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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 26th April 2023 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12:00pm- 12:30pm | 2023 FULL 15220 | A Phase 3 Placebo-controlled Study of Milvexian after an Acute Ischemic Stroke or High-Risk Transient Ischemic Attack | Dr. Karim Mahawish | Ms Helen Walker & Mr Barry Taylor |
| 12:30pm- 12:45pm | 2023 AM 5744 | Outpatient balloon induction: an RCT | Dr Michelle Wise | Ms Helen Walker & Ms Patricia Mitchell |
| 12:45pm- 1:05pm | 2023 NC 8194 | A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Two-Arm, Phase 2 Study of ME-401 in Subjects with Follicular Lymphoma After Failure of Two or More Prior Systemic Therapies | Dr Eileen Merriman | Ms Helen Walker & Mx Albany Lucas |
| 1:05pm-1:35pm | 2023 EXP 12204 | Chiropractic adjustment and autonomic nervous system function | Ms Nitika Kumari | Dr Cordelia Thomas & Ms Patricia Mitchell |
| 1:35pm- 2:00pm |  | Break 25 minutes |  |  |
| 2:00pm-2:30pm | 2023 FULL 15380 | Duration of cardiac antimicrobial prophylaxis outcomes study | Dr Kelly Byrne | Ms Sandy Gill & Mr Barry Taylor |
| 2:30pm-3:00pm | 2023 FULL 15301 | A Phase 2 Study Evaluating INCB099280 in Participants With Select Solid Tumors Who Are Immune Checkpoint Inhibitor Naive | Ms Penelope Eadie | Ms Jessie Lenagh-Glue & Mx Albany Lucas |
| 3:00pm-3:30pm | 2023 FULL 15579 | IMVT-1402-1001: A Study to Evaluate a monoclonal Antibody, IMVT-1402, for the Potential Treatment of Autoimmune Disorders, in Healthy Participants | Dr Rohit Katial | Ms Sandy Gill & Ms Patricia Mitchell |
| 3:30pm-4:00pm | 2023 FULL 13154 | ITCC-101/APAL2020D (A sub trial of the PedAL relapsed acute leukemia screening protocol) | Dr Andrew Cameron Wood | Dr Cordelia Thomas & Mr Barry Taylor |
| 4:00pm-4:30pm |  | Break 30 minutes |  |  |
| 4:30pm-5:00pm | 2023 EXP 15148 | Tū Whakaruruhau: The New Zealand Methamphetamine Treatment Evaluation Study | Associate Professor David Newcombe | Dr Cordelia Thomas & Mx Albany Lucas |
| 5:00pm-5:30pm | 2023 FULL 15364 | QASC AUSTRALASIA | Dr Julia Slark | Ms Jessie Lenagh-Glue & Mr Barry Taylor |
| 5:30pm-6:00pm | 2023 FULL 15199 | COG ACNS1821: A Study of the Drug Selinexor with Radiation Therapy in Patients with Newly-Diagnosed DIPG and HGG | Dr Andrew Dodgshun | Ms Sandy Gill & Ms Patricia Mitchell |

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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) | 22/03/2020 | 22/03/2024 | 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 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, that apologies had been received by Dr Patries Herst.

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 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 28th March 2023 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2023 FULL 15220** |
|  | Title: | A Phase 3 Placebo-controlled Study of Milvexian after an Acute Ischemic Stroke or High-Risk Transient Ischemic Attack |
|  | Principal Investigator: | Dr. Karim Mahawish |
|  | Sponsor: | Janssen Research & Development, LLC |
|  | Clock Start Date: | 31st March 2023 |

Dr Karim Mahawish, Ms Sharon Cheung and Ms Pallavi Wyawahare 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 approach was made to participants deemed to be competent and not impaired enough to be considered unable to give consent.

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 some strokes may rob the participants of the ability to write with their dominant hand and that provision should be made for either authorising someone to sign on their behalf or signing with the non-dominant hand.
2. The Committee queried why there was so much variability in the period of participation in study. The Committee also queried how the participants may be selected to be participating for such potentially different time periods. This should be clarified in the PISCF.

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

1. Please include a statement noting that should the participant not be able to write that this could be managed through the acknowledgement of the circumstances under which this signature has been obtained.
2. Please remove options from the template as several points have been retained where they are not relevant to the study.
3. Please provide a safety plan for the EQ5D5L questionnaire. Please detail how quickly the answers to these questionnaires will be viewed and responded to and what potential follow up may occur and how timely this will be.
4. Please amend home visit study statements to note that these will only be undertaken with the participant’s consent.
5. Please remove or amend reference to home visits as occurring in accordance with local or country home healthcare laws as this is not relevant to New Zealand.
6. Please remove the “etc” from the contraception statement relating to continuing the study drug.
7. Please include the term “general practitioner” (GP) to mention of doctors or healthcare providers where this is what is being referred to and is more commonly used terminology in New Zealand. Please ensure consistency on the phrasing used.
8. Please amend the use of the phrase “left out” where referencing the drug potentially causing severe rashes.

**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 Ms Helen Walker.

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| **2** | **Ethics ref:** | **2023 AM 5744** |
|  | Title: | Outpatient balloon induction: an RCT |
|  | Principal Investigator: | Dr Michelle Wise |
|  | Sponsor: |  |
|  | Clock Start Date: | 15th March 2023 |

Dr Michelle Wise and a research team member 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 what activity was planned for this data. The Researcher noted that the planned activity was to identify who would have been suitable for participation but did not actually end up on the study either because they declined or because they were not approached and then looking into the characteristics of their data to observe the comparability with the study population.
2. The Committee noted that there was no feasible provision for a waiver of consent in this case. *National Ethical Standards* para *7.2-7.21*

Summary of outstanding ethical issues

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

1. The Committee noted that there were potentially 2 cohorts of people that would be approached for this activity. The Committee noted that accessing the notes of those who have not given consent for participation. The Committee- in particular- took issue with the fact that one group of people whose data would be reviewed had already declined participation. These people should not be approached as they have already declined. *National Ethical Standards* para *7.2-7.21*
2. The Committee queried how people who were not approached but may have been eligible would be incorporated into the study. The use of patient notes without their consent is not acceptable. This is an ethical issue and a legal issue. Should this activity go ahead it would need to be consented as per the Code of Rights, particularly given that the contact details of these people have already been accessed. *National Ethical Standards* para *7.2-7.21*
3. The Committee suggested creating a new application for this activity because it is outside of the boundaries of the study being amended .

**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 NC 8194** |
|  | Title: | A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Two-Arm, Phase 2 Study of ME-401 in Subjects with Follicular Lymphoma After Failure of Two or More Prior Systemic Therapies |
|  | Principal Investigator: | Dr Francisca Reed |
|  | Sponsor: | INC Research New Zealand Limited |
|  | Clock Start Date: | 14th April 2023 |

No one from the research team was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that there was no response from the sponsor to the request from the Committee for further information as to the cancellation of the trial conduct in New Zealand at the time of the meeting.
2. The Committee agreed unanimously to cancel the ethical approval of this application due to the conduct of the sponsor and were concerned at the lack of provision of further aid for participants. *National Ethical Standards* para *10.9, 10.15-10.15a & 11.37.*

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 escalation of the committee’s concerns would be required in conjunction with revoking the approval for this application given the removal of access to the study drug despite benefit.
2. The Committee noted that it is not acceptable for trials to be terminated for solely commercial reasons and that treatment for participants who have derived benefit from the study drug should be made available on compassionate grounds. *National Ethical Standards* para *10.15-10.15a & 11.37.*

**Decision**

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

The Committee noted that there would be ongoing action taken by Manatū Hauora and and by Te Whatu Ora to further investigate this matter and ensure that adequate action is taken to address this situation.

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| **4** | **Ethics ref:** | **2023 EXP 12204** |
|  | Title: | Chiropractic adjustment and autonomic nervous system function |
|  | Principal Investigator: | Ms Nitika Kumari |
|  | Sponsor: | New Zealand College of Chiropractic |
|  | Clock Start Date: | 23rd March 2023 |

Ms Nitika Kumari and Mr Imran Khan Niazi 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 there was a check inbuilt within the first consultation to ensure the screening was thorough.

Summary of outstanding ethical issues

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

1. The Committee noted that there was no answer to C4 that was adequate to describe how the study may be beneficial to Māori. For future reference, there needs to be inclusion of statistics on how this may affect Māori.
2. The Committee noted the timeline in the protocol requires revision as it is no longer accurate.
3. The Committee queried if people with fully controlled hypertension would still be excluded and why. The Committee also queried if pregnant people would also be excluded. These should be expanded upon and included in the PIS.

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

1. Please specify what screening questions will be asked
2. Please specify what is meant by “smokes”, if this is vaping and cigarette smoking this should be noted.
3. Please use Lay terminology as to what the study will entail.
4. Please review for spelling and grammar.
5. Please review for plain and clear English.
6. Please specify that the discomfort may be “physical’.
7. Please specify what reimbursement is for and how this will be accrued.
8. Please fully describe the acronym for New Zealand College of Chiropractic (NZCC) the first time it is used and then only use the acronym going forward.
9. Please specify that coded data may be sent overseas and for what reason and what it may be used for or describe clearly what otherwise may occur.
10. Please remove repeated sentences on withdrawal.
11. Please specify what video recording may occur in the study as has been mentioned in the withdrawal information on page 7.
12. Please specify what technology and what privacy guidelines are being referred to in the consent form. This needs to be explained in the PIS. There should be no new information introduced in the consent form.
13. Please specify what risk is being understood and if it is the risk of the chiropractic intervention.
14. The Committee noted that in the data section and the consent relating to this, there should be a note made that any data up to the point of withdrawal may be used.

**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 Mrs Patricia Mitchell and Dr Cordelia Thomas.

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| **5** | **Ethics ref:** | **2023 FULL 15380** |
|  | Title: | Duration of cardiac antimicrobial prophylaxis outcomes study |
|  | Principal Investigator: | Dr Kelly Byrne |
|  | Sponsor: | Monash University |
|  | Clock Start Date: | 13th April 2023 |

No one from the research team 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 how the bacterial resistance would be measured.

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

1. Please create and provide a safety plan for the use of quality-of-life (QoL) questionnaires asking questions on suicidality and depression. This should include when the responses will be recorded, reviewed and what follow up may be provided in a timely manner.
2. Please include a statement noting that the general practitioner (GP) will be notified of participation.
3. Please remove quotations around the phrase “standard of care” (SoC).
4. Please include an estimated number of participants in New Zealand.

**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 Barry Taylor.

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| **6** | **Ethics ref:** | **2023 FULL 15301** |
|  | Title: | A Phase 2 Study Evaluating INCB099280 in Participants With Select Solid Tumors Who Are Immune Checkpoint Inhibitor Naive |
|  | Principal Investigator: | Ms Penelope Eadie |
|  | Sponsor: | IQVIA |
|  | Clock Start Date: | 13th April 2023 |

Ms Sandra Hargrove and Ms Penelope Eadie 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 what the compensation may cover. The researcher noted that the compensation would be sufficient to ensure that there would be no extra expenses occurred as a direct result of participating.
2. The Committee clarified that tissue may be returned from overseas during the life of the trial.
3. The Committee noted that the study did not in fact use Kaupapa Māori methodology.
4. The Committee clarified that the researchers would be trusting applicants to take the pregnancy tests.
5. The Committee noted that there would be no future use of data or tissue for research, this would only be utilised in an anonymous form to develop an investigator’s brochure.

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 provision of a safety plan for the filling in of questionnaires that address mental health issues. The timeframes for review and possible referral should be included.
2. The Committee requested in all PISs that mention of ‘Māori health support’ be amended to ‘Māori cultural support’.
3. The Committee requested that all documents be proofread and amended to only refer to the section of the study or specific sub-study that they pertain to.
4. The Committee requested that the participants be given the option for the provision of their own genetic information as it will be collected as part of the study. The Committee also suggested including language to the effect of ensuring that participants are notified should their genetic tests provide further information in the future of significance to their health.
5. The Committee requested that all PISs be reviewed to clearly state that the study cannot be cancelled by the sponsor for purely commercial reasons.

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

1. Please revise to remove gendered language. Please refer to the HDEC templates for guidance.
2. Please remove all references to the “AIDS Virus” this is stigmatizing and not appropriate.
3. Please remove reference to reimbursement for time and effort.
4. Please amend reference to taking medication for the study with orange juice or yoghurt as this may impact the activity of the treatment.
5. Please include that the tissue may be returned to participants only during the life of the trial.
6. Please specify what the physical exam will entail and if there will be removal of clothing.
7. Please amend mention of the vaginal ring as this is not available in New Zealand.
8. Please amend the wording around the “first well-baby visit” to relate to Well Child (the New Zealand equivalent).
9. Please include an explanation in words of the side effects as well as the percentages.
10. Please ensure that the language concerning the follow up of participants who withdraw involves the obtaining for that person’s consent to do so.
11. Please clarify why both urine and blood pregnancy tests are being done.
12. Please review for typos.
13. Please amend the word “instructed” where referring to the participants filling out a response in the app. Consider replacing with “ask” or “requested”.
14. Please amend the unnecessary information as to the ways in which the person may become pregnant.
15. Please amend reference to ethnicity being private as per data privacy laws as this is not correct in New Zealand.
16. Please clarify that future use of research will only be used in an anonymous form.

**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 Mx Albany Lucas and Ms Jessie Lenagh-Glue.

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| **7** | **Ethics ref:** | **2023 FULL 15579** |
|  | Title: | IMVT-1402-1001: A Study to Evaluate a monoclonal Antibody, IMVT-1402, for the Potential Treatment of Autoimmune Disorders, in Healthy Participants |
|  | Principal Investigator: | Dr Rohit Katial |
|  | Sponsor: | PPD |
|  | Clock Start Date: | 6th April 2023 |

Ms Courtney Rowse, Miss Holly Thirlwall and Dr Rohit Katial 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 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 is expiring in June and that this has been acknowledged by the sponsor and this will be renewed.
2. The Committee noted that the inclusion of wording to the effect of “advance global health” in the advertisement is not appropriate and should be amended to be less inducing.
3. The Committee requested that the Māori values not be so extensive as this appears overstated in its current form.
4. The Committee queried the exclusion of all pre-menopausal women and if there would be possibility for people on approved forms of contraception.

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

1. Please include that participants will be prompted around withdrawal of data and that their samples will not be used unless they consent.

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

1. Please explain whole genome sequencing.

**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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| **8** | **Ethics ref:** | **2023 FULL 13154** |
|  | Title: | ITCC-101/APAL2020D (A sub trial of the PedAL relapsed acute leukemia screening protocol) |
|  | Principal Investigator: | Dr Andrew Cameron Wood |
|  | Sponsor: | Leukemia & Lymphoma Society PedAL Initiative, LLC |
|  | Clock Start Date: | 13th April 2023 |

Mr Saswata Ray, Dr Andrew Cameron Wood and Ms Sarah Hunter 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 people would be eligible for this study and that there would be about 2-4 people.
2. The Committee clarified that were there reconsent at 16 that they will be reconsented with the full consent form.
3. The Committee clarified that there was lots of discussion with the youngest children (below 7) without an assent form as this has proven to be far less helpful than having play therapists etc. especially where there is history of cancer treatment as is the case in this study and the study activities will be largely standard of care.
4. The Committee clarified the safety plan for a positive pregnancy test.
5. The Committee clarified that the questionnaires were all done in the clinic and would be reviewed immediately.

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 there be a ‘younger children’ and ‘older children’ PIS and that the younger children forms be simplified a great deal so that younger people may understand it fully. The language currently used is too complex.
2. The Committee raised that the inclusion of pregnancy testing in all participants who menstruate could be troubling. This should be more specifically detailed as to being a thing generally as standard of care in the PIS.
3. The Committee queried the language used in the promise questionnaires and how this would be different depending on who was responding to them. Please clarify who will

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

1. Please include that likely only 2-4 children will be in New Zealand.
2. Please amend the font used so that it is consistence throughout.
3. Please specify what data concerning the transplant will be collected.
4. Please review for typos concerning the local blood tests.
5. Please remove reference to the NuvaRing, this is not available in New Zealand.
6. Please amend the availability of results concerning the study to be provided to participants without having to request them.
7. Please include the word “Starship” to “the hospital will hold your data”.
8. When first mentioned, please note that “Study doctor” should be referenced as “Starship doctor”.
9. Please finish the sentence “I consent to my GP or other health professionals being” and amend the following sentence on the next page which beings with “abnormal”. There is likely some missing information that requires correcting.
10. Please note that mention of results directing treatment should be done first and foremost in the information sheet as no new information should be given in the consent form.
11. Please amend wording and simplify and clarify where “you and your child” may be confusing.
12. Please include images to help explain the study.

**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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| **9** | **Ethics ref:** | **2023 EXP 15148** |
|  | Title: | Tū Whakaruruhau: The New Zealand Methamphetamine Treatment Evaluation Study |
|  | Principal Investigator: | Dr David Newcombe |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 13th April 2023 |

Dr David Newcombe, Dr Rodrigo Ramalho, Ms Sophia de Fossard, Dr Janie Sheridan, Ms Pam Armstrong and others 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 the safety plan for the interviewers. The researchers noted that the emotional and physical needs had been planned out thoroughly and there was planning to debrief and ensure that professional boundaries were maintained and addressed how training would aid in this process.
2. The Committee and the researchers noted that there was a wealth of data in non-treatment groups but that this could not happen due to funding.
3. The Committee clarified that there were several quantitative questions that would address non-treatment participants. These were for the collection of quantitative data of participants who would not be undergoing treatment but would be able to provide invaluable data for comparison. Forms would be amended to show only relevant information dependent on treatment or non-treatment.

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 suggested interviewers attend meetings in pairs, however, due to constraints in staffing and the feelings of people who are sharing their stories there would be people attending in pairs if necessary, should there be potential for risk.
2. The Committee noted that after a long period, sending letters to people in the mail about the study may not be appropriate as this may not be practical as people move around a lot. The Committee suggested a website for the plain English summary. Letters pose some security risk in terms of the implications that receiving these summaries may be damaging. Consider some method of returning results other than mail.
3. The Committee queried the support that may be provided for non-treatment group participants who were taken to an emergency room. The Committee noted that the support person may not be available and that there might need to be someone else involved at this point.

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

1. Please amend wording around people who will be included in the study specifically that people not in treatment may still be using methamphetamines.
2. Please state how people will be selected for the qualitative part of the study. If it is just the first people who volunteer, then state this. Using words to the effect “Once 30 people have been selected, other people will not be selected.’ and positive phrasing to encourage and improve feelings of inclusion for Māori is recommended.
3. Please review for typos and grammar.
4. Please specify that not all participants selected may end up taking part in the study due to the number of people in the study.
5. Please state whether transcripts will be available for applicants to review their own transcripts.
6. Please amend the consent form and PIS to be consistent regarding sharing information of health issues to the GP.
7. Please state that the private quiet room will be within the treatment centre.
8. Please refer to general practitioner (GP) rather than “usual doctor” or add in brackets ‘GP’ after referring to this.
9. Please review the sentence on contacting or following up with the GP for grammar and spelling errors and soften the statement referring to mental health conditions.
10. Please ensure any reference to the trainee interviewer in the PIS is consistent in the consent form. If this should not be included, please remove.

**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 Mx Albany Lucas and Dr Cordelia Thomas.

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| **10** | **Ethics ref:** | **2023 FULL 15364** |
|  | Title: | QASC AUSTRALASIA |
|  | Principal Investigator: | Dr Julia Slark |
|  | Sponsor: | Australian Catholic University |
|  | Clock Start Date: | 6th April 2023 |

Dr Eileen Gilder 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 recognised that due to the high turnover of medical staff that there may be a need for the clinic champions to be able to be replaced or covered for. The researcher noted that there were some plans around staff training to ensure that the sites were adequately covered for this role.
2. The Committee noted that as the data is standard of care and no further intervention is being provided and that this is essentially audit activity there would be no consenting of patients.

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 clarified the inclusion of the cost-benefit sub-study in the New Zealand PISs is not relevant to New Zealand. Please clarify that data linking may be used from New Zealand even if this sub study is not active.

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

1. Please consider the inclusion of the champion’s name on the form as this may require further pressure to fill these roles where it may take some time in practice.
2. Please amend the consent form regarding withdrawal to not have a yes/no option as the use of data after withdrawal is already set out in the information sheet.

**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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| **11** | **Ethics ref:** | **2023 FULL 15199** |
|  | Title: | COG ACNS1821: A Study of the Drug Selinexor with Radiation Therapy in Patients with Newly-Diagnosed DIPG and HGG |
|  | Principal Investigator: | Dr Andrew Dodgshun |
|  | Sponsor: | Children’s Oncology Group |
|  | Clock Start Date: | 13th April 2023 |

No one from the research team 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 Committee requested the following changes to all Participant Information Sheet and Consent Form (PIS/CF):

1. Please note under "Organisations that may look at and/or copy your records" the National Cancer Institute (NCI) that the first time this acronym appears it should be written in full and then referred to from that point as NCI.
2. Please note that all consent forms require an option concerning the sending of samples and data overseas.
3. Please include the cultural statement as outlined in the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc) in the future unspecified research (FUR) PIS.

**Decision**

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

* 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).*

## General business

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

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| --- | --- |
| **Meeting date:** | 23rd May 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 6:10pm.