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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 28 May 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00 - 12:30pm | 2024 FULL 19596 | PRIME Trial - Prevention of Reperfusion Injury in Myocardial Infarction | Dr Adrian Owen | Patricia & Helen |
| 12:30 - 1:00pm | 2024 FULL 20124 | M20-465 Hidradenitis Suppurativa: Lutikizumab in Adult and Adolescent Subjects with Moderate to Severe Hidradenitis Suppurativa | Prof Marius Rademaker | Patries & Alice |
| 1:00 - 1:30pm | 2024 FULL 18070 | The PRECeDe Trial | Prof Katie Groom | Barry & Sandy |
| 1:30 - 2:00pm | 2024 FULL 20252 | AROAPOC3-3004: A Study to Evaluate Plozasiran in Adults with Severe Hypertriglyceridemia (Shasta-4 Study) | Prof Russel Scott | Patricia & Cordelia |
| 2:00 - 2:30pm |  | BREAK (30 mins) |  |  |
| 2:30 - 3:00pm | 2024 FULL 19922 | Phase 3 Study of the Safety and Immunogenicity of COVID-19 and Influenza Combination Vaccine and a Standalone Influenza Vaccine in Participants 60 Years or Older | Dr Dean Quinn | Patricia & Sandy |
| 3:00 - 3:30pm | 2024 FULL 20405 | Safety and Effectiveness of the Omnipod 5 SmartAdjust 2.0 System in Individuals with Type 1 and Type 2 Diabetes | Dr Martin de Bock | Barry & Cordelia |
| 3:30- 4:00pm | 2024 FULL 20041 | Phase 1 trial of intraperitoneal lignocaine implant for pain relief in abdominal surgery | Prof Andrew Hill | Patries & Alice |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/05/2018 | 22/05/2020 | Present |
| Mrs Sandy Gill | Lay (Consumer/Community perspectives) | 22/05/2020 | 22/05/2023 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Dr Cordelia Thomas | Lay (the Law) | 22/12/2020 | 22/12/2024 | Present |
| Ms Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Apologies |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Apologies |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Alice McCarthy | Lay (the Law) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that apologies had been received from Mrs Jessie Lenagh-Glue and Mx Albany Lucas.  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mr Barry Taylor and Ms Alice McCarthy confirmed their eligibility and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 19596** |
|  | Title: | PRIME Trial - Prevention of Reperfusion Injury in Myocardial Infarction |
|  | Principal Investigator: | Dr Adrian Owen |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 May 2024 |

Dr Adrian Owen was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the control group would be anonymised data from historic cases.
2. The Committee clarified that the study commencement date in the study should be amended in the study protocol to note that this would not be before the application is approved by an HDEC.
3. The Committee queried why the adverts exist. The researcher clarified that this was largely for staff and participants as a reminder rather than for recruitment.

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 delayed or deferred consent does not comply with Right 7(1) of the Code of Health and Disability Services Consumers’ Rights. The committee discussed whether Right 7(4) applied to these participants and concluded that informed consent was required. The Committee suggested a short consent form for those who would be recruited on intake. Those who are not able to consent or not properly consented due to staff shortage should not be included in the study. The consent would be documented and then once the participant was more stable, they would then be provided the full information sheet for further information and then at that stage given a chance to withdraw their data. The short information sheet and consent should involve what the study is about and the risks of the study. This should also state that more information would be given later and an opportunity to withdraw. *National Ethical Standards* para *7.16*
2. The Committee suggested that those individuals not being delivered the initial dose of the intervention should not be included in the study due to potential impact on the data collection and analysis. The Committee noted that this group could potentially be important for future studies concerning this intervention but that it could complicate the design of what is currently proposed.
3. The Committee requested that the consent for Future Unspecified Research be on a separate form. *National Ethical Standards* para *7.57*
4. The Committee queried the statement “but we would like to passively follow you up” where referring to withdrawal from the study.
5. The Committee requested that a plan be made for approach for recruitment to the study so that there is a reduction in the coercion felt by participants. It is not appropriate for the clinician to be the person making the approach to the potential participants. *National Ethical Standards* para *7.18*
6. The Committee noted that talking to Pasifika and Māori colleagues does not constitute consultation. Please provide proof of actual consultation and note if this has also included the data sovereignty. *National Ethical Standards* para *3.3*
7. The Committee noted that for future applications the concept of whakamā and handling situations that may be sensitive with whānau is important and should be considered in making an application.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *National Ethical Standards* para *7.16, 7.19 & 7.15*:

1. Please amend the style of the PIS to read as paragraphs. The bullet points are very clinical and hard to digest.
2. Please remove tick boxes from parts of the consent form that are not truly optional.
3. Please list the full associated risks in taking part in the study not just the safety of paracetamol.
4. Please note that the statement “There will be no cost to you for your treatment” is not accurate and should be amended. If there is reimbursement for patients that need to come back to the clinic, please state this clearly and define how and for what.
5. Please review for plain language and please provide a lay title for the study and for adverts.

**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:** | **2024 FULL 20124** |
|  | Title: | M20-465 Hidradenitis Suppurativa: Lutikizumab in Adult and Adolescent Subjects with Moderate to Severe Hidradenitis Suppurativa |
|  | Principal Investigator: | Prof Marius Rademaker |
|  | Sponsor: | AbbVie Ltd |
|  | Clock Start Date: | 16 May 2024 |

Dr Marius Rademaker and Ms Neerja Singh 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 the burden on participants of the questionnaires. The researcher clarified that the first questionnaire takes a bit longer but the average time for questionnaires is 5-10 minutes. The Committee also clarified which questionnaires would be filled in at the clinic rather than those done at home.

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 a safety and follow up plan (to be included in the PISCF) and for questionnaires involving depression and anxiety. This should include when the questionnaires are reviewed after completion, what action will be taken by whom and what referrals or pathways for follow up are in place for participants indicating mental distress. Please note that the wording around this in the PISCF and asking that they come forward to talk to researchers is not appropriate.
2. The Committee requested clarification as to why HIV, HBV and HCV are exclusions in this study. That they are a “standard exclusion” is not adequate. Please provide a scientific basis as justification for this exclusion.
3. The Committee queried if participants would be granted koha on top of expenses as a token of appreciation if there is a koha please state how much this will be.
4. The Committee requested provision of a current medical indemnity certificate for the PI as the one provided expired January 2024.
5. The Committee requested justification as to why there is such a high number of questionnaires included in this study.

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

1. Please clarify if this drug is first in human or otherwise how many people have had this medication.
2. Please remove all gendered language.
3. Please read for readability of sentences.
4. Please simplify statements that are non-lay such as “changes in lipids” on page 12.
5. Please do not describe placebos as a “fake drug”. Please amend to something along the lines of “a medication that looks the same but with no active ingredient”.
6. Please provide a simple diagram of the study on page 3 indicating exactly what is happening to the different study groups and at what time. This process is unclear and poorly described at present.
7. Please include a table of summary for the questionnaires, including when they will be filled in and how long they will take each.
8. Please clarify whether participants are expected to go into the clinic for any visits and how this will work and intersect with statements concerning the participants’ ability to give themselves injections. Please be clear around this process and what actually will be done by participants at home and what will be done by health practitioners.
9. Please ensure that the risk section is clarified and reviewed for readability. Please standardise fonts and remove unnecessary sections such as “safety topics of interest” and please ensure that only sections that pertain to the participants is included in lay language.
10. Please amend reference to blood measurements in terms of teaspoons. This should be presented in millilitres.
11. Please remove the option (tick boxes) for general practitioners to be notified, this should be mandatory for this type of study.
12. Please amend the period data will be stored to be consistent across all documents and clearly defined. “as long as required by local laws” is too vague. Please note this period in a number of years, preferably 10.
13. Please amend “Māori health support”, to “Māori cultural support”.
14. The study screening uses different language for 'females who are able to get pregnant' and 'females of childbearing potential'. Please amend to only use “people of childbearing potential”.
15. Please move the section in the risks that discusses how the study works to the start of the PIS. This should be one of the first things read by participants.
16. Please clarify if karakia will be possible at time of tissue destruction.
17. Please remove the words “also known as the AIDS virus” as this is stigmatising and not appropriate language.
18. Please rephrase the pregnancy risk information in the consent form to note that there is no risk should a person father a child whilst on the study.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Patries Herst and Ms Alice McCarthy.

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| **3** | **Ethics ref:** | **2024 FULL 18070** |
|  | Title: | The PRECeDe Trial |
|  | Principal Investigator: | Prof Katie Groom |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 May 2024 |

Dr Katie Groom, Ms Elisa Tam and another member of the study team were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

**Summary of resolved ethical issues**

1. The Committee queried the number of questionnaires being used in the study. The researcher noted that this was to measure the ways that the pregnant parents were impacted more holistically and that this has been supported by feasibility studies.

Summary of outstanding ethical issues

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

1. The Committee noted that the AQoL-8D and other mental health questionnaires could be potentially triggering to participants. Please provide a detailed safety plan for participants both at home and in the clinic that clearly outlines the timeliness of response, the methods of follow up and the ways that mental distress will be managed. Please include this in the participant information sheet as well as the protocol.
2. The Committee queried the AQoL-8D questionnaire being used as it is extremely invasive into the lives of the pregnant parent and a less invasive questionnaire would be more appropriate and ethical given the scope of the study.
3. The Committee suggested that the research team utilise the New Zealand relevant sections [HDEC Data and Tissue Management Plan template](mailto:https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-tissue-management-template-Nov2022.docx) as there is important information missing from the document supplied.
4. The Committee noted that the language used in the advertisements was misleading. Mention of “prevention of respiratory distress” is not accurate given that this is investigational research. Please amend these to note that the possibility to reduce or prevent respiratory distress is being determined.

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

1. Please remove the option for general practitioners to be notified, this should be mandatory for this type of study.
2. Please move the information around asking for an interpreter to the start of the PIS of the consent form.
3. Please clarify what information is collected on the baby after the initial blood glucose tests.
4. Please explain and clarify what data linking will take place and why.
5. Please acknowledge the concept of whakamā as there may be feelings of shame around the child being unwell.
6. Please amend the PIS to state the approving HDEC is Central, not Northern B.
7. Please include the cultural statement per the [HDEC template](mailto:https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).
8. Please set the contact details out more clearly.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).
4. Please supply a more detailed data management plan to ensure the safety and integrity of participant data. 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).*
5. Please provide more detail in study documentation to ensure participant safety if there are potential concerns with their well-being raised as part of this study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4-8.6, 8.9)*
6. Please update the advertisements, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).

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

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| **4** | **Ethics ref:** | **2024 FULL 20252** |
|  | Title: | AROAPOC3-3004: A Study to Evaluate Plozasiran in Adults with Severe Hypertriglyceridemia (Shasta-4 Study) |
|  | Principal Investigator: | Prof Russel Scott |
|  | Sponsor: | IQVIA RDS Pty. Ltd |
|  | Clock Start Date: | 16 May 2024 |

Miss Julia O’Sullivan, Ms Lucy Druzianic, Miss Kayla Malate, Dr Jane Kerr and Dr Prasanna Karunaseker were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that should the participants be believed to have familial chylomicronaemia syndrome (FCS) the genetic testing for this would only be undertaken after consultation with experts in this field based on the questionnaire results. This is unlikely to occur given this condition is incredibly rare.

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 inclusion of so many documents in the application that are not applicable to HDECs and the New Zealand context.
2. The Committee requested an updated insurance certificate once able to be provided.
3. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
   1. Please clarify if data and tissue will be anonymised. Please amend if not.
   2. Please clarify if data will be linked.
   3. Please note that without sufficient justification, data should not be kept for 25 years. Please review this with the sponsor, particularly where this is not consistent with the other information concerning data storage.

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

Main PIS/CF:

1. Please include the number of participants in New Zealand.
2. Please include words instead of symbols for greater than or equal to when referring to 18 years and over.
3. Please specify if a gender matched clinician and support person will be available for physical exams and if clothes will need to be removed.
4. Please amend wording around providing consent to read “you must provide written consent”.
5. Please remove mention of tablespoons as measurements of blood. Please amend these measurements to be in millilitres.
6. Please amend “Māori health support”, to “Māori cultural support”.
7. Please specify if there will be compassionate supply after the trial.
8. Please remove mention of the Nuvaring.
9. Please amend mention of the “Family Doctor” to be “General Practitioner”.
10. Please remove gendered language in the heading of the pregnancy and contraception sections.
11. Please be clear and explain why people may or may not be invited to the open label study.
12. Please review for repetition on page 15 and 16.
13. Please remove mention of privacy law and replace with the Privacy Act.
14. Please rephrase the wording around what research is and is not reviewed by an HDEC.

Future Unspecified Research (FUR) PIS/CF:

1. Please be clear and consistent with length data will be stored. This should be consistent across all study documentation.
2. Please remove the bullet point in the CF stating, “I want my identity to be kept with my blood sample.” as study samples will be coded.
3. Please amend “Māori health support”, to “Māori cultural support”.
4. Please remove the words “may be” when speaking on reimbursement.

Genetic FUR PIS/CF:

1. Please make it clear that participation in this part of the study is only for those suspected to have genetic (FCS).
2. Please amend “Māori health support”, to “Māori cultural support”.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).
4. Please supply a more detailed data management plan to ensure the safety and integrity of participant data. 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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Cordelia Thomas and Mrs Patricia Mitchell.

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| **5** | **Ethics ref:** | **2024 FULL 19922** |
|  | Title: | Phase 3 Study of the Safety and Immunogenicity of COVID-19 and Influenza Combination Vaccine and a Standalone Influenza Vaccine in Participants 60 Years or Older |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: | PPD, part of ThermoFisher Scientific |
|  | Clock Start Date: | 16 May 2024 |

Dr Dean Quinn, Ms Amy Tong and Ms Katie Kennett were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee note that the insurance is set to end before the study does, please ensure that a new one is uploaded prior to this occurring.

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 what Future Unspecified Research (FUR) was actually intended to be undertaken in this study given the data that would be collected is very specific to vaccines. The Committee noted that this is just optional future use not unspecified.
2. The Committee requested clarification as to why there were references to pregnancy when participants are over 60 years old. Please remove this.
3. The Committee requested clarification on how much money is likely to provided in order to be assured that this could not be seen as inducement to participate.
4. The Committee noted that in the application the study team noted that the trial may end for “administrative reasons”. Please clarify what these may be.
5. The Committee suggested that the FUR be developed instead into a separate PIS given this is not unspecified research that does not involve genetics. Amending the one used for the Phase 2

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

1. Please amend the sentence, “will ask questions about you, including your age, date of birth, and sex” to read ‘gender’ instead of ‘sex’.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Sandy Gill and Mrs Patricia Mitchell.

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| **6** | **Ethics ref:** | **2024 FULL 20405** |
|  | Title: | Safety and Effectiveness of the Omnipod 5 SmartAdjust 2.0 System in Individuals with Type 1 and Type 2 Diabetes |
|  | Principal Investigator: | Dr Martin de Bock |
|  | Sponsor: | Insulet Corporation |
|  | Clock Start Date: | 16 May 2024 |

Dr Martin de Bock, Dr Tom Wilkinson and Mrs Sue Hurd 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 the exclusion of pregnant people given they can have diabetes and would be treated for it as anyone else needs to be. The researcher noted that this is due to this being a first in human and that in this field there are specific groups set up to be able to intake pregnant people.
2. The Committee clarified that there would be no ability of the research team to provide compassionate access to devices.
3. The Committee clarified that the peer review was responded to where possible.
4. The Committee clarified that the adhesive did not require a glue-remover.
5. The Committee noted that for future applications in the cultural section please acknowledge that whakamā and the taking of blood are both considerations.

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 how the participant records would be accessed to recruit. The researcher noted that the participants are already in the clinic and that the potential participants are approached and requested to be forwarded to the study team for approach.
2. The Committee requested that the insurance certificate ends in September, please provide an updated one.
3. The Committee suggested being able to provide child-specific koha such as warehouse vouchers or prezzy cards.
4. The Committee queried how the privacy of children and adolescents would be maintained during consenting for pregnancy tests. The Committee requested that the process around this be protocolised.
5. The Committee requested the Investigators Brochure.

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

Main PIS/CF

1. Please include an image of the device being worn.
2. Please amend wording from “volunteer” to “participant”
3. Please explain the meaning of “blinded”.
4. Please clarify why there are two of “Period 1” rather than “Period 1” and “Period 2”. Consider amending this so that it is clearer by use of headings.
5. Please explain how “some visits may occur on the same day”.
6. Please specify the amount of blood in millilitres rather than in teaspoons.
7. Please clarify the process for people who may not have a general practitioner (GP).
8. Please clarify the value of the voucher mentioned on page 9. Will this be in addition to coverage of parking and travel expenses?
9. Please amend mention of the “Usual Doctor” to be clearer as to which doctor this is referring to.
10. Please clarify the eligibility of funding on page 13 and particularly the possibility to self-fund.
11. Please amend “Māori health support”, to “Māori cultural support”.
12. Please note that reference to the partner becoming pregnant is not mentioned in the PIS. If this is not necessary in the consent, then please remove mention of the partner becoming pregnant.
13. Please amend reference to “blousing” to instead be “bolusing” on page 2 of the consent form.
14. Please include mention of potential for future contact in the information sheets rather than including this for the first time in the consent form.

Parent/Caregiver PIS/CF:

1. Please ensure that the language around “you”, “your child” etc., is consistent and please be aware with the wording around the child and their assent.
2. Please clarify whether the parents will be responding to questionnaires. This would require more information to what will be collected about them separate to their children. In the consent form this could then be separated out into “I give consent for my child” and then further down “I consent to this information being collected about myself”.
3. Please note that the sentence around the responsibilities for undertaking responsibility to prevent pregnancy needs to be amended to say instead that “parents will undertake responsibility to share the risks and inform children about participating and becoming pregnant”.
4. Please include information to state that there will be an option for participants to sign on to an extension for 6 months.

Older Child PIS/CF:

1. Please include the cultural paragraph from the main PISCF in the older children PISCF.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Barry Taylor and Dr Cordelia Thomas.

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| **7** | **Ethics ref:** | **2024 FULL 20041** |
|  | Title: | Phase 1 trial of intraperitoneal lignocaine implant for pain relief in abdominal surgery |
|  | Principal Investigator: | Prof Andrew Hill |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 May 2024 |

Dr Andrew Hill and Ms Claudia Paterson were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the manufacturers have no input into the study and that all the money is publicly and university funded and no “sponsor” is involved.
2. The Committee clarified that the product is as long as it needs to be to be effective for the person it is being used in.
3. The Committee clarified that the design of the product is to ensure that a malfunction could not occur and at no point would a toxic dose be part of the provision of this product. The researcher noted that should anything occur and if there were issues the product could be immediately and easily removed.
4. The Committee clarified the amount of bloods taken at the periods it would be taken was not for adverse effects but in fact largely for pharmacokinetic purposes.
5. The Committee clarified that should there be an allergy to lignocaine this would be monitored closely but it is very unlikely.
6. The Committee clarified that there is potential for patenting but that currently there is no commercial benefit to the investigators. Eventually this may change but as of this point there is only commercial potential at this point.
7. The Committee clarified that the data would not be used in future studies but would actually be used as proof of concept to make a phase 1 or 2 study happen.

Summary of outstanding ethical issues

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

1. The Committee requested that Māori cultural contacts be provided for participants and noted that this is the researcher’s responsibility to provide.
2. The Committee requested that Māori consultation occur on the site level prior to the study being commenced.

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

1. Please include a photograph to show the size and scale of the device to contextualise this for people.
2. Please refrain from using italics.
3. Please note that General Practitioner notification should be mandatory for this type of study. Please remove this option from the consent form.
4. Please consider making the risk section clearer through use of some spacing and better paragraphing.
5. Please review for plain and lay language.
6. Please reword the data use section to note that this will not be used for future research but will be used to prove that research should happen.
7. Please be clear around the side effects of lignocaine rather than referring to the Medsafe guidelines.
8. Please ensure that the language is consistent and refers to the participants with “you” and “yours”.
9. Please remove the inclusion of the pregnancy information in the consent form or at least amend the wording around why the participant’s partner may be at risk if they become pregnant.
10. Please update the footers of the PISCF to be accurate.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).
4. Please supply evidence of Māori consultation to ensure the study is appropriate for a New Zealand context *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Patries Herst and Mrs Alice McCarthy.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 27 June 2024 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 4:00pm.