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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27th June 2023 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12:00pm- 12:30pm | 2023 EXP 15241 | Smart Patient Cohort Builder | Dr Clement Korenbaum | Ms Helen Walker & Dr Patries Herst |
| 12:30pm- 1:00pm | 2023 EXP 17879 | ACT for Pēpi: A digital intervention trial targeting stress for parents and caregivers with preterm babies in the neonatal intensive care unit (NICU) | Dr Jane Alsweiler | Mx Albany Lucas & Ms Jessie Lenagh-Glue |
| 1:00pm-1:30pm | 2023 FULL 18148 | ProstACT Global ANZ | Dr Remy Lim | Ms Sandy Gill & Mrs Patricia Mitchell |
| 1:30pm- 2:00pm | 2023 FULL 18050 | LUM-201-02: An Extension Study to Monitor Long-Term Safety of LUM-201 Treatment in Children with Idiopathic Growth Hormone Deficiency | Dr. Esko Wiltshire | Mrs Patricia Mitchell & Mrs Helen Walker |
| 2:00pm-2:30pm |  | **Break 30 minutes** |  |  |
| 2:30pm-3:00pm | 2023 FULL 15463 | Paediatric Rehabilitation: What's important to you? | Dr Lynne Clay | Mx Albany Lucas & Dr Cordelia Thomas |
| 3:00pm-3:30pm | 2023 FULL 15631 | Improving Quality of Life to Prevent Challenging Behaviour in Adults with Intellectual or Developmental Disability | Ms Sophia Kennedy | Ms Jessie Lenagh-Glue & Mrs Patricia Mitchell |
| 3:30pm-4:00pm | 2023 FULL 13849 | SWiFT study of whole blood in frontline trauma | Dr Richard Charlewood | Dr Cordelia Thomas & Dr Patries Herst  |
| 4:00pm-4:30pm | 2023 FULL 16702 | BP43437: A Study to Evaluate Forimtamig in Combination with Other Treatments in Multiple  | Prof Peter Browett | Ms Helen Walker & Mx Albany Lucas |
| 4:30pm-5:00pm | 2023 FULL 12714 | Marine oxygen carrier (M101) for organ preservation in liver transplantation | Associate Professor Louise Barbier | Ms Sandy Gill & Dr Patries Herst |
| 5:00pm-5:15pm | 2023 FR 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 Francisca Reed | Dr Patries Herst, Mrs Helen Walker, Ms Sandy Gill, Dr Cordelia Thomas , Mx Albany Lucas, Ms Jessie Lenagh-Glue & Mrs 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 |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that no apologies had been received.

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 23rd May 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 EXP 15241** |
|   | Title:  | Development of a cohort builder tool to facilitate the inclusion of patients into clinical trials in oncology  |
|   | Principal Investigator:  | Dr Clement Korenbaum |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 15 June 2023 |

Dr Clement Korenbaum, Dr Ben Lawrence, Dr Yaniv Gal, Rachel Owens and Dr Robert Cartwright 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 data would be requested from the hospitals prior to being transferred and immediately deidentified by a validated tool. The human versus machine testing would then occur and discrepancies identified. At that stage, reidentification may occur to seek an explanation for any discrepancy. This reidentification would only be undertaken by hospital clinicians who would have access to that data ordinarily. This data would then be discarded to prevent privacy breach.
2. The Committee clarified what the “unknown data” that had been used for pre-training was just data that was not part of this experiment.

**Decision**

This application was *approved* by consensus.

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| **2**   | **Ethics ref:**   | **2023 EXP 17879** |
|   | Title:  | A digital Acceptance and Commitment Therapy and education intervention (ACT for Pēpi) targeting stress for parents and caregivers with preterm babies in the neonatal intensive care unit (NICU): a randomised controlled cluster trial |
|   | Principal Investigator:  | Dr Jane Alsweiler |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 15 June 2023 |

Dr Jane Alsweiler, Anna Serlachius and Dr Kristin Ginsburg 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 Māori voiced video was in production but was dependent on funding.
2. The Committee clarified that each group would have access to different websites and resources.

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 why the REDCAP scores would only be checked every 4 days. This should be managed to be reviewed more frequently to reduce risk.
2. The Committee noted that the language used for koha may need to be changed to not denote that “time” had been reimbursed to reduce the potential for this becoming taxable.
3. The Committee requested that at discharge, all participants be given access to the stress reduction education as stress may be an ongoing situation for all the individuals involved in the study. This can be done following the 3-month questionnaire and would be considered more ethical. The Committee noted that it would be preferable for this education to be provided before the 3-month check in if possible.
4. The Committee queried if the social workers would have the capacity to be referred to. The researchers clarified that whilst in the Neonatal Intensive Care Unit (NICU) this would be possible, but this will need to be amended for the 3-month check. This needs to include a plan for individuals who may have indicated distress. Any plan for managing distress should be included in the participant information sheet (PIS).
5. The Committee requested clarification if all the questionnaires would be used at every point in the study.
6. The Committee noted that the exclusion criteria of being depressed or anxious or medicated for these reasons was not accurate and that the statement that people would not be asked about self-harm or suicidality was not correct.

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

1. Please include warnings and safety plans for the questionnaires and the contents concerning depression, anxiety, and suicidality.
2. Please amend the wording “we will ask for permission to refer you” where referring to mental health services. This is an ethical obligation and should not be left to the “permission” of the person.
3. Please clarify that each group will have access to different modules and resources.
4. There is no mention of being contacted when the child is older, except for the three month-post discharge contact. In the consent form, there is a tick box asking permission to contact the child when they are older – this needs to be clarified that either this refers to the 3-month post discharge check, or if this is referring something else, then that must be covered in the PIS first.
5. Please remove “read to me in my first language”.
6. Please amend the language used around the withdrawal of data or remove the optional tick boxes if this is not an option.
7. Please ensure that contacting parents once the baby is older is raised first in the PIS before being brought into the consent form.
8. Please ensure that the statement “I consent to the research staff accessing my baby's medical records” is first explained in the PIS.
9. Please note that wider whanau members cannot consent for the disclosure of data to the research team. These groups should have a separate PIS/CF to ensure the legality of this process whilst also ensuring the inclusion of these groups.
10. Please include gender neutral terms for “parent” and “grandparent”.
11. In one paragraph, low risk is stated several times. Please remove this paragraph altogether because the risk is that participants may become anxious by all the texts messages and emails and the need to do these modules every day.
12. Please remove all tick boxes in the consent form where there is no option.
13. Please include a statement per contacting a general practitioner (GP) to inform of any significant results. This should not be an option in the consent form as it is mandatory.
14. Please amend all consent forms as extended whānau cannot give consent. Please only include parents/guardians.

**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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| **3**   | **Ethics ref:**   | **2023 FULL 18148** |
|   | Title:  | A multinational, multicenter, prospective, randomized controlled, open label Phase 3 study with best standard of care with and without 177Lu-DOTA-rosopatamab for patients with PSMA expressing metastatic castration-resistant prostate cancer progressing despite prior treatment with a novel androgen axis drug |
|   | Principal Investigator:  | Dr Remy Lim |
|   | Sponsor:  | Telix International Pty Ltd |
|   | Clock Start Date:  | 15 January 2023 |

Dr Remy Lim, Dr Rosane Joseph, Dr William Xu, Dr Andrew Henderson, Brenda Cerqueira 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 when the quality-of-life questionnaires would be reviewed.
2. The Committee clarified that a karakia could be made available overseas. The Committee suggested that this could be noted on the samples with a ‘K’ on the container.
3. The Committee noted that the pregnant participant information sheet/consent form (PIS/CF) was not reviewed, and this should be submitted as an amendment should a pregnancy occur.
4. The Committee clarified the use of "If using your own transport, you will be reimbursed according to the mileage rates as specified by the New Zealand Inland Revenue Department (IRD)".
5. The Committee noted the language for sponsors for terminating the study. The researcher clarified that this was further explained in the protocol which notes that the study will not be terminated for commercial reasons.

Summary of outstanding ethical issues

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

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

1. Please include warnings and safety plans for the questionnaires and the contents which concern depression, anxiety, and suicidality.
2. Please amend language of inclusion where mentioning "male participants aged 18 and over" this should state instead "patients with prostate cancer aged 18 and over..." to be more inclusive of transgender women and other gender non-conforming people (e.g., nonbinary, takatāpui).
3. Please move information pertaining to who can take part in the study under the relevant heading as currently it is under the “what does my participation involve”.
4. Please include less common side effects to the list of side effects.
5. Please provide a lay title for participants.
6. Please provide a table of procedures for ease of understanding.
7. Please note that the participation statement on page 7 and the radiation effect statement on page 9 are not complete sentences, please amend.
8. Please note that the wording around potential benefits should explain that there may be no actual benefits given this is experimental work.
9. Please use the consistent terminology when referencing general practitioners (GPs) or usual doctors.
10. Please remove the information pertaining to the publishing of results from the “rights to access” section. This should be under the correct heading.
11. Please explain what the “images” are that will be collected in the PIS as this is a concept only introduced in the consent form.
12. Please clarify if removal of clothing will be required during an examination, if a chaperone is permitted and if a gender-matched examiner will be possible.
13. Please clarify that the spread of testing over several days will not require participants to stay on site for that period but that it will be separated into several visits.
14. Please amend risks to note the number of people effected in words for example, ‘1 in 100 people’.
15. Please remove the word “additional” where concerning costs of the study.
16. Please note that “Māori health support” should read “Māori *cultural* support”.
17. Please note that the GP must be informed. This needs to be explained in the PIS and should not be optional in the consent 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).*

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

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| **4**   | **Ethics ref:**   | **2023 FULL 18050** |
|   | Title:  | LUM-201-02: An Extension Study to Monitor Long-Term Safety of LUM-201 Treatment in Children with Idiopathic Growth Hormone Deficiency |
|   | Principal Investigator:  | Dr. Esko Wiltshire |
|   | Sponsor:  | Novotech (New Zealand) Limited |
|   | Clock Start Date:  | 15 June 2023 |

Sana Oladi and Dr Jonathan Barrett 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 only be one participant on the study carrying over from the last study.
2. The Committee clarified the age group of the participants.
3. The Committee clarified the similarities of this study to the last study.

Summary of outstanding ethical issues

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

1. The Committee requested that should the participants turn 16 during the study that these people are consented as adults once they reach this age. Information sheets and consent forms should be provided to this effect as an amendment at this time.
2. The Committee requested for explanation of how the child’s comfort and dignity would be protected during the Tanner exam.
3. The Committee requested a koha be provided for the child’s involvement in the study. This could be a gift voucher rather than monetary.
4. The Committee requested clarification for the sponsor to change language concerning a termination of the study. The Committee note that it is not acceptable for a sponsor to terminate the study for purely commercial reasons.
5. The Committee noted that the insurance provided ceases before the start of the next study. Please provide a new document that aligns with this submission.

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

Assent Form:

1. Please clarify the intent of the study in a short excerpt at the start of the PIS. Please explain clearly this is just an extension study with same assessments held on a 6-monthly basis rather than 3-monthly.
2. Please review for plain language.
3. Please include how frequently the Tanner exams will take place.
4. Please include an option for the participant to be given the option for a support person to be made available.
5. Please allow for participants to receive the option for a gender matched examiner for the Tanner exam and include how frequently that this exam will be performed. If this is not possible, please include the option for a gender matched health practitioner to be present (e.g., a nurse).
6. Please address the management of pregnancy testing and the protection of participants confidentiality and safeguarding.
7. Please review for repeat sentences, such as, “If your child participates in this study, you and/or your child will be expected to”
8. Where referring to Medsafe please state that this is the body who as approved the drug rather than being vague.
9. Where referring to “parent or guardian” please use instead “mum or dad” in the assent.
10. Please remove “if you are female” from the statement “If you are female, we don’t want you to get pregnant”. The gendered language is unnecessary.

Parental PIS/CF:

1. Please explain how a pregnancy test may be conducted and how the confidentiality of these children will be protected.
2. Please review for plain language.

**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 Patricia Mitchell and Mrs Helen Walker.

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| **5**   | **Ethics ref:**   | **2023 FULL 15463** |
|   | Title:  | Setting the research agenda for tertiary paediatric rehabilitation in Aotearoa New Zealand using a Priority Setting Partnership process |
|   | Principal Investigator:  | Dr Lynne Clay |
|   | Sponsor:  | Auckland University of Technology |
|   | Clock Start Date:  | 15 June 2023 |

Dr Jimmy Chong 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 New Zealand law does not allow proxy consent for adults with intellectual disabilities. This predicates a need to support them to consent for themselves or else apply [Right 7(4) of the Code of Health and Disability Services Consumers’ Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/). *National Ethical Standards* para 7.18 & 7.70
2. The Committee noted that people 16 and over can consent for themselves if they are competent to do so. This needs to be amended to be consistent with the law. *National Ethical Standards* para 7.18, 6.25-6.27 & 6.20
3. The Committee queried if all people who are invited/identified will be included. If there is a possibility that some who express interest may miss out, then this should be included in the participant information sheet (PIS).
4. The Committee queried how the researchers will ensure diverse sampling of participants.
5. The Committee requested an assent for children participating and appropriate participant information sheets for this group. Please refer to the [HDEC assent form instructions](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/hdec-assent-form-instructions-and-checklist-may18.doc) for guidance. *National Ethical Standards* para 6.20
6. The Committee noted that any participants who turn 16 during the study will need to be reconsented once turning 16 years old. *National Ethical Standards* para 6.20
7. The Committee noted that the focus groups should be recorded to maintain accuracy with the recordings then transcribed and anonymised.
8. The Committee requested that plans to manage potential upset about suggested questions that subsequently are not given priority in stages 2 and 3.
9. The Committee requested the following changes to the Draft Survey:
	1. Please amend one page one, "we will make sure that nobody can tell which things you told us”, as this is not something researchers can guarantee.
	2. Please separate the section "for people who are currently or have been an inpatient at The Wilson Centre" into two sections as it is currently confusing to answer the concurrent questions

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

1. Please use the ACC statement as per the HDEC [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) as the current statement is not sufficient. *National Ethical Standards* para 7.15
2. Please clarify if interviews will be transcribed and if these will be able to be checked and amended by participants. *National Ethical Standards* para 7.16
3. Please be clear who may be taking notes during focus groups and what purpose this may be for. *National Ethical Standards* para 12.21
4. Please provide an explanation of how the hui or focus group would be structured. It may be that 30 minutes is too short a time for this.
5. Please provide Māori cultural and advocacy contacts.
6. Please include footers with versioning and dates.
7. Please include the rights to access and correct information.
8. Please amend to state that for oral consenting, the person asking the questions should state their role and name and this information should be recorded. *National Ethical Standards* para 7.20-7.21
9. Please include a confidentiality statement concerning the identity of members of a focus group in the PIS/CF.
10. Please note that no new information can be introduced in the CF. Please ensure that all information is first expressed in the PIS. *National Ethical Standards* para 7.20
11. Please clarify under the “discomforts or risks” section that not all questions will make the final cut and that this is not on grounds of validity of the questions.
12. Please reword the reimbursement statement to be less ambiguous.
13. Please note that there is whakamā inherent in these issues and it may be useful for the researcher to be aware of this when conducting the research.

**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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| **6**   | **Ethics ref:**   | **2023 FULL 15631** |
|   | Title:  | Active Support as an Antecedent Intervention for Challenging Behaviour in Adults with Intellectual or Developmental Disability |
|   | Principal Investigator:  | Ms Sophia Kennedy |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 15 June 2023 |

Dr Amarie Carnett and Sophia Kennedy 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 who the organisational consent form would be filled out by.
2. The Committee clarified who would also be accessing the inter-observer data.
3. The Committee clarified how consent will be obtained from those with reduced capacity to consent. The consent process would also be dynamic and ongoing throughout the whole course of the study.
4. The Committee clarified the process should a staff member in the study were to leave the study for some reason. The researcher noted that there would be over-recruitment to attempt to mitigate the effect of this should it occur. Staff members replacing these former participants would also be trained but that this data would not be included in the study.
5. The Committee noted that there was grant money noted in the application summary and the researcher noted that the number noted had been reduced but that the funding remaining would be sufficient.
6. The Committee clarified the ratios of caregivers to residents.

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 consideration be given to how privacy and confidentiality may be impacted by observation of more than one person in these homes.
2. The Committee requested clarification on how the separation of an organisation as a legal entity from the individual who will be filling the consent on behalf of the organisation. This could be managed by ensuring there is a statement to the effect of: “You have been asked to give consent on behalf of your organisation and that consent has been granted as shown…” to ensure that there is recognition of the authority of that manager to make that decision.
3. The Committee queried how participants may be barred from participation if one part of the resident-carer dyad will not be willing to participate.
4. The Committee noted that the Health Information Records Act requires data be retained for 10 years. Please amend the necessary documentation to this effect.
5. The Committee noted that there is the possibility for this study to contribute to prejudice towards Māori. The Committee suggested that the way in which this research is phrased could impact Māori in a similar manner to work previously has to discriminate against Māori.
6. The Committee requested how the recruitment of employees reads as coercive, particularly around the way in which the wording “If your organisation provides consent, *you* will be asked to pass on participations sheets to…” some thought needs to be given as to how the employees will be protected and not feeling coerced into participation.

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

All:

1. The Committee requested version and dates in footers of all PIS/CFs.

Organisational PIS/CF

1. Please ensure that it is clearly stated that this is being agreed upon by the organisation and ensure that the language used when describing the organisation is consistent. The form should refer to “the organisation’ and not “you”.

Staff Member PIS/CF:

1. Please remove wording to the effect of “should you not participate; this will not affect your job in any way…” as the researcher cannot guarantee this.
2. Please remove wording to the effect of “if you say no, your life will not change…” as the researcher cannot guarantee this.

Support Person PIS/CF:

1. Please remove the word “your” from statements concerning collection of information as this may not always be the support person’s data, as in most cases it will be the resident’s information.

**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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| **7**  | **Ethics ref:**   | **2023 FULL 13849** |
|   | Title:  | SWiFT study of whole blood in frontline trauma |
|   | Principal Investigator:  | Dr Richard Charlewood |
|   | Sponsor:  | New Zealand Blood Service |
|   | Clock Start Date:  | 15 June 2023 |

Dr Richard Charlewood 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 requesting retrospective consent for the blood that was received in the emergency scenario was not appropriate. The consenting process should only be for anything occurring after this point. To this point, the Committee suggested that the study should only concern what occurs after the person is brought to hospital.
2. The Committee noted that the consent forms and information sheets would not be able to be used in their current state given that in New Zealand it is not legal to give consent on an adults’ behalf. *National Ethical Standards* para 7.18 & 7.7.
3. The Committee noted that there is a number of cultural considerations such as whakamā, the tapu of the head and tissues such as blood. These need to be given recognition in your application and acknowledged in the participant information sheet/consent forms (PIS/CFs). *National Ethical Standards* para 3.3
4. The Committee requested assent forms and consent and participant information sheets for parents of children who may be included in the study (Please see the [HDEC assent form instructions and checklist for guidance).](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/hdec-assent-form-instructions-and-checklist-may18.doc) The Committee requested, to this effect, that there should be reconsent processes and forms should a child be recruited and turn 16 during the study. *National Ethical Standards* para 6.25-6.27
5. The Committee noted that it is a requirement for ethnicity data to be collected in New Zealand. Please amend all documentation to reflect this.
6. The Committee requested that there be information included in the study documentation per the justification of participants to receive the study procedure if they cannot give consent. This must comply with [Right 7(4) of the Code of Health and Disability Services Consumers’ Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/). *National Ethical Standards* para 7.70
7. The Committee noted that there were contradicting opinions given in the peer review provided. The Committee requested that this be reviewed and the points raised addressed and a rebuttal provided or utilise the HDEC [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx) and have it filled in by a singular expert in the field in New Zealand to review it. *Health and Disability Ethics Committee Standard Operating Procedures* para 10 & *11*. *National Ethical Standards* para 9.25 & 9.32
8. The Committee suggested that the HDEC [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-tissue-management-template-Nov2022.docx) for the Data and Tissue Management Plan be at least referred to so that the necessary things are detailed in the application.
9. The Committee queried why the quality of life (QOL) survey was being used in this application. The justification that there could be a better QOL response is likely to be biased due to the traumatic situation the participants have been in. *National Ethical Standards* para 8.3
10. The Committee asked when the questionnaires would be filled in and in what frequency. These questions being asked demand timely and thorough follow up and a plan for referral to further care. The Committee suggested that should this be a required part of the study that provides actual data that may show improved outcomes given the nature of the questions. This increased chance of causing a triggered response would be unethical. *National Ethical Standards* para *8.3 & 8.4*

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

1. Please refer to the HDEC [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) for an ACC statement that is adequate.
2. Please ensure that there are footers with versions and dates included.
3. Please note that there is no proxy consent in New Zealand. This needs to be amended for the New Zealand research sites. *National Ethical Standards* para 7.18 & 7.70
4. Please remove the statement “all participants will give consent” as this cannot be assured.
5. The statement that “you will have no responsibilities” is incorrect as there will be active participation and follow ups as part of this study. Please amend. *National Ethical Standards* para 7.16

**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 16702** |
|   | Title:  | AN OPEN-LABEL, RANDOMIZED PHASE IB/II STUDY EVALUATING SAFETY, TOLERABILITY, AND CLINICAL ACTIVITY OF FORIMTAMIG-BASED TREATMENT COMBINATIONS IN PARTICIPANTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA |
|   | Principal Investigator:  | Prof Peter Browett |
|   | Sponsor:  | Roche Products (New Zealand Ltd) |
|   | Clock Start Date:  | 15 June 2023 |

Dr Harry Chou, Holly Thirwall and Courtney Rowse 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.

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

1. Please make it abundantly clear that the forimtamig will not be available to participants after the study ends.
2. Please clarify that the combination treatment is potentially available for participants following the study. Please specify for how long this compassionate provision may be for and that participants will not be paying for this treatment.
3. Please provide a safety plan for the quality of life (QOL) questionnaire and the follow up and referral that may be arranged for this.
4. Please specify the minimum SPF rating required for participants to use and please specify if this may be possible to be provided to participants.
5. Please clarify what costs may be incurred for medical treatment for the participants as part of the study.
6. Please amend "you will be asked to drink plenty of fluids before your administration of forimtamig and/or suggest hospitalisation.
7. Please amend "your doctor should monitor your signs and symptoms", followed by "your doctor will monitor your signs and symptoms" in following sentence. If required, remove the former.
8. Please clarify the references to “fatalities” by using more direct wording or being clearer with the concepts in case some people may not know what “fatal” means.
9. Please amend "Tikanga advise" to read "tikanga advice".
10. Please amend the sentence, "you will have the option to continue you're your respective combination partner…" for typos.

**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).*

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| **9**   | **Ethics ref:**   | **2023 FULL 12714** |
|   | Title:  | Marine oxygen carrier (M101) for organ preservation in liver transplantation: a randomised exploratory study |
|   | Principal Investigator:  | Associate Professor Louise Barbier |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 15 June 2023 |

Associate Professor Louise Barbier and Dr John McCall 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 donors would all be deceased.
2. The Committee clarified that should the participants decline to participate this will in no way impact their treatment. These participants will be consented as soon as they are on the list for donations and then randomised once they are receiving the organ.
3. The Committee clarified when the M101 would be introduced to the organ this would permit for last minute withdrawals upon reconsent.

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 creating a reconsent process for participants at the point of transplant given the period of time that may have passed between the point at which they were put on the list and the time of transplant.
2. The Committee requested use of the HDEC data and tissue management plan [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-tissue-management-template-Nov2022.docx) to provide sufficient information per the HDEC requirements.

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

1. Please review for typos.
2. Please correct the error on page 2 “pot-transplant”.
3. Please adjust the wording concerning benefits of the study. This should be rephrased to be more realistic.
4. Please be more prescriptive about the genetic research that will be conducted to reduce potential concerns and be more simplified.
5. Please remove tick boxes where yes is the only option in the consent form.
6. Please specify that the consent for blood samples concerns extra blood testing that is not standard of care.
7. Please specify that data withdrawal can only be done until the point that it is analysed.
8. Please include the Central HDEC as the approving committee for the application in the PIS.

**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 supply a more detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **10**   | **Ethics ref:**   | **2023 FR 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:  |  |
|   | Clock Start Date:  | 15 June 2023 |

Dr Francisca Reed was present via videoconference for discussion of this final report.

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 this was a review of a final report for a study which was requested for review at a full meeting due to prior submission being declined for finishing for commercial reasons but continuing in another country.
2. The Committee noted that the outcome was exceptional given the reluctance of the sponsor to provide the drug on compassionate grounds given the drug was beneficial to the participant.
3. The researcher detailed the history of the study and this case.

**Decision**

This application was *approved* by consensus.

## General business

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

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| **Meeting date:** | 25th July 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 5:24pm.