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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 12 October 2021 |

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| **Time** | | **Review Reference** | | **Project Title** | | **Coordinating Investigator** | | **Lead Reviewers** | |
| 10.55 - 11.20am | | 21/STH/233 | | PD genes and exposures | | Dr Toni Pitcher | | Amy/Dominic | |
| 11.20-11.45am | | 2021 FULL 11060 | | A Study to Evaluate the Efficacy and Safety of Astegolimab in Patients with Chronic Obstructive Pulmonary Disease (COPD) | | Doctor Andrew Veale | | Mira/Tony | |
| 11.45-12.10pm | | 2021 FULL 11320 | | NEOLEV3 High dose levetiracetam for the treatment of neonatal seizures | | Doctor Cynthia Sharpe | | Devonie/Dominic | |
| 12:10-12:30pm | |  | | Break (20 minutes) | |  | |  | |
| 12.30 - 12.55pm | | 2021 FULL 11246 | | A Study to Treat Small to Medium Sized Abdominal Aneurysms | | Associate Professor Andrew Holden | | Amy/Dominic | |
| 12.55 - 1.20pm | | 2021 FULL 11162 | | Study of efficacy, safety, and tolerability of LNA043 in patients with symptomatic knee osteoarthritis. | | Dr Nigel Gilchrist | | Mira/Dominic | |
| 1.20 - 1.45pm | | 2021 FULL 11166 | | Respiratory Health in Tamariki with Cerebral Palsy in New Zealand | | Professor N. Susan Stott | | Devonie/Tony | |
| 1.45-2.10pm | | 2021 FULL 11202 | | GRIT Study | | Dr Samantha Lee | | Amy/Tony | |
| **Member Name** | | **Member Category** | | **Appointed** | | **Term Expires** | | **Apologies?** | |
| Dr Sarah Gunningham | | Lay (other) | | 05/07/2016 | | 05/07/2019 | | Apologies | |
| Dr Devonie Waaka | | Non-lay (intervention studies) | | 18/07/2016 | | 18/07/2019 | | Present | |
| Assc Prof Mira Harrison-Woolrych | | Non-lay (intervention studies) | | 28/06/2019 | | 28/06/2020 | | Present | |
| Dr Paul Chin | | Non-lay (intervention studies) | | 27/10/2018 | | 27/10/2021 | | Apologies | |
| Mr Anthony Fallon | | Lay (consumer/community perspectives) | | 13/08/2021 | | 13/08/2024 | | Present | |
| Mr Dominic Fitchett | | Lay (the law) | | 05/07/2019 | | 05/07/2022 | | Present | |
| Ms Amy Henry | | Non-lay (observational studies) | | 13/08/2021 | | 13/08/2024 | | Present | |

**Welcome**

The Chair opened the meeting at 10:30am and welcomed Committee members, noting that apologies had been received from Dr Paul Chin and Dr Sarah Gunningham.

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 14 September 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **21/STH/233** |
|  | Title: | PD Genes and Exposure |
|  | Principal Investigator: | Dr Toni Pitcher |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 20 August 2021 |

Dr Toni Pitcher was not present for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of outstanding ethical issues**

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

**INFORMED CONSENT**

1. The Committee considered that as all participants will undergo a video call it is difficult to see why informed consent cannot be achieved in the same manner. The study involves more than a simple questionnaire; there are significant implications regarding incidental findings, return of results, and future unspecified research. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.1).*

**DATA MANAGEMENT**

1. No information is provided in the data and tissue management plan or application form about the video recordings. Clarify how long video footage will be retained for, why it needs to be retained, where it will be stored, and measures taken to protect confidentiality. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

**CLINICALLY SIGNIFICANT FINDINGS**

1. The presence of inherited genetic abnormalities associated with Parkinson’s Disease is a possibility. Describe the processes in place for return of results, and the options available to participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*

**CONFLICT OF INTEREST**

1. The answer to question r.5.4.1. states there is a COI but does not state how this will be mitigated. Describe the recruitment process for patients under the clinical care of an Investigator. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.23).*

**QUESTIONNAIRES**

1. Please use the New Zealand census ethnicity categories rather than adding ‘New Zealander/Kiwi/Pākehā ‘to the New Zealand European ethnic group category.

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

**PISCF PD**

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

1. The Committee recommends adapting the HDEC template.
2. Clarify process and timing, i.e. how are screening questions dealt with, what is the order of events and approximate timeframes between specific stages.
3. No information regarding future unspecified research (FUR) is presented in the information form, only in the consent form. Please create a separate FUR form as an addendum to the main PIS.
4. Clarify whether ethics approval been obtained for the NHI data-linking described that is 'outside the current study' (p4)
5. Please include a statement advising that sending tissue overseas is optional
6. Please address the breadth of genetic testing (WGA)
7. Please address the return of individual results and GP notification, including mental health issues / non-actionable CS results / results with implications for blood relatives
8. Please include information on the withdrawal of tissue
9. Please include information on re-identification risks specifically associated with genetic research.
10. Please include information on the nature of questionnaires (includes mental health questionnaires)
11. Please include information on data management.

**PISCF CONTROL**

1. In addition to the above points please clarify how the individual's contact details were obtained, and why they have been asked to take part.

**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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| **2** | **Ethics ref:** | **2021 FULL 11060** |
|  | Title: | A Study to Evaluate the Efficacy and Safety of Astegolimab in Patients with Chronic Obstructive Pulmonary Disease (COPD) |
|  | Principal Investigator: | Dr Andrew Veale |
|  | Sponsor: | PPD |
|  | Clock Start Date: | CLOCK START DATE |

Dr Andrew Veale 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 queried how participants would be recruited. The Researcher explained when they do a lung function test every patient is asked if they want to join a clinical research database. The researcher stated patients have been referred by a specialist and the study team confirms with the specialist that the patient is suitable for the study before enrolment.
2. The Committee queried if participants would be provided with a device to access the E-Diary. The Researcher confirmed they would loan participants a device for the duration of the study and there are enough to replace one if it breaks or is lost.
3. The Committee explained that a pregnancy follow-up PISCF should only be submitted in the event that a participant or their partner becomes pregnant in the study. If this situation occurs please submit an amendment with the pregnancy PISCF.

**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 clarification on what medicines participants would have to stop taking to participate in the study. The Researcher stated participants would not need to withdraw as the study will add to standard care rather than withdraw. The Committee requested more information in the Participant Information Sheet and Consent Form (PISCF) to explain this so participants understand they will be allowed to stay on their regular medication.
2. The Committee queried the risks of the procedure. The Researcher stated typically it would be a local reaction to the injection and systemic reactions in a previous study were very low. The Committee queried where the injection would be given. The Researcher stated in the abdomen. The Committee requested this information be added to the PISCF.
3. The Committee requested information on the potential for a systemic flu-like response to appear be added to the PIS. The Committee advised that known side effects needed to be listed along with their predicted rate of occurrence (e.g. 1 in 10 people experienced nausea).
4. The Committee queried if the study involved mandatory genome analysis. The Researchers confirmed SNP analysis was required for entry. The Committee requested that information explaining why this is mandatory be included in the PISCF so it is very clear to potential participants what is required of them.
5. The Committee noted the application stated participants would not be eligible for ACC-equivalent compensation and queried why. The Researcher stated they were unsure as they usually operate on an ACC basis. The Committee stated that for the study to be approved, the Sponsor must confirm that the commercial insurance cover in place will provide compensation that as at least ACC-equivalent. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
6. The Committee noted a conflict between the data management plan and the PIS. The Data management plan states tissue collected prior to withdrawal will continue to be used whereas the PIS states it will not undergo any further testing. Please clarify what is intended.

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

**MAIN PISCF**

1. The Committee requested a section of the form discuss COPD medications.
2. Please provide a lay title for each PIS (page 1)
3. Consider bolding the information that this is a trial of an experimental medicine (and add not approved by Medsafe in NZ) on Page 2.
4. Please state where in the body the sub-cut injections will be given (Page 2)
5. Provide more explanation on which medications are not allowed in the study, or to enter the study, especially commonly prescribed medicines for COPD and those needed in an exacerbation (page 3).
6. Regarding side effects (page 9) please give some idea of the expected frequencies of adverse events (using data reported in earlier studies).
7. Please consider a smaller footer which is more separate from the main text for easier reading.
8. The Sponsor does not match the Sponsor listed in the application form. Please reconcile (p1).
9. Some of Section 1.4 does not relate to eligibility, e.g. initial statement and fasting requirements (p3); please delete or move elsewhere.
10. Split contraceptive requirements and COPD med requirements into separate subheadings (p6)
11. Explain what a biomarker is the first time the term is used (p7)
12. Amend the statement at the end of page 7 to state that screening samples may be used for 'future research involving the study drug and/or COPD. This may include...' to make it very clear that the research described subsequently pertains to the first statement (p7).
13. The application form states that no mandatory genomic research will be undertaken (including mandatory genomic biomarker analysis). Clarify why the subheading 'genome testing' (p7) and 'handling of genetic information (p13), and information about return of genomic results (Section 2.2) are included in the main PISCF and delete if not applicable to mandatory participation.
14. Increase the font size of potential drug risks to full size; this is a critical consideration for participants (p9)
15. Amend section 9.1 to reflect the New Zealand health care system (p10)
16. Clarify what 'Your study data may be .... linked to other data collected from you' means. What data will be collected that is not study-specific? (p11).
17. Delete optional tickboxes for GP notification and study data withdrawal; these are mandatory components of study participation (CF)

**FUR PISCF**

1. Please try not to use words like ‘sub-study’ which may not be understood by a lay person.
2. Please add a sub-heading for genomic studies and provide more information about how information and results will be handled
3. Please explain more clearly how many extra visits are needed for the blood tests.

**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 Mr Anthony Fallon and Dr Mira Harrison-Woolrych.

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| **3** | **Ethics ref:** | **2021 FULL 11320** |
|  | Title: | NEOLEV3 High dose levetiracetam for the treatment of neonatal seizures |
|  | Principal Investigator: | Dr Cynthia Sharpe |
|  | Sponsor: | University of Minnesota |
|  | Clock Start Date: | 30 September 2021 |

Dr Cynthia Sharpe 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 queried whether the issues raised during the peer review process had been resolved. The Researcher confirmed they were all addressed with the resubmission.

**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 the study will need to be registered on a WHO-approved clinical trial registry before it commences.
2. Please ensure the Sponsor signs the form in the Ethics Review Manager before resubmitting.
3. The Committee requested the Researcher supply a tissue and data management plan and recommended adapting the [HDEC tissue and data management template.](https://ethics.health.govt.nz/system/files/documents/pages/hdec-data-tissue-management-template-oct2020.docx) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.5; 14.16).*

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

1. Please undertake a revision to use lay-friendly language; for example, some parents may not understand what ‘randomisation’ and ‘study phases’ are.
2. Please insert a statement advising that follow-up will be done by accessing the participant’s clinical records.
3. Please insert a statement advising that data from the study procedures will go into the participant’s permanent health records.
4. The Committee recommended adapting the HDEC template section regarding use of data, as this contains prompts for all the information required (i.e. who has access to coded information, potential future uses of data and whether it will be sent overseas etc.).
5. The Committee requested additional information about the optional EEG database and the inclusion of a statement on ownership rights of data submitted to it.
6. The Committee requested a statement advising that no karakia will be available during the destruction of tissue samples be added to the PIS.
7. The Committee advised the PIS was not very readable for a parent who had to make this decision reasonably quickly and requested it be simplified. The Committee stated splitting the content into bullet points and short paragraphs may make it easier to manage.

**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 Mr Dominic Fitchett and Dr Devonie Waaka.

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| **4** | **Ethics ref:** | **2021 FULL 11246** |
|  | Title: | A Study to Treat Small to Medium Sized Abdominal Aneurysms |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | Nectero Medical, Inc |
|  | Clock Start Date: | 23 September 2021 |

Associate Professor Andrew Holden 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 queried whether the study required approval from SCOTT. The Researcher stated they had consulted with SCOTT who declined to review the application as it is on a device and not a new drug.
2. The Committee noted the application stated data would be stored in an identifiable form whereas the PIS states it will be deidentified. The Researcher stated any source documents on site would be stored in archiving boxes and confirmed any data sent to the Sponsor would be deidentified.

**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 ensure New Zealand is listed as an insured territory on the insurance certificate.
2. The Committee advised the study will need to be registered on a WHO-approved clinical trial registry before it commences.
3. The Committee noted the data management plan states there may be individual results that are clinically significant but not actionable and participants are informed of this possibility in the PIS and notified in accordance with their stated wishes. The Committee noted there was no where in the PIS or on the consent form for participants to indicate their wishes. Please include this.

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

1. The Committee requested the Researcher insert a black box on the front of the PIS to state that this is the first time this device will be studied on human participants. The HDEC template has an example of this.
2. Please undertake a general revision to replace technical language with something more lay friendly. (e.g. people may not understand what a ‘bench top model’ is).
3. The Committee queried whether the tannin compound to be used was part of a licensed product anywhere. The Researcher stated they were not aware of any. The Committee requested it be made clear in the PIS that this is an experimental product and include any potential risks associated with the compound.
4. Please add information explaining how participants will be given fentanyl and midazolam during the treatment.
5. Please replace any references to the NTB HDEC with the STH HDEC.
6. Please replace ‘your doctor’ with ‘study doctor’ so participants understand it will not be their usual GP but a specialised study doctor that will care for them during their participation.
7. Please include any risks of ionising radiation (above standard care).
8. On page 6 it might be clearer/easier to understand risks in terms of frequency (e.g. between 1 and 10 people out of 100 will experience X).
9. The Committee noted two paragraphs merging together on page 8.
10. Please state whether or not the livestream is recorded.
11. Please include information so participants understand that even though it is study data the results of procedures (e.g. imaging, blood tests) will go in the participant’s (identified) clinical records.
12. Please clarify how long participants are required to use contraception for.

**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:** | **2021 FULL 11162** |
|  | Title: | Study of efficacy, safety, and tolerability of LNA043 in patients with symptomatic knee osteoarthritis. |
|  | Principal Investigator: | Dr Nigel Gilchrist |
|  | Sponsor: | Novartis Pharmaceuticals |
|  | Clock Start Date: | 23 September 2021 |

Dr Nigel Gilchrist 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 queried whether there were any specific adverse events of interest in the study. The Researcher stated other than the pain/discomfort of the injection they were not aware of any.
2. The Committee queried if the study would supply a device for participants to complete the E-Diary. The Researcher confirmed it would.
3. The Committee noted the study would involve tissue being sent overseas and this has implications for any Māori participants that may donate tissue. The Committee requested the Researcher be mindful of this for future applications.

**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 study may not ask specific mental health questions but chronic pain can have an association with depression and ongoing mental health concerns. The Committee requested the Researcher provide information about the processes in place in the event a participant in the study displays signs of mental distress or suicidal ideation. This information should also be included in the PISCF. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*

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

1. The Committee requested a general revision of the PIS to simplify it, standardise formatting, and make it easier to read.
2. Please include the location (e.g. city or country if known) of labs where tissue is being sent in the PIS.
3. Please include a statement advising whether a karakia will be available at the time of tissue destruction.
4. Please state what happens to mandatory tissue samples if the participant withdraws from the study and whether these will continue to be used, are able to be returned or will be destroyed.
5. Please include more information on how the treatment would be given (e.g. an injection to the knee).
6. Simplify the 'Study Treatment' section significantly; currently difficult to follow (p3).
7. Delete repeated information re number of participants (p4)
8. Simplify all explanations regarding assessments. Use terms like 'in a row' rather than 'consecutive'. Information overload is a real risk here (p5 on)
9. Delete 'Only one knee (study knee or target knee) will be chosen and will receive the study treatment, however assessments may be conducted also on the other knee' (p6); it is a direct duplicate of a previous sentence.
10. Simplify assessment table significantly (e.g. group all questionnaires together as 'questionnaires' and summarise what they cover)
11. Simplify fasting requirements, this can be explained in 1 or 2 short sentences. (p5)
12. Make it clear that participants should not withdraw pain (or other medication) for study entry prior to consultation with his or her specialist / primary health care provider (p5)
13. Remove optional sample descriptions from main PISCF (p10,12)
14. Explain what synovial fluid is, the first time it is referenced (p11)
15. 'These safety and efficacy samples are part of your routine care' is incorrect; they are being performed purely for the purposes of the study (p11). Delete.
16. Give total blood vol (in mLs) for the study and delete individual sample amounts in table (p12)
17. State where overseas samples will be stored and analysed (p12)
18. State what an 'immune reaction' may consist of (p13)
19. Side effect frequencies are misleading (b/w 1 in 100 and 1 in 10, not ‘about 1 in 100’)
20. Review all risk descriptions and use simpler, shorter words and sentences (risk section).
21. Give equivalent background radiation exposure for required AP knee films (p14)
22. Re-write contraceptive section in lay terms and use common NZ examples (15).
23. Include alternative options (continue with standard care, join another clinical trial) (p16)
24. Rewrite to make it definitive that reimbursement will be made. If there is a cap, this must be clearly stated (p16).
25. Refer to identified information, not Personal Information (p19)
26. p20 states the study may be stopped if the drug is found to be effective and no further testing is required. Confirm in this instance that participants on active treatment are given the option of completing the scheduled active treatment period.

**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 Mr Dominic Fitchett and Dr Mira Harrison-Woolrych.

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| **6** | **Ethics ref:** | **2021 FULL 11166** |
|  | Title: | Respiratory Health in Tamariki with Cerebral Palsy in New Zealand |
|  | Principal Investigator: | Professor N. Susan Stott. |
|  | Sponsor: | Auckland District Health Board |
|  | Clock Start Date: | 23 September 2021 |

Professor Susan Stott 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 queried whether participants who completed the questionnaire but did not consent to the data linking would help fulfil the study’s objectives. The Researcher stated this group would just be used to assess the feasibility and acceptability of the questionnaire itself so would still contribute to the 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 identifiability of data. The Researchers stated it would be encrypted and could not be reidentified. The Committee noted it was not entirely clear that the questionnaire and data would be sent to the Ministry of Health and requested additional information explaining this be added to the data management plan and PISCF. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).
2. The Committee requested the Researcher amend the protocol to include what action would be taken if a participant in the study displays signs of mental distress or suicidal ideation. This information should also be included in the PISCF. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
3. Amend the title on all study documentation to reflect the study population, which includes adults.

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

1. Please rename the main information sheet to be the main ‘adult PIS’. Similarly please delete the reference to 0-16 on the parent/guardian PIS as participation is determined by competence not age alone.
2. Please create unique information sheets for each targeted audience and only reference one of the three options within.
3. Please revise the wording in the information sheets to reflect the reality that the ability to provide informed consent is based on a person’s capacity not their age.
4. The Committee suggested splitting the legal guardian form into two or three separate forms.
   1. The first for a legal guardian of a 16/17 year old without capacity to consent;
   2. The second for a welfare guardian or EPOA for an adult (i.e. 18 or over) without capacity to consent; and
   3. The third for a family member of an adult (i.e. 18 or over) without capacity to consent, this one being to capture the family member’s views on whether their family member would like to be involved in the study (the current legal guardian form is pretty close to what is required for this one, especially once reference to ‘legal guardian’ and ‘consent’ are removed).
5. Please include the aim of the research in all information sheets so participants understand the objective of the study.
6. Please clarify the statement on page 2 of the assent form on sending NHI and change it to specify “your” NHI.
7. Amend information regarding stigmatisation to refer to any at-risk minority (p4).
8. Review need for ACC statement; delete if no risk of study-related injury (p4).
9. State that there are no direct benefits to study participation (p4).
10. Delete optional tickbox for questionnaire completion; this is mandatory in order to take part in the study (CF).
11. Please change Cook Island Māori to Cook Islands Māori.

**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 Mr Anthony Fallon and Dr Devonie Waaka.

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| **7** | **Ethics ref:** | **2021 FULL 11202** |
|  | Title: | GRIT Study |
|  | Principal Investigator: | Dr Samantha Lee |
|  | Sponsor: | University of Canterbury |
|  | Clock Start Date: | 23 September 2021 |

Dr Samantha Lee 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 outstanding ethical issues**

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

1. The Committee queried the age range of participants. The Researcher stated they were originally hoping to see them at 16 and 17 years old but the COVID-19 pandemic has delayed this and some are now 18 years old. The Committee noted the protocol still refers to 16 to 17 year olds and may need updating to reflect this.
2. The Committee queried whether all participants understood the nature of the study. The Researcher stated they have not been made aware on the information sheets and it is up to the mother to tell their children whether or not they were exposed as the researcher does not feel comfortable disclosing this.
3. The Committee queried whether participants could find out from any study publications or by looking the study up on the internet. The Researcher stated if they learned the true subject of the study they still would not know whether they were in the opiate-exposed group or control group.
4. The Committee considered that if a participant requested a summary of the study results (as they are entitled to do) and learned that half of participants were born to a mother on the methadone programme this could be distressing. The Committee considered that participants would understandably be upset that they were not told what their data and genetic information is being used for. The Researcher stated the information on any opiate use is health information related to the mother and so it is not their place to reveal that to the mother’s child without her permission.
5. The Researcher stated the mothers in the study agreed to participate as they would receive complete confidentiality and did not anyone to know they had been in a methadone programme in the past. The Committee stated it would be reasonable to contact the mothers/caregivers and give them advanced warning that this new phase of the study is going to begin. The Committee stated if any mothers/caregivers did not want participants they are caring for to continue in the trial then they may withdraw before the new phase begins. The Committee stated it is important to be transparent about the reasons of the study and the Researchers would need to find a mechanism to sensitively disclose the reason of the study without unduly identifying anyone or breaking anonymity.
6. The Committee accepted that it is the mother’s health information, but noted the issue is that by withholding important information about the study the participants are not providing fully informed consent. The Committee stated the study would need to be upfront about what it is studying. The Committee clarified that it can still be blinded and participants do not need to be told which group they belong to but the study would need to disclose that there is an opiate-exposed group and a control group.
7. The Committee noted that only participants who consent for themselves should be invited to participate in the genetic research.

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

**PISCF – MAIN / YOUNG PARTICIPANTS**

1. Please be transparent regarding the study (as discussed above).
2. Please separate out mandatory tests from any optional components to the study so participants can clearly understand what is required and what is optional.

**PISCF - CAREGIVER**

1. State that the questionnaire will include questions about drug use.
2. Make mandatory reporting requirements much clearer.

**GENETIC RESEARCH**

1. Given this is optional and exploratory, consent should only be sought for those teens providing independent informed consent.
2. The risk of potential re-identification through database matching etc should be discussed (could the genetic dataset be matched with a police genetic data-base, for example?)

**OBLIGATORY REPORTING**

1. Confirm whether the research team processes for reporting of illegal substance use by the caregiver when there are children / teens in the household are consistent with New Zealand reporting requirements. If confirmed by the researcher, clarify in the PIS that illegal drug use will not be reported to authorities.

**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 the full committee online via the Ethics Review Manager.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 09 November 2021 |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting.

* Dr Mira Harrison-Woolrych

The meeting closed at 3:00pm.