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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 16th May 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12:30pm-1:00pm | 2023 FULL 15417 | FASD system research - phase 2 | Dr Elizabeth Smith | Ms Sandy Gill and Mr Derek Chang |
| 1:00pm-1:30pm  | 2023 FULL 17811 | CaPTO\_2 Study | Dr Kamran Zargar-Shoshtari | Ms Catherine Garvey and Dr Sotera Catapang |
| 1:30pm-2:00pm | 2023 FULL 15207 | Equity in Employment for Disabled People | Ms Angela Desmarais | Mr Jonathan Darby and Mr Derek Chang |
| 2:00pm-2:30pm | 2023 FULL 13403 | A feasibility study of non-invasive auricular vagus nerve stimulation in people with rheumatoid arthritis | Mr Ankit Parimal Parikh | Ms Sandy Gill and Dr Kate Parker |
|  |  | **BREAK 30 MINUTES** |  |  |
| 3:00pm-3:30pm | 2023 FULL 15635 | Feasibility Study of Electronic Implementation of Patient-Reported Outcome Measures (PROMs) in Paediatrics Diabetes | A/Prof Martin de Bock | Mr Jonathan Darby and Dr Kate Parker |
| 3:30pm-4:00pm | 2023 FULL 15445 | Police Delivery and Disability | Dr Brigit Mirgin-Veitch | Mr Jonathan Darby and Dr Sotera Catapang |
| 4:00pm-4:30pm | 2023 FULL 16773 | Moderate to Severe Hidradenitis Suppurativa: Evaluation of Upadacitinib in Adult and Adolescent Subjects | Dr Marius Rademaker | Ms Catherine Garvey and Dr Andrea Forde |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mr Derek Chang  | Non-lay (Intervention studies)  | 08/07/2022 | 08/07/2025 | Present |
| Dr Kate Parker  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present  |
| Dr Andrea Forde | Non-lay (Intervention studies)  | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey  | Lay (the Law) (Chair) | 19/03/2019  | 19/03/2022  | Present |
| Dr Sotera Catapang  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present  |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Apologies |
| Ms Sandy Gill | Lay (Consumer/Community perspectives)  | 22/05/2020 | 22/05/2023 | Present |

## Welcome

The Chair opened the meeting at 12pm and welcomed Committee members, noting that apologies had been received from Ms Jade Scott.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Sandy Gill confirmed their eligibility and were co-opted by the Chair as a member 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 18th April 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 15417** |
|   | Title:  | Research to inform the FASD Action Plan - Phase 2: Research on the whole-of-system response to young people aged 11-18 years with diagnosed and suspected Fetal Alcohol Spectrum Disorder (FASD) in Aotearoa New Zealand |
|   | Principal Investigator:  | Elizabeth Smith |
|   | Sponsor:  | Te Whatu Ora |
|   | Clock Start Date:  | 4 May 2023 |

Carmen Lau and Dr Elizabeth Smith 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 how and why the group who are suspected to have a FASD diagnosis would be excluded.
2. The Researchers clarified that they will actively assess participants’ ability to consent continuously throughout the study.
3. The Committee queried the response to the question on stigmatisation in the HDEC application form. The Committee queried how the Researchers would avoid stigmatisation given the sensitivity of data and given the potential for a high level of Māori participation. The Researcher noted that there would be no reporting on the ethnicity data collected, which could avoid some stigmatising effect.
4. The Committee queried how the recruitment would be conducted. The Researcher noted that an email would be sent through FASD networks and a group within Te Whatu Ora would interact with families already engaged in similar work and then give them the option to opt-in.
5. The Committee noted that some participants in this and other FASD research may experience whakamā and that this should be noted in future work undertaken by the research team.
6. The Committee queried if there was any response to the peer review query that 5 interviews per site is low. The researchers acknowledged the concern and resolved to increase the number of whānau interviews. Participant numbers would still be noted as a limitation in the report.
7. The Committee clarified the process for follow up should a participant disclose information that gives rise to a risk of harm.

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 it was appropriate for 16-18-year-olds with FASD to assent.
2. The Committee requested that the assent forms be revised (specifically the inclusion of 16–18-year-olds) and that the consenting process in the protocol be documented to represent the actual process for assessing capacity for consent. The assent forms should be separated into ‘younger’ and ‘older’ assent forms and the consent form could be for anyone deemed competent.
3. The Committee requested that the protocol be amended to note that the stages are not date correctly due to delays in HDEC review.

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

1. Please note the possible risks of the study.
2. Please clarify if there will be any future use of the data collected as part of this study.
3. Please include footers and headers with versions and dates.
4. Please provide a detailed safety plan for responding to any risk to or by the participants that may be disclosed during interviews.
5. Please provide an ACC statement as per the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).

**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 Mr Derek Chang.

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| **2**   | **Ethics ref:**   | **2023 FULL 12811** |
|   | Title:  | Carcinoma Prostate Treatment Outcomes Part 2: Quality of Life |
|   | Principal Investigator:  | Associate Prof Kamran Zargar Shoshtari |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 4 May 2023 |

Dr Ramya Nagarajan 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 the first part of the study, “CaPTO” was a review of existing data and was approved by Southern HDEC.
2. The Committee clarified that the questionnaire produced by the Researchers for use in the study has not been validated and was intended to be further researched using data from this study as a starting point. This was a stated goal of the protocol but may not be achievable if the tool is not validated.
3. The researcher confirmed that they will not offer electronic versions of the invitation, participant information sheet (PIS) and quality-of-life (QoL) data collection.

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 understood the application to be seeking a waiver of consent to obtain limited data for the purposes of the researcher identifying eligible participants from the CaPTO-1 study and approaching them for qualitative data collection in this study, CaPTO-2. The Committee was concerned that responses from the researcher suggested ongoing data collection to the present time in reliance on the approval by Southern HDEC of CaPTO-1 for retrospective data collection and review, based on the Committee’s understanding that the approval related to data collected between 2008-2018.
2. The Committee requested that the Researcher provide further details in the letter inviting participants to take part, namely the reason for contact, data already collected under ethics approval and the scope of the study.
3. The Committee requested that additional information be provided to participants in order for them to be able to communicate with the research team, namely contact phone and email addresses for the Researchers and that these methods will not be at cost to the participants.
4. The Committee requested amendments to the protocol to clearly outline the process of recruitment, follow up contact with participants and the means by which a participant might opt out (including declining to respond).
5. The Committee noted that the non-validated quality-of-life (QoL) questionnaire should not be used. The Researcher noted that the other two questionnaires are validated and so there would be some data generated.
6. The Committee queried the timeframe for the collection of data from the required number of participants, by the Researcher alone, and whether this is achievable in the stated timeframe.
7. The Committee noted that the submission states that this study uses Kaupapa methodology, which it does not. Please amend this in the resubmission.
8. The Committee requested clarification in application section C18. Please elaborate in your resubmission in what way this may be difficult for people with disabilities.
9. The Committee requested a plan for management of disclosure of depression/anxiety through the questionnaires, and confirmation of when the responses would be received and reviewed by the researcher. The Protocol should include a specific, prompt pathway and timeframes provided for follow-up of such a disclosure. *(National Ethical Standards for Health and Disability Research and Quality Improvement, Table 8.2).*
10. The Committee queried if the statement in the PIS of “Māori men with prostate cancer are more likely to have a severe form of the disease, so we want to study why this happens…” is relevant given that does not appear to be an explicit objective of this study.
11. The Committee queried why the Researcher did not intend to collect disability data.
12. The Committee requested provision of the data sharing agreements with all registries utilised in the study for review. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.14 and 12.15).*
13. The Committee requested the following changes to the Invitation Letter *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.7-11.9)*:
	1. Please add a timeframe within which the researcher will attempt to make contact should the participant not respond.
	2. Please add that the participant’s details will be deleted if they do not respond or decline to participate.
	3. Please provide a phone number as well as an email address for participants to contact the researchers.
	4. Please ensure that this contact number will not be at a cost to the participant.
	5. Please refer to the ethical approval relating to the collection of data for the purpose of identifying and contacting eligible participants not only to the data collection in CaPTO part 1. Subject to confirmation of the scope of the previous ethics approval the researcher may require a waiver to collect and use this information.
	6. Please check that envelopes are clearly marked as private and confidential for the addressee only.

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

1. Please include a separate section as to what data has been collected for the purposes of CaPTO-2, ethics approval and how the person may decline to participate and withdraw their data and that the data will be deleted upon receiving the notice to decline.
2. Please amend the wording around the selection to participate to state that people have been “invited”, rather than “choose” or “picked”.
3. Please amend or delete reference to the prospective “you’ll get an information pack if you are one of the men in the sample” as the pack will be sent along with this information sheet.
4. Please amend the second bullet point on page 5 referencing the notification of a participant’s usual doctor “if a study test gives an unexpected result…” The wording should reflect the plan for follow up of responses in the questionnaires, and participants should be provided with details of how to obtain support should the QoL questionnaires/study participation give rise to concerns.
5. Please add a timeframe within which participants may withdraw their data gathered in CaPTO-2.
6. Please amend the reference to approving HDEC from Northern B to Northern A.

**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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| **3**   | **Ethics ref:**   | **2023 FULL 15207** |
|   | Title:  | Equity in Employment: the (un)employment experiences of disabled people in Aotearoa New Zealand |
|   | Principal Investigator:  | Ms Angela Desmarais |
|   | Sponsor:  | Disabled Persons Assembly NZ |
|   | Clock Start Date:  | 4 May 2023 |

Ms Angela Desmarais 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 interviews and the focus groups would be on an expression of interest basis, and participants could participate in one or both. The primary focus group outreach will be to rural groups. This will also be conducted with several co-facilitators in Māori and Pasifika groups.
2. The Committee clarified the number of people that would likely be included in each interview/focus groups.
3. The Committee clarified that there was an error in the submission concerning a focus on Pasifika (C8).
4. The Committee queried whether a pre-screening process may be required because of the collection of demographic and disability data once the interview has commenced. The Researcher noted the possibility of including a means of screening potential interview participants in the survey and will consider this further.

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 being put into a draw for prizes as part of participating would be permissible and not inducing to participants. Please include this in the participant information sheet (PIS).
2. The Committee requested a plan be provided to detail how confidentiality will be managed and how focus group participants will be advised of and consent to confidentiality provisions.
3. The Committee suggested that separate information sheets be provided for the focus groups.
4. The Committee queried the strict age criteria. The Committee clarified for the Researcher that 16-year-olds can legally consent for themselves. Please adjust documentation accordingly.
5. The Committee suggested a thorough proof reading of the call for participants document.

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

1. Please clarify or remove the sentence “We also want to know what makes it hard, or easy, to employ disabled people” this needs to be tailored to the requisite group being asked this question.
2. Please include a “prefer not to answer” option for any of the questions relating to income.
3. Please clarify storage of data periods, how the data will be handled and who will have access to this data.
4. Please ensure that participants are aware of their right to decline and withdraw from the study, and the timeframe to withdraw.
5. Please ensure that participants are aware that audio recordings are part of the data that will be collected.
6. Please include any potential risks including privacy breach and possible distress.

**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 Jonathan Darby and Mr Derek Chang.

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| **4**   | **Ethics ref:**   | **2023 FULL 13403** |
|   | Title:  | A feasibility study of non-invasive auricular vagus nerve stimulation in people with rheumatoid arthritis. |
|   | Principal Investigator:  | Mr Ankhit Parikh |
|   | Sponsor:  | Exsurgo Ltd |
|   | Clock Start Date:  | 4 May 2023 |

Mr Ankhit Parikh and Gwyn Lewis 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.

Dr Andrea Forde declared a potential conflict of interest. The Committee determined there was no conflict and Dr Forde remained for the discussion of the application.

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 if the device had been built and tested. The Researcher noted that the device to be used is a commercial device that is currently in use, but that the measuring sensors are developed by the research team and being tested currently.
2. The Committee clarified the exclusion of non-English speakers.
3. The Committee clarified that the Researchers would attempt to recruit Māori participants to fulfil at least half of the target recruitment.
4. The Committee clarified that the sponsor would not be receiving any identifiable data from the study but they would have access to results.
5. The Committee clarified who will provide insurance.
6. The Committee clarified that the blood samples would be taken to measure inflammatory biomarkers and to measure any reduction of inflammatory biomarkers.
7. The Committee clarified that Doctor Ng would not be conducting the consent process on their own patients.
8. The Committee queried how people would be recruited to the study. The Researcher described that a rheumatologist would forward potential participants to the research nurse to provide information to the participants before being consented.
9. The Committee noted that the peer review was done by a researcher at the Royal College of Chiropractors. The Researcher noted that the reviewer was doing research in the field and that the reviewer was familiar to Auckland University of Technology and had been chosen on these grounds.
10. The Committee queried the embargo on the thesis that will concern this study. The Researcher noted that this will be private due to the potential disadvantage that this could pose for Exsurgo in development of the Investigational Product.

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 all information concerning the devices to be tested be included into the protocol. The Committee noted that the protocol currently does not describe the sensors, the commercial device that will be used and the way in which the test will be conducted and that this needs to be clear. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
2. The Committee noted that the protocol must include that these sensors have been tested in humans prior to this study and any relevant findings. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
3. The Committee requested clarification in the protocol as to the way in which non-use or non-compliance would be managed. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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

1. Please clarify what sensor will be used once this is determined from the pilot study.
2. Please ensure that diagrams are labelled.
3. Please clarify the modification of medication and how this may be managed should a participant experience a significant flare.
4. Please specify how participants may withdraw especially in cases where the participant may be experiencing pain while using the study device at home.
5. Please include information as to why the blood sample will be taken, where it will be stored, for how long and how it will be destroyed.
6. Please state that karakia will not be available for blood samples on destruction.
7. Please remove mention of benefit as this is a feasibility study.
8. Please include mention of the tablet and app and whether this will require internet access, and if this will be provided for participants should this be necessary.
9. Please provide a safety plan addressing when the questionnaires will be seen by the research team and what steps will be taken to follow up any concerns identified in questionnaire responses.
10. Please inform participants if their data or tissue will be sent overseas.
11. Please amend the ACC statement, using the wording for commercial studies in [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc), but noting that the Medicines NZ guidelines are not applicable to device studies.
12. Please specify that the commercial device that may be available for purchase after the study will not include the sensor, as the sensor is the device under study.
13. Please be clear around the procedure in place if participants forget to use their device and how this will be managed, noting that device use is remotely monitored by the study team.
14. Please clarify what is meant by “severe health” and “severe mental health” conditions.
15. Please remove mention of “legal representative” as this is not relevant.

**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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| **5**   | **Ethics ref:**   | **2023 FULL 15635** |
|   | Title:  | Feasibility Study of Electronic Implementation of Patient-Reported Outcome Measures (PROMs) in Routine Paediatric Diabetes Care |
|   | Principal Investigator:  | Associate Professor Martin de Bock |
|   | Sponsor:  | The Clinician Ltd |
|   | Clock Start Date:  | 4 May 2023 |

Associate Professor Martin de Bock 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 all patients who are seen at the site are eligible for inclusion in the study, which will collect standard of care PROMs data. The research element is the use of third-party software through which the PROMs would be collected.
2. The Committee clarified that the Sponsor would not be receiving any commercial benefit from the study. The Sponsor would not be receiving any identifiable data. The Researcher noted that anonymised responses would be stored on the Sponsor’s servers and they theoretically could access scores to questions.
3. The Committee clarified that the participant would be sent either an email or a text message that would prompt them to complete the PROMs.
4. The Committee clarified that the data would be sent overseas.
5. The Committee noted that the prompt would be age-appropriate and would be sent to parents or caregivers where the relevant PROMs are to be completed on behalf of a child.
6. The Committee noted that 12–15-year-olds should be able to consent but acknowledged the researcher’s explanation that given that the PROMs are to be completed by parents/guardians, this would not be practicable.
7. The Committee clarified how the assessment of response would be reviewed.
8. The Committee clarified that there may be some potential for registration of the electronic tool in New Zealand when there is new legislation.
9. The Committee queried how some questions asked of child participants about their parents/caregivers would be managed. The Researcher noted that the question was an important and validated one in use as standard of care.

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 insurance certificate is expired and that this will need to be updated and provided for review. This certificate should also name the clinical trial directly and not be a general cover.
2. The Committee requested that the assent forms be separated into a younger child and older child grouping rather than just one form for all ages.
3. The Committee requested that the Under 11 assent information forms be clearer in their explanation of the study and its purpose.
4. The Committee requested that in places where the New Zealand Privacy Act 1993 was cited that this be replaced by the 2020 Act.
5. The Committee noted that the Ethics 0800 number is no longer operating, and that this should be amended with the updated Ministry of Health call centre for general enquiries if the participant has a complaint or concern.

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

15-17year-old PIS/CF:

1. Please revise the age range for this PIS.
2. Please include the Māori cultural support number.

Parent PIS/CF:

1. Please amend the document to better clarify what the parents will be doing in participation for themselves as well as what they will be undertaking on behalf of their child.
2. Please include that data will be sent overseas in the consent form.
3. Please ensure that the risks include distress from questions that may be asked of them.
4. Please include that data will also be sent to the sponsor.
5. Please include that an alert will be sent immediately to the researcher should risk be identified by a response in the app. This statement should also include a plan for how this will be forwarded to the appropriate practitioners for managing any potential distress or mental health issue.

**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 Kate Parker and Mr Jonathan Darby.

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| **6**   | **Ethics ref:**   | **2023 FULL 15445** |
|   | Title:  | Police Delivery and Disability |
|   | Principal Investigator:  | Dr Brigit Mirfin-Veitch |
|   | Sponsor:  | Understanding Police Delivery Research Programme |
|   | Clock Start Date:  | 4 May 2023 |

Dr Brigit Mirgin-Veitch, Dr Robbie Francis Watene, Dr Kelly Tikao, Kate Diesfled, Lydie Schmidt, Wallace Noble, and Eden Tuisula Cruice 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 queried how bias may be assessed and managed. The Researcher reassured the Committee that this had been thoroughly thought through and planned for as they wished to collect data from as many sources and forms of disability as possible.
2. The Committee clarified that whānau responses would not be presented as the disabled person’s experience.
3. The Committee clarified that there would be no matching of experiences shared to the police participants in a later stage.

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 for 2 researchers to attend meetings that would take place in a bedroom or other sensitive spaces.
2. The Committee queried the process for responding when Researchers may be in a situation that may be dangerous and the appropriate follow up period for an alert. The Researcher agreed to amend the time for response to 30 minutes.
3. The Committee requested detail in the participant information sheet (PIS) and adverts for the process of recruitment of whānau.
4. The Committee queried how researchers would ensure that those with low-literacy abilities would be included in the research. The researcher clarified that there would be a number of tools developed in a variety of accessible formats.
5. The Committee requested a separate PIS for whānau/family members.

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

1. Please proofread for spelling mistakes.
2. Please include a paragraph at the beginning of the PIS stating that a participant may withdraw at any point and that all activity will be ceased immediately upon this withdrawal.
3. Please include a statement informing participants that their written story would be provided to them before formal inclusion in the report and that up till that point they may access and correct their written story.
4. Please include a number for the Māori cultural support contact.
5. Please clarify how you will respond to participants who experience distress or give information which requires follow up for their wellbeing.

**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 Jonathan Darby and Dr Sotera Catapang.

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| **7**  | **Ethics ref:**   | **2023 FULL 16773** |
|   | Title:  | A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study to Evaluate Efficacy and Safety of Upadacitinib in Adult andAdolescent Subjects with Moderate to Severe Hidradenitis Suppurativa Who Have Failed Anti-TNF Therapy |
|   | Principal Investigator:  | Dr Marius Rademaker |
|   | Sponsor:  | AbbVie Ltd |
|   | Clock Start Date:  | 4 May 2023 |

Dr Marius Rademaker and Neerja Singh 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 standard of care was not overly effective, and this was the primary consideration for the use of placebo in the study. The researcher noted that participants will have been afflicted by this condition for a long period of time with only pain relief in the form of treatment.
2. The Committee queried the number of questionnaires being utilised in the study. The researcher noted that they were all validated but that there could be no consolidation of these into a shorter format due to the international centres wanting to collect different end points through these different questionnaires.
3. The Committee noted that any significant adverse events would be reported to CARM as well as the internal adverse event board at AbbVie.
4. The Committee noted that there was no general exclusion for vaccinations, only those that are live.

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 lack of independent peer review provided to this Committee. The Committee requested that in the absence of independent peer review, a copy of the internal peer review or information about the name and number of ethics Committees that have provided ethical review to international sites be provided to the Committee.
2. The Committee requested that the wording relating to pregnant people “may be advised” in the eventuality of a positive pregnancy test be amended to say, “will be advised”.
3. The Committee noted that young people who are deemed competent to do so should be offered the opportunity to consent for themselves and that anyone over the age of 16 must be permitted to consent for themselves.
4. The Committee requested a review of all participant-facing documentation that uses Americanised terms and that these be replaced by a New Zealand analogue where possible, or otherwise removed.
5. The Committee queried what the images taken would be used for and that this be included in the Data Management Plan and Protocol. The Committee noted that any images that are taken must be deidentified before sending overseas.
6. The Committee noted that no results of pregnancy tests should be mandatorily discussed with parents in the case of adolescents. Communication should be undertaken with consent.
7. The Committee requested that it be made clear that adolescents are permitted a sex-matched practitioner and a support person during Tanner staging.
8. The Committee requested that the clinical trial registration be amended to a registry that is World Health Organisation recognised.
9. The Committee requested that all mention of DHBs be amended to Te Whatu Ora localities.
10. The Committee requested a safety plan be provided for the responses that may alert the research team to mental distress indicated in a questionnaire by participants. This alert will be monitored by the sponsor’s system. The researchers will be alerted within 2 hours. This detail should be included in the participant information sheets.

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

1. Please clarify what the images may be used for.
2. Please remove mention of “public record”, where referencing medical history that may be accessed for study purposes.
3. Please amend all headings to be white on blue text to ensure ease of readability.
4. Please make the notification of the General Practitioner (GP) of participation in the trial mandatory.

**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 Catherine Garvey and Dr Andrea Forde.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 20th June 2023 |
| **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 4:30pm.