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| **Committee:** | Northern B Health and Disability Ethics Comittee |
| **Meeting date:** | 7th February 2023 |
| **Zoom details:** | 96507589841 |

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| **Time** | **Review Reference** | **Project Title**  | **Coordinating Investigator** | **Assigned Lead Reviewers** |
| 11.30am-12.00pm | 2023 FULL 15137 | BP44118: A Study to evaluate a new monoclonal antibody against hepatitis B virus in Healthy Participants and in Patients with Chronic Hepatitis B | Prof. Edward Gane | Ms Maakere Marr & Mrs Leesa Russell |
| 12.00pm-12.30pm | 2023 FULL 13751 | ESsCAPE - trimodulin for severe community-acquired pneumonia | Dr Colin McArthur | Mr Ewe Long & Ms Joan Petit |
| 12:30pm-1:00pm | 2023 EXP 13205 | Ronnie Gardiner Method, Music and Movement Therapy Clinical Trials | Dr Jaimie Wilkie | Ms Kate O'Connor & Mr Barry Taylor |
| 1:00pm-1:30pm | 2023 FULL 12852 | LOGGIC/FIREFLY-2: DAY101 vs. Standard of Care Chemotherapy in Paediatric Patients with Low-Grade Glioma Requiring First-Line Systemic Therapy | Dr Karen Tsui | Ms Kate O'Connor & Dr Amber Parry-Strong |
| 1:30pm-2:00pm |  | Break 30 minutes |  |  |
| 2:00pm-2:30pm | 2023 FULL 12544 | IMPEDE PKD trial | Professor Suetonia Palmer | Ms Kate O'Connor & Mrs Leesa Russell |
| 2.30pm- 3.00pm | 2023 EXP 15087 | Describing care pathways for patients with delirium discharged from hospital. | Dr Engelina Groenewald | Ms Maakere Marr & Ms Joan Pettit |
| 3.00pm-3.30pm | 2023 FULL 11419 | Evacuate RCT | Dr Martin Punter | Mr Ewe Leong Lim & Dr Amber Parry Strong |
| 3.30pm- 3.45pm |  | Break 15 minutes |  |  |
| 3.45pm- 4.15pm | 2023 FULL 15093 | Do injuries to the brain affect how people think in the longer term | Professor Alice Theadom | Mr Barry Taylor & Mr Ewe Leong Lim |
| 4.15pm- 4.45pm | 2023 FULL 13633 | RESTORE study - nutRitional rEsponSe TO chyme Reinfusion thErapy | Professor Rozanne Kruger | Ms Kate O'Connor & Mrs Leesa Russell |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Kate O’Connor  | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |
| Mrs Leesa Russell | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present  |
| 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 | Apologies |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Mr Ewe Leong Lim | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |

## Welcome

The Chair opened the meeting at 11:00am and welcomed Committee members, noting that apologies had been received from Ms Alice McCarthy

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 6th December 2022 were confirmed.

## New Applications

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| **1**   | **Ethics ref:**   | **2023 FULL 15137** |
|   | Title:  | BP44118: A Study to evaluate a new monoclonal antibody against hepatitis B virus in Healthy Participants and in Patients with Chronic Hepatitis B |
|   | Principal Investigator:  | Prof. Edward Gane |
|   | Sponsor:  | Hoffman-La Roche Ltd |
|   | Clock Start Date:  | 26January 2023 |

Professor Edward Gane, Courtney Rowse and Holly Thirwall 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 Māori staff would not be sought to advise on tikanga and that there would be dedicated Māori consultation independent to the staff on site as their participation would be dependent on them being on shift.
2. The Committee clarified that the independent consultant (Dr Helen Wihongi) would be the individual to consult for the application of the Māori values listed in the application.
3. The Committee clarified the inclusion of New Zealand Chinese participants in cohorts 1-5.
4. The Committee clarified the Anti-Drug Antibody (ADA) response to the monoclonal antibody under study would not prevent participants from receiving other medications for this condition as there is little to no possibility for cross-reaction.
5. The Committee queried as to why the NZCR standard cautions not to take part in sperm/egg donation during the study had been removed/omitted.
6. The Committee clarified that the participants would already be on standard of care 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 requested rewording in what way will NZCR consider whakapapa, whanaungatanga, manaakitanga, rangatiratanga, etc, if Māori staff aren't able to advise on tikanga. Please clarify how those cultural values will be addressed during the study and phrase that accordingly on the PIS/CF.
2. The Committee requested that the fibroscan results be provided to their general practitioner or their regular care team.

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

1. Please amend the typo “expect hay fever” that should say ‘except hay fever’.
2. Please re-include NZCR standard cautions not to take part in sperm/egg donation during study that seem to be removed/omitted.
3. Please include all risks as listed in the application in the PIS/CF.

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

1. Please amend for consistency as the body of this document states that storage will be for 25 years, whereas the consent form says 15 years.
2. Please note that the statement regarding withdrawal suggests that participants can withdraw tissue after participation, but the DTMP states it will be anonymised and not re-identifiable. Please amend for consistency.

**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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| **2**   | **Ethics ref:**   | **2023 FULL 13751** |
|   | Title:  | ESsCAPE - trimodulin for severe community-acquired pneumonia |
|   | Principal Investigator:  | Dr Colin McArthur |
|   | Sponsor:  | Biotest AG |
|   | Clock Start Date:  | 26January 2023 |

Dr Colin McArthur and Ms Yan Chen 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 how the placebo arm was better-off than if they were not to participate in the study. This largely would include more intensive follow up with subsequent potential for response with more health interventions later. There would also be additional testing for these participants that may influence further therapy that typically would not be provided in standard of care (SOC).
2. The Committee clarified that distress identified through use of the Nottingham Health Profile instrument would be addressed at the root of the issue rather than addressing the distress. This would be referred to another health provider
3. The Committee clarified that SOC procedures had not been included in the study information sheets or protocol.
4. The Committee clarified that the tissue use that was consented by relative, whānau and friend would only be that which was core to the study. Any other tissue, including for non-core PK studies, would be optional and only in the case where the participant became competent and could consent to this themselves.
5. The Committee clarified that the potential for karakia would be reliant on whānau views but that this would only be for SOC samples.
6. The Committee noted that the pregnant partner or pregnant participant information sheets would not be reviewed at this time and should be sent for approval as an amendment if it becomes necessary.

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 that the research team look to work with Dr Paul Young (a prominent researcher in this area) to better account for possibilities and scenarios around the participant and their relative, whānau and friends that could be added to the New Zealand addendum to the protocol. The more reflective of likely contexts and scenarios at the start avoids having to apply for approval by amendment later.
2. The Committee noted that the additional pharmacokinetic sampling that is optional would not be possible without consent from participants. Permission from a friend or relative would not be sufficient for these activities.
3. The Committee requested that the insurance cover be clarified from the perspective of New Zealand consent and legal requirements, especially in relation to the legal position surrounding proxy consent here.

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

1. Please remove yes/no boxes for general practitioner notification as this should be a mandatory part of participation.
2. Please include safety data as included in the protocol. Please include some numerical data around study procedures for reassurance.

**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 Ewe Leong Lim and Ms Joan Petit.

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| **3**   | **Ethics ref:**   | **2023 EXP 13205** |
|   | Title:  | Ronnie Gardiner Method, Music and Movement Therapy Clinical Trials |
|   | Principal Investigator:  | Dr Jaimie Wilkie |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 26January 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 noted that the university needs to provide assurance via a principal researcher who works for the university not on an honourary basis.
2. The Committee queried as to how this study planned to use kaupapa Māori methodology given no research staff members are Māori.
3. The Committee noted that Māori consultation cannot be done at a later stage and should be considered at the beginning of the research process to ensure that considerations for Māori are met from the start. *National Ethical Standards* para 3.1 & 3.3
4. The Committee noted that access to both arms of the trial to individuals is not equipoise.
5. The Committee requested detail as to the business model for the Ronnie Gardiner Method (RGM) in New Zealand, who trains practitioners, what connections the investigators have to this business and what materials and methods are used and if they have been validated in any way.
6. The Committee noted that there was no clear recruitment strategy. This needs to be outlined in the protocol. Please include inclusion criteria and how capacity will be ascertained by the research team. Each part of the study must have a clearly defined recruitment strategy and any advertisements must be provided before use.
7. The Committee queried how inclusion and exclusion criteria would be assessed and by whom and if use of the Montreal Cognitive Assessment (MoCA) is intended, how people who score lower than they anticipated will be supported.
8. The Committee noted that the Sponsor should be listed as the University of Auckland and not the funder (Sommerset). Localities should also be listed, and any consultation processes required as part of Locality Approval should be undertaken.
9. The Committee requested provision of any measures or tools listed in the protocol for review.
10. The Committee noted that the protocol is lacking in the information required of researchers as set out in the NEAC national ethics guidelines. *National Ethical Standards* para *9.7& 9.7a*
11. Please provide a participant information sheet for the rest-home repeated measure trial for the Committee to review.
12. The Committee queried if the statement in B1.1 of the submission, stating that there is direct benefit to participants, is scientifically proven. If so, please include this in the submission or correct as required.
13. The Committee noted there was no information provided on the incidence of MCI in older Pasifika peoples and why there is no targeting of this population given the statements around cultural significance in the submission. The Committee noted that if this is a cultural bias reflected by the residence of corporate aged care and retirement chains this should be adequately addressed in the submission.

The Committee requested the following changes to the Data Management Plan (DMP):

1. Please ensure that the statements regarding the stopping of the trial are consistent with those presented in the [HDEC DMP Template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) to avoid confusion.
2. Please use the [HDEC DMP Template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) to properly address what is required as part of HDEC review. Specifically, this must include plans for collection, storage, access, and destruction of records.

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

1. Please ensure that the details of data privacy and inclusion and exclusion criteria are included in the body of this document. Please refer to the [HDEC PIS Template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc) for guidance. *National Ethical Standards* para 7.15
2. Please include detail on the pre and post cognitive screening and any other assessments undertaken. *National Ethical Standards* para 7.15
3. Please clarify if costs of travel will be reimbursed and if so in what form and how much.

**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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| **4**   | **Ethics ref:**   | **2023 FULL 12852** |
|   | Title:  | LOGGIC/FIREFLY-2: DAY101 vs. Standard of Care Chemotherapy in Paediatric Patients with Low-Grade Glioma Requiring First-Line Systemic Therapy |
|   | Principal Investigator:  | Dr Karen Tsui |
|   | Sponsor:  | DayOne Biopharmaceuticals |
|   | Clock Start Date:  | 26 January 2023 |

Dr Jane Wylie, Peter Manley, Ben Tsao, Saswata Ray and Dr Karen Tsui 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 noted that the age of diagnosis can be from infancy to young adulthood.
2. The Committee noted that the pregnant partner or pregnant participant information sheets would not be reviewed at this time and should be sent for approval as an amendment if it becomes necessary.
3. The Committee clarified that optional tissue would only be gathered if there was already a planned surgery planned as standard of care (SOC).
4. The Committee noted that the children in the study would require the genetic abnormality to be included in the study.
5. The Committee clarified that the chemotherapy options were all approved for use in New Zealand.
6. The Committee noted that the testing done on tissue for future research would be unspecified but related to the questions addressed in this specific study on this specific cancer. The Committee noted that it was not acceptable to bank minor’s tissue in a tissue bank, particularly where genetic testing may be conducted.

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 all references to Central HDEC be amended to Northern B HDEC.
2. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
	1. Please ensure there is no confusion as to the form the data and tissue will be stored in as there is an option for return of tissue the samples will be deidentified and coded rather than anonymised. Please make sure this is consistent throughout.

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

1. Please consider removing the “flip of a coin” be rephrased as feedback from cancer-affected participants has been negative towards this specific phrase.
2. Please remove ethnicity collection from the consent form as this is not an appropriate place for this collection.
3. Please remove the onus from participants to ask for reimbursement, this should be phrased in a way that makes it clear that travel costs will be covered.

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

1. Please repeat the tissue bank information in this form.

**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).*
* 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).*

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| **5**   | **Ethics ref:**   | **2023 FULL 12544** |
|   | Title:  | Implementation of Metformin theraPy to Ease Decline of kidney function in Polycystic Kidney Disease (IMPEDE-PKD) RandomisedPlacebo-Controlled Trial |
|   | Principal Investigator:  | Professor Suetonia Palmer |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 26 January 2023 |

Professor Suetonia Palmer 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 suggested using the invitation through email and potentially attaching the information sheets to this.
2. The Committee clarified that a genetic diagnosis or a non-genetic more traditional diagnosis would have been provided to the participants. This may be provided on a locality level.
3. The Committee clarified the run-in period and the justification of the use of this over metformin for tolerance and dose finding. The Committee also noted that the 12-week period would not be enough for clinical benefits to be observed.
4. The Committee noted that there was no funding currently for koha, but should funding become available, there would be provision.

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 that invitations to join the study would be through the medical teams of those participants with a letter of invitation or via contact when they visit clinic or by phone call. The Committee requested provision of the script for the telephone call and the letter of invitation.
2. The Committee requested that the information that would be provided to Kidney Health be provided to the Committee for review. The Committee noted that any recruitment adverts would need to be provided for review.
3. The Committee requested that the linking to the data in the Integrated Data Infrastructure (IDI) be optional.
4. The Health Economic Data linking would be limited to the participants consenting to the study, the Committee requested that this be an option in the study and that this be clearly outlined in the protocol and the PISCF.
5. The Committee requested the specifics of the screening process be provided for review.
6. The Committee requested the following changes to the Data Management Plan (DMP):
	1. The Committee noted that the data management plan states that National Health Index (NHI) numbers would be sent to the Accident Compensation Corporation and to the Ministry of Health. Please correct this.
	2. The Committee requested more clarity around what identifiable information would be shared, with whom and for what purposes.
	3. The Committee requested that only what is necessary be kept in an identifiable form and that all documentation note this.

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

1. Please remove the word “treatment” when referring to the intervention as it could be misleading.
2. Please include websites for click-through options where physical copies of the application be provided.
3. Please amend the mention of the study being funded by the New Zealand Government.
4. Please include the Privacy Act 2020 rather than the Health Information Privacy Code.

**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 Leesa Russell and Ms Kate O’Connor.

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| **6**   | **Ethics ref:**   | **2023 EXP 15087** |
|   | Title:  | Describing care pathways for patients with delirium discharged from hospital. |
|   | Principal Investigator:  | Dr Engelina Groenewald |
|   | Sponsor:  | Te Whatu Ora- Counties Manukau |
|   | Clock Start Date:  | 26 January 2023 |

Dr Engelina Groenwald and Dr Danielle Diamond 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 the timeline for recruitment in the clinic.
2. The Committee noted that the questionnaire had been submitted as an appendix to the protocol.

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 protocol be put in place for the researchers to plan for potential events or things that could go awry as part of visits to participant’s houses.
2. The Committee requested the following changes to the Data Management Plan (DMP):
	1. The Committee requested that the storage, access, and destruction of the recordings be accounted for in the data management plan.
	2. The Committee requested that any potential identifiable quotations be obscured or otherwise removed to protect the participants privacy.

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

1. Please reframe the Participant as “person who had delirium”
2. Please address concern for abuse more explicitly, especially around where confidentiality may be breached for these reasons.
3. Please specify what the $50 voucher is for.
4. Please formalise what would make someone a participant. Please specify who will be eligible for the koha and how this will be provided and if it will be for each adult participating or if it is only for the person diagnosed with delirium.
5. Please amend this form to make sure it addresses the person as the patient who had delirium rather than the family member of that person.

**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 Maakare Marr and Ms Joan Petit.

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| **7**   | **Ethics ref:**   | **2023 FULL 11419** |
|   | Title:  | Ultra-Early, minimally inVAsive intraCerebral haemorrhage evacUATion versus standard trEatment (EVACUATE) |
|   | Principal Investigator:  | Dr Martin Punter |
|   | Sponsor:  | The University of Melbourne |
|   | Clock Start Date:  | 26 January 2023 |

Dr Martin Punter, Dr Timothy Kleinig, 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 clarified that there would be several follow ups additional to standard of care for participants randomised to standard of care.
2. The Committee clarified the funding source for the study and that the device would be supplied and technical support given but no funding from the device providers. The device providers would also have no access to participant data
3. The Committee queried the capacity of the hospitals to provide the surgery within the 8-hour timeframe. The researcher clarified that the timeframe was reasonable and that this had been discussed in detail with the medical staff at the sites.

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 as New Zealand does not permit research with proxy consent. A welfare, guardian or enduring power of attorney cannot give consent to enrol an adult into a medical experiment in New Zealand. The Committee noted that under Right 7.4 of the Patient Code of Rights would permit a participant to be enrolled if there is an argument for the clinical best interest for both arms of the study. The Committee noted that the Researcher would need to provide evidence that the participants would be better off by participating than they would be receiving usual care. The Committee suggested the Researcher converse with Dr Paul Young who has experience in this field. A New Zealand addendum to the global protocol would be required with specific information pertaining to if participants never recover or if potential participants do not have family or friend support, for example. (*National Ethical Standards for Health and Disability Research and Quality Improvement, chapter 7).*
2. The Committee queried the multitude of variables and how analyses would be consistent should there be multiple sources of data. Please provide an adequate justification for the use of several variables and how this may impact the outcomes of the data analyses.
3. The Committee queried if the IDI would be used in this study and that use of this data and linkage would need to be detailed in the resubmission in order to be able to access and use this.
4. All Information Sheets (for consenting participants if applicable, and for continued use of data upon recovery of capacity, and information for relatives/whānau/ friends ascertaining the participant’s wishes) would need to be aligned to accompany the resubmission (*National Ethical Standards for Health and Disability Research and Quality Improvement, chapter 7).*

**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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| **8**   | **Ethics ref:**   | **2023 FULL 15093** |
|   | Title:  | Do injuries to the brain affect how people think in the longer term? A study of people who have and have not experienced injuries tothe brain in Corrections |
|   | Principal Investigator:  | Professor Alice Theadom |
|   | Sponsor:  | Auckland University of Technology |
|   | Clock Start Date:  | 26 January 2023 |

Professor Alice Theadom and Sam Guy 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 Researcher had an onsite contact and had a very clear plan for visiting the prison.
2. The Committee clarified that the Researcher had resolved issues to access participants information and facilitate recruitment through the prison intranet.
3. The Committee queried the assessment tool’s ability to show differentiation between language skills and brain injury. Particularly those that were rooted in literacy or complex vocabulary. The Researcher clarified that the participants would only be tested to the point of natural endpoint rather than being literacy dependent. The researcher also clarified that the testing battery is not capable of diagnosis.

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 may be participants with ongoing appeals and that clarification would be necessary to note that information would not be privileged information. The Committee recommended excluding those persons still subject to appeal or on appeals that are relevant to mental capacity (such as insanity or drug use).

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

1. Please remove the option to notify a general practitioner as this should be mandatory.

**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)*
* 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).*

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| **9**   | **Ethics ref:**   | **2023 FULL 13633** |
|   | Title:  | Nutritional response to chyme reinfusion therapy in patients with Type 2 Intestinal Failure in New Zealand |
|   | Principal Investigator:  | Professor Rozanne Kruger |
|   | Sponsor:  | Massey University |
|   | Clock Start Date:  | 26 January 2023 |

Professor Rozanne Kruger, Andrew Xia and Professor David Rowlands 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.

Mr Ewe Leong Lim declared a conflict of interest and the Committee decided to recuse the member from the discussion and the member decided to leave the meeting prior to the application being seen.

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 where in their medical journey are participants are approached to participate in the study. The Researcher responded that this is when they are diagnosed with type 2 intestinal failure after bowel resection surgery. . After discussion, the Committee noted the vulnerability of the participants which the Researchers acknowledged but was assured that they would have adequate time to consider their participation.
2. The Committee noted the involvement and significant conflict of interest (COI) of the founder of the device given they could refer patients to the trial. Based on the study documentation, this COI is not managed. The Researcher responded that they do not see any patients in the hospital and is not involved with the care of these 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 raised the following about the application form:
	1. The Committee noted that parts of the application (notably the cultural section refers to an unrelated study concerning bowel cancer, and treatment. This has resulted in some information missing for this specific study.
	2. C3 of the application should state ‘Yes’.
	3. For C 18.2, Enduring power of attorney is not required if someone has diminished capacity to consent. After discussion the Committee and Researchers agree that this study should be limited to those who can consent for themselves. Questions around engaging with diminished capacity consent processes does not need to be interacted with. The answer to D8 will need to be amended too.
2. The Committee requested the following changes to the protocol (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8):
	1. With 8 participants, please be clear that this is a pilot study. End point currently suggests it is a pilot, but framing needs to be clearer that this is about reviewing guidelines, acceptability of treatment etc.
	2. The Committee noted that the aim of the protocol mentioned testing a novel device. This does not appear to relate to this study but was unclear from the information presented for review. This statement needs to be referenced: Recently, an Auckland-based research group has invented and validated a novel automated chyme reinfusion device (bolus), that overcomes the disadvantages of the abovementioned system." (Page 2)
	3. Protocols for research in human participants standardly include safety plans, information for reporting and monitoring of adverse events, information about recruitment and screening, where the laboratory work will take place and by who, what kinds of tests will take place with the various tissue and information provided. For example, the protocol should seek to answer if participants be recruited from hospital and seen there, does Massey have a suite appropriate for infusion monitoring and medical staff on site for adverse event management, how will adverse events be recorded and managed, when will the Researchers stop the study if it is unsafe, what potential side effects might participants have from the isotype and how will these be managed on the day, etc.
	4. Aspects of device regulation and pilot studies need to be referenced in the protocol.
	5. The isotopes require a material data and safety sheet or investigator’s brochure.
3. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP) (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17*):
4. Section 4 is currently inaccurate, as Future Unspecified Research (FUR) is not currently separate
5. 10.1 mentions that tissue samples are being transported by cars. The Committee queried if these are private vehicles, and in what kind of biohazard containment etc. Specific protocols around tissue transportation needs to be provided and in line with relevant laws and guidelines.
6. The Committee noted that references to this being a novel device is overstated as this is already considered part of the usual care pathway in the hospital.
7. Further, the Committee stated that though this reinfusion is usual care pathway, there is some benefit to the manufacturers and distributors of the device given there are co-researchers who have roles with the device company. The commercial aspect hasn’t been drawn out in the study documentation provided. This fundamentally changes who pays for study related injury, and with the current information provided, the Committee could not determine where that balance lies. The Researchers clarified that these co-researchers involved in corporate entity do not have a say in the protocol and data analysis, but the company will get the results. The Committee requested further detail in the study documentation that the dual roles that some of the research team have of maintaining an interest in the company and that the balance of benefit is not weighted towards the company and is purely academic. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.23).*
8. There is currently no information about how the comparator study on 4 healthy participants are being recruited, nor is there a participant information sheet/consent form (PIS/CF) provided for them.
9. The Committee suggested engaging with Māori on the potential tapu of putting ‘waste’ back into the body. Any results of this engagement should be outlined in study documentation for participants to consider.
10. The Committee noted that the evidence of consultation supplied is not the right document.
11. The Committee requested that the recruitment documentation doesn’t oversell participation and can be amended to just inform potential participants what the study is about rather than promising benefit. In addition, the way it is currently framed is not consistent with the purpose of the study.
12. The Committee noted that the documentation suggests other data is being collected during the infusion timeframe, stating that they like seeing all information collection sheets if other information beyond the provided questionnaires is being administered during this time.
13. The Committee queried if any health information will be used by accessing their health records. The Researcher confirmed that clinical notes will be accessed. The Committee requested that this is detailed in the protocol, DTMP and PIS.

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. PIS and CF is quite dense and technical, please review for lay language. Table in protocol for timing of drinks could be good to be used in the PIS.
2. The Committee noted there are missing sections of the participant information sheet to obtain fully informed consent. The Committee recommended the Researcher adapt the [PIS template available on the HDEC website](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc).
3. Use of samples for future unspecified medical or scientific purposes. You note there is that possibility, and consent for that must be separately obtained using a distinct Information Sheet and Consent Form. . Remove references to future sample research from the body of the main Information Sheet.
4. Please state the regulatory status and class of the device being used.
5. Some definitive statements should be worded a bit less promotionally i.e. CRT is very effective in reducing dependence on PN. 'Some studies have shown' would be better here.
6. State how the isotype drink tastes and what volume will be consumed.
7. Clarify which samples are going overseas and which are staying here.
8. An ACC or ACC- equivalent statement needs to be on this PIS/CF. This can be found in the HDEC template, and the one selected must align with whether this is a commercial or investigator led study.
9. Data use statements from the HDEC template should be included and amended for the study.
10. Risk of blood draw and use of device needs to be outlined.
11. “Māori agenda” should be changed to “Māori protocols”.
12. Please include further detail around what is required of participants such as the day 21 follow up. Please include when, where, what happens, for how long, and if it is an extra visit beyond standard of care – whether transport and parking will be reimbursed, etc.

**Decision**

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

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 02 March 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 2:20pm