood tests outlined do not need to be stored at -80 degrees. The Committee stated that if there is leftover use to be sent to a biobank, the information sheet being provided to participants needs to be uploaded. In addition, the protocol does not state the intention for samples to be sent to a biobank. If samples are to be banked for future use or study only tests, all documentation must be clear on this. The Committee stated that the tissue management plan would need to comply with the national standards in terms of outlining what samples are being used for and where they are being sent, and some detail about the biobank. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.16, 14.17 & 15.19).* This can be done in combination with the data management plan. Use of the [HDEC template](https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans) is not mandatory but is encouraged to be adapted or used as a guide.
7. The Committee requested a safety protocol for interviewers conducting home visits. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).*
8. The Committee stated that the data management plan is not well localised (i.e. does not mention REDCap, audio files, children’s storage of data, how questionnaires are handled, etc.) A different team is involved, so their involvement and what is being shared with them needs to be explained in all relevant documentation. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15)*
9. The Committee suggested the researcher refrain from using the word ‘anonymous’ when referring to identifiability in all documentation when things are coded/de-identified.
10. The Committee stated that it is not clear who administers the questionnaires and how these are completed. They further noted that identifiers need to be removed from questionnaires.
11. The Committee queried if a food diary/journal is being used. The researcher responded that at this stage, they are not. The Committee requested that the mention of a food journal in the participant information sheet is removed.
12. The Committee were satisfied that My Food Bag could ensure safety legislation around food is handled, but requested that if this study is in a commercial arrangement with My Food Bag/any other businesses or if they somehow get a profit due to this study, this needs to be disclosed. Please review all documentation around that.
13. The Committee stated there is some contradiction in the documentation about whether or not samples are being sent overseas. Please review and amend for consistency. If samples are being sent overseas, please ensure the overseas statement from the HDEC template is included.

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

Main PIS/CF

1. Please ensure the consent form does not raise anything new that is not first mentioned in the main body of the PIS. Please review.
2. The Committee queried the inclusion of a pregnancy section in the CF. Remove this if not relevant.

Consumer Sub-study PIS/CF

1. The Information sheet for the qualitative study does not have all sections required for fully informed consent such as explanation of what identifiable information will be collected, who it will be shared with, a compensation section, etc. The Committee recommended the Researcher adapt the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-feb-2020-270220.doc)
2. Please include an outline of the food and health questionnaires such as how many there are, what kinds of questions these will ask and how much time it takes to complete them.
3. The Committee queried how reassurance can be given that the identity will remain completely anonymous throughout the process given participants can see each other in the focus groups. As per point 9, please amend ‘anonymous’.
4. Please consider some risks to participants such as the possibility of feeling like they’ve failed.
5. The Committee queried if on page 3 the participants will be given a copy of their comments to check for accuracy, given the importance of how some of their quotes may be used.
6. Continued use of data on withdrawal is stated to be optional in the PIS but appears to be mandatory in the CF. Please amend.
7. Please ensure the consent form does not raise anything new that is not first mentioned in the main body of the PIS (e.g. consenting to collection of health information about themselves for the sub-study). Please review.

Child’s Assent Form

1. As per point 3, age-group specific assent forms are required. These all must also be made for all relevant aspects of the study e.g. optional qualitative sub-study, and Tissue Future Unspecified Research (FUR) if seeking this.

Optional Tissue FUR PIS/CF

1. Please explain what genetic testing will be undertaken.
2. This PIS complies with the NEAC Standards for biobanking for Tissue FUR (standard 7.58) BUT it does not comply with the genetic research Standards 14.27 – 14.41.
3. This PIS is missing sections about identifiable and de-identified information in separate sections and who it will be shared. Some of that information is in the PIS but the Committee stated it would be much easier to understand if it is put into the relevant sections and headers.
4. Please state whether any accompanying data and if there is data FUR to ensure compliance with standard 7.57.
5. Please include a risk and benefit section.
6. Please include a statement on participants’ rights to access and correct any information collected about them.
7. The Committee noted to include a statement on what will happen if the results of the genetic research have significant consequences for the participant and their family.
8. The Committee requested clarification on what results will be posted on the website and communicated to the Research Advisory Group for Māori at CCDHB (i.e. study results, individual results).
9. Please clarify if blood samples will be destroyed or returned by overseas labs.
10. In the CF, the committee queried if the consent options for tissue being sent overseas and genetic research is truly optional if that is the aim of this PIS/CF.

Decision

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above. The Committee recommended resubmitting to the Northern A HDEC.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 15 June 2021, 01:00 PM |
| **Meeting venue:** | ONLINE - Zoom Meeting |

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**

The Committee noted that the exclusion of abstinence as an acceptable form of contraception in the HDEC template should be reviewed.

The meeting closed at 4.35pm