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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 19th July 2022. |
| **Zoom details:** | https://mohnz.zoom.us/j/9481145912 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12:30pm – 1:00pm | 2022 FULL 13020 | The CI-DEX Study | Associate Professor Holly Teagle | Dr Sotera Catapang & Ms Catherine Garvey |
| 1:00pm - 1:30pm | 2022 FULL 12863 | Advanced MR Imaging at Mātai | Dr Daniel Cornfeld | Dr Kate Parker & Mr Jonathan Darby |
| 1:30pm – 2:00pm | 2022 FULL 12524 | Australia and New Zealand Liver and Intestinal Transplant Registry | Professor Ed Gane | Ms Jade Scott & Dr Leonie Walker |
| 2:00pm – 2:30pm | 2022 FULL 12565 | TETON-2: Study of Inhaled Treprostinil in Idiopathic Pulmonary Fibrosis. | Dr Michael Epton | Dr Andrea Forde & Ms Catherine Garvey |
|  |  | *Break (30 minutes)* |  |  |
| 3:00pm – 3:30pm | 2022 FULL 12656 | CPAP-RT: Phase II Trial of CPAP for Motion Management in Breast Radiotherapy; and Lung & Liver SABR | Dr Ken Rantshilane | Dr Andrea Forde & Dr Leonie Walker |
| 3:30pm – 4:00pm | 2022 FULL 12295 | Evaluation of pain among the patient treated with different available external splintage device for simple wrist fracture | Dr Pranesh Kumar | Dr Sotera Catapang & Mr Jonathan Darby |
| 4:00pm – 4:30pm | 2022 FULL 12983 | BOLD-EXT | Dr Helen Evans | Ms Jade Scott & Dr Leonie Walker |
| 4:30pm – 5:00pm | 2022 FULL 12878 | PCT in the ICU | Dr Jacqueline Hannam | Dr Kate Parker & Mr Jonathan Darby |

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

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members.

The Committee noted an error of omission in the agenda and that Dr Andrea Forde was in attendance.

With that correction The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 21st June were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 13020** |
|  | Title: | The CI-DEX Study |
|  | Principal Investigator: | Associate Professor Holly Teagle |
|  | Sponsor: | Cochlear Limited |
|  | Clock Start Date: | 7th July 2022 |

Minal Menezes, Mr Phil Bird, Mr Michel Neeff, Neil Heslop, Jill Mustard and Associate Professor Holly Teagle 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 exclusion of participants required that they would be unable to have a second implant in the contralateral ear for at least twelve months would not be an issue to potential participants in clinical practice.
2. The Committee clarified how the assessment of English-speaking ability would occur (as fluency is necessary for completion of study tests)
3. The Committee queried the exclusion of pregnant and lactating women from the study cohort. The researcher advised that elective surgery was delayed in the case of pregnancy and lactation as there are potential effects on the ability to eat and drink due to nausea, or the possibility of impaired balance.

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 the devices would be publicly funded. However, the researcher explained that this will not detract from the number publicly available as the investigational study implants will be provided in addition to the standard implants. This will need to be amended in the Participant Information Sheet and other documentation as currently this does not reflect what the researcher stated.
2. The Committee requested clarification as to the use of supplementary dexamethasone and the researcher clarified that the investigators in New Zealand do not routinely use this based on their clinical judgment and evidence as to efficacy. This needs to be reflected and clarified in the Participant Information Sheet.
3. The Committee queried the choice to not collect ethnicity data. This is a requirement of the NEAC standards and as such ethnicity data will need to be collected for New Zealand participants. This can be done as a New Zealand specific procedure, rather than adjusting the international protocol.

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

1. Please amend to make this more appropriate for a New Zealand audience. Specifically, please ensure that there are no references to the Australian sites, investigators and compensation information, emergency contact details and that these are replaced with the corresponding New Zealand equivalents.
2. Please ensure that the information regarding the identifiable information access by the sponsor is correct and is in line with the response made to the original submission in relation to the attachment of identifying data to each device. The sponsor should not receive identifiable data of its participants. There should only be coded information supplied.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Catherine Garvey and Dr Sotera Catapang.

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| **2** | **Ethics ref:** | **2022 FULL 12863** |
|  | Title: | Advanced MR Imaging at Mātai |
|  | Principal Investigator: | Dr Daniel Cornfeld |
|  | Sponsor: | Matai Medical Research Institute |
|  | Clock Start Date: | 7 July 2022 |

Dr Daniel Cornfeld 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 machine vendors and the research team have an agreement to gain access to the new testing sequences. This would not give the vendor any access to identifiable patient data.
2. The Committee clarified that there would be an online consent form. This would be undertaken to improve the information security around data collection.
3. The Committee clarified that Māori consultation was underway.

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 concerns around the robustness of the process for data collection and storage. The Committee requested that there be some separation of the clinical and research data. This could include the research notes and may require some thought as to how best to separate the data sets.
2. The Committee noted that it is a NEAC requirement to collect ethnicity data in New Zealand and this will need to be separated with the study data from the clinical data. (*National Ethical Standards* para *9.10 & 9.20.)*
3. The Committee noted that there will need to be a sponsor for this study and a determination made as to appropriate insurance.
4. The Committee requested the following changes to the Data Management Plan (DMP):
   1. Please clarify what information or data would go to the imaging vendor. *National Ethical Standards* para *12.31-12.39.*
   2. Please remove references to the ‘Study monitor’.
5. The Committee requested the following changes to the Protocol:
   1. Please refer to the [HDEC SOPs](https://ethics.health.govt.nz/operating-procedures/) and [NEAC standards](https://neac.health.govt.nz/publications-and-resources/neac-publications/national-ethical-standards-for-health-and-disability-research-and-quality-improvement/) to ensure that the protocol meets the requirement for HDEC review. *National Ethical Standards* para *9.7a & 9.8.*
   2. Please ensure that there is a plan set out to inform general practitioners of any incidental findings.

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

1. Please amend the statement concerning the collection of name and date of birth to state that this would be collected. *National Ethical Standards* para 7.15 & *7.16.*
2. Please amend the statement of images being used for secondary research as this would need to be consented separately. This would need to be separate as this is data collected for research not for clinical treatment. *National Ethical Standards* para *7.57.*
3. Please refer to the [HDEC PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for information that is requisite for HDEC review as currently this document is too brief. *National Ethical Standards* para 7.15 & *7.16.*
4. Please ensure there is a statement concerning any incidental findings being reported to a general practitioner and a request to consent to this. Please include any risks to this effect in a risk section. *National Ethical Standards* para 7.15 & *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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| **3** | **Ethics ref:** | **2022 FULL 12524** |
|  | Title: | Australia and New Zealand Liver and Intestinal Transplant Registry |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | Victorian Liver Transplant Unit, Austin Hospital |
|  | Clock Start Date: | 7 July 2022 |

Professor Ed Gane and Christine Crooks 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 registry would be optional.
2. The Committee clarified that the intestinal transplants received in New Zealand are performed solely in Melbourne. As such there is no living donor information in the information sheets to this effect for the New Zealand arm of the registry.
3. The Committee requested that the protocol addendum be provided for review.
4. The Committee requested the following changes to the Data Management Plan (DMP):
   1. Please provide the described ADHB data sharing agreement.
   2. Please provide the governance plan for this registry, including the structure, policy etc.
   3. Please provide more information as to the matching of the registry data to other datasets in the future. Specifically, that the matching will be to health registries.

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

Main:

1. Please ensure that all PISs explain that the registry is optional.
2. Please correct the typo for ‘registry’.
3. Please state that the data will be stored indefinitely.
4. Please clearly state that the chances of a participant receiving a liver transplant would not be impacted by declining to be part of the registry.

6–12-Year-Old Participants

1. Please consider simplifying the wording to make it more lay-friendly and make it easier for a child to understand.
2. Please consider using different wording around the term ‘registry’, please try to be more explanatory.

**Decision**

This application was *approved with non-standard conditions* 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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| **4** | **Ethics ref:** | **2022 FULL 12565** |
|  | Title: | TETON-2: Study of Inhaled Treprostinil in Idiopathic Pulmonary Fibrosis. |
|  | Principal Investigator: | Dr Michael Epton |
|  | Sponsor: | PPD, Thermo Fisher Scientific |
|  | Clock Start Date: | 7 July 2022 |

No one from the research team was present via videoconference for discussion of this application. The Committee waited 10 minutes before proceeding with the discussion.

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 requested justification for the placebo in this study and if there was sufficient justification for use. (*National Ethical Standards* para *9.7a & 9.8)*
2. The Committee requested more information as to the standard of care in New Zealand for Idiopathic Pulmonary Fibrosis and if this would be available or provided to participants in the study. (*National Ethical Standards* para *9.7a & 9.8)*
3. The Committee queried if participants not on the background drugs used for IDL would be provided this drug or if there would be no recruitment of this cohort and how this would affect the study. (*National Ethical Standards* para *9.7a & 9.8)*
4. The Committee requested notice of SCOTT approval as accessing the full decision and reasoning would be helpful. (*National Ethical Standards* para *9.25-9.32)*
5. The Committee requested more transparency be provided around the investigational use of the nebuliser device for this indication as this is the first time it has been used in the treatment of IPF manner and that is not clearly laid out in the study documentation. (*National Ethical Standards* para *7.15)*
6. The Committee noted that the statement concerning the ceasing of the study for any reason was in fact incorrect and should be amended to include that the study cannot be ceased for commercial reasons of the sponsor.
7. The Committee noted that the insurance was set to expire in November, this will need to be renewed. (*National Ethical Standards* para *17.1-17.6)*

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

1. Please include a statement that the study device has not been tested for this indication prior to this study. (*National Ethical Standards* para *7.15)*
2. Please ensure it is very clear to participants how titration must be clinician-directed and safeguards to avoid participants altering dosing of their own accord between study visits.
3. Please include a statement concerning the risk of sending data overseas. (*National Ethical Standards* para *8.3 & 8.4)*

**Decision**

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

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| **5** | **Ethics ref:** | **2022 FULL 12656** |
|  | Title: | CPAP-RT: Phase II Trial of CPAP for Motion Management in Breast Radiotherapy; and Lung & Liver SABR |
|  | Principal Investigator: | Dr Ken Rantshilane |
|  | Sponsor: |  |
|  | Clock Start Date: | 7th July 2022. |

Dr Ken Rantshilane 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 requested further information on the recruitment process, such as who will approach potential participants and the relationships between the recruiter and the treating physician. The Researcher explained that the radiation oncologists at the treatment site will be made aware of the study and will be able to invite potential participants to be involved. They will discuss the trial in detail with the participant and will give them a participant information sheet (PIS) and will encourage the participant to take some time to consider being involved in the study.
2. The Committee asked how the study team will mitigate any risk of claustrophobia when using the Continuous positive airway pressure (CPAP) machine. The Researcher noted that the respiratory doctor has experience managing this and will provide support if it is needed. The staff will be trained by respiratory physicians in the use of the CPAP device.

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 the exclusion of pregnant or lactating women from the study, given that this group is not routinely excluded from all radiation therapy. The Researcher noted that pregnant and lactating women can be included on a case-by-case basis, as there are variables to consider. However, the Researcher agreed that if a pregnant or lactating female has been cleared for radiation therapy as part of their standard care, that they should also be considered for the study. The Committee requested that this be amended and clarified in the study protocol.
2. The Committee noted that data needs to be held for 10 years after the conclusion of the study. Please amend this in line with (*National Ethical Standards for Health and Disability Research and Quality Improvement para 12.13).*
3. Please provide evidence of professional indemnity for Committee review.

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

1. Please ensure Participants are made aware of any time added due to additional scans (i.e., 30 minutes for CPAP scan).
2. Please clearly outline the purpose of the study, the use of the CPAP machine and how results will be determined in terms of discussing with participants which mode of breathing they will be assigned.
3. Please update reference to the Privacy Act 1993 to Privacy Act 2020.
4. Please review the participant-facing documents to ensure they are lay-friendly (I.e., explain acronyms such as DIBH).
5. Please include a compensation statement. Please consider referring to the [HDEC PIS template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
6. Please update the listed advocacy and HDEC email. The listed emails should be [advocacy@advocacy.org.nz](mailto:advocacy@advocacy.org.nz) and [hdecs@health.govt.nz](mailto:hdecs@health.govt.nz).
7. Please change the statement on optional notice to the Participant’s General Practitioner as it is mandatory that any significant incidental findings are reported.
8. Please remove the Waikato District Health Board logo from the study documents.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Andrea Forde and Dr Leonie Walker.

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| **6** | **Ethics ref:** | **2022 FULL 12295** |
|  | Title: | Evaluation of pain among the patient treated with different available external splintage device for simple wrist fracture |
|  | Principal Investigator: | Dr Pradesh Kumar |
|  | Sponsor: | Whitecross Ltd |
|  | Clock Start Date: | 7th July 2022. |

Dr Pradesh Kumar was not present via videoconference for discussion of this application. The Committee waited 10 minutes before proceeding with discussing the submission.

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 current protocol is not aligned with the *National Ethical Standards for Health and Disability Research and Quality Improvement* guidelines. Please review Chapter 9.7a and 9.8 of the Standards for more information on the requirements of a study protocol.
   1. Please change the language in the protocol from past-tense to future-tense.
   2. Please include more information on the study sites/localities.
   3. Please provide more information on the number of participants (45) and the decision for the 3 – 16-year-old age range. The Committee noted that there is a significant difference between the anatomy of a 3-year-old and a 16-year-old’s wrist and noted that younger participants will have a different pain threshold to older participants and asked how this will be managed by the study team to ensure this is consistent in the study outcomes.
   4. The Committee raised the use of the Wong Baker Face Pain Scale and asked for clarification on who will be conducting the examination as interpretation of the facial expressions may vary and influence the study data. The Committee also asked for clarification on when the pain will be recorded (i.e. will the Participant be at rest or mobilising).
2. The Committee noted that the peer review needs more information (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.25).* Please consider using the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) Independent peer review is required.
3. Please include more information on the current choice of splints and how these will be given to participants (i.e., will they be randomised or sequential).
4. The Committee noted the Researchers commercial interest in the study splint, Zero-Cast, and raised that this presents a conflict of interest. As per the Standards, Researchers must identify and minimise any conflict of interest or commitment and Researchers must identify real, potential, and perceived conflicts of interest, and then manage, reduce or eliminate them (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.23 – 11.23b).* The Committee requested that the Researcher provides a response on how they will minimise any commercial conflicts of interest.
5. The Committee noted that the submission states that the study will follow Kaupapa Māori methodology, however there is no evidence of this. Please amend or remove if incorrect.
6. Please provide a more detailed, study-specific Data Management Plan. Please consider using the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) as a guide.
7. The Committee noted t hat participants presenting with an injury are covered by ACC. The Committee wondered if ACC had been involved in developing the study.

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

1. Please provide a PIS/CF that is written for the parents or guardians of the participants.
   1. Please provide an assent form for participants who are not able to provide consent. This should be determined by competency, not just age.
   2. Please consider using the [HDEC PIS/CF templates](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) as a guide for all PIS/CFs.
2. Please provide more information on whether the Zero-Cast can be removed and the reasons it can be removed (i.e. for bathing).
3. Please provide a statement on compensation statement (i.e. whether the study has insurance, or whether the participants will be covered by ACC).

**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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| **7** | **Ethics ref:** | **2022 FULL 12983** |
|  | Title: | BOLD-EXT |
|  | Principal Investigator: | Dr Helen Evans |
|  | Sponsor: | Albireo AB & Syneos Health |
|  | Clock Start Date: | 7th July 2022 |

Dr Helen Evans was not present via videoconference for discussion of this application. The Committee waited 10 minutes before reviewing the submission.

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 study drug will be offered to study participants following the conclusion of the trial if it is showing to be of clinical benefit.

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 submission mentions there may be some impact on clinic space and asked that with the current pressure on the health system whether this can be managed even given the small recruitment numbers.
2. The Committee asked for more information on whether there will be a change to the dose of the drug following the previous studies.
3. Please clarify the drug dosage of the participants receiving placebo in previous primary research study who will join the extension study.
4. The Committee asked for clarification on the use of Body Mass Index (BMI) in calculating the dosage amounts.
5. Please ensure it is clear when unblinding will occur.

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

1. Please review the patient-facing documents for phrases such as ‘your tissue’ and replace it with ‘your child’s tissue’.
2. Please clearly state at which point in the study the participants will be unblinded.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Leonie Walker and Jade Scott.

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| **8** | **Ethics ref:** | **2022 FULL 12878** |
|  | Title: | PCT in the ICU |
|  | Principal Investigator: | Dr Jacqueline Hannam |
|  | Sponsor: | The University of Auckland, Ethics and Integrity Department |
|  | Clock Start Date: | 7th July 2022. |

Dr Jacqueline Hannam 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 asked for more information on opt-out consent process being used within the study. The Committee acknowledged that this was due to participants being unconscious at the time of enrolment, however queried whether consent could be sought once the participants regained consciousness or capacity to consent. The Researcher confirmed that family or whānau would be informed about the study and could opt-out of the study if they felt the participant would not give consent. Retrospective consent could be sought if the participant regains consciousness and is assessed as having capacity to consent.
   1. The Committee asked how much impact waiting for consent from all participants who regain consciousness may have on the expected participant numbers. The Researcher explained that this would likely impact expected participant numbers as well as research objectives. Only more acute participants would be expected to recover enough to provide informed consent, whilst those who will benefit most in the future will be ICU patients who are more severely affected.
   2. The Committee raised that the Researcher should seek a waiver of consent to use the discarded tissue and to clearly outline the reasoning for doing so in the study documents. The Committee noted that proceeding without consent is not clear in the study documents and raised that proceeding without consent must be in the best interest of the Participant. In this case, the use of the tissue will not directly benefit the ICU patient but will inform future standards of care to other ICU patients. Because of this, please consider applying for a waiver of consent for secondary use (re-use) of human tissue and ensure it is consistent with the requirements set out by *National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.49 – 7.56.*
2. Please update the Data Management Plan as it currently states there are no biobanks in the study, however the Auckland Regional Tissue Bank is being used for storage of tissue before it is transferred for batch analysis to the Liggins Institute.

**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:

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| **Meeting date:** | 16th August 2022 |
| **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 5:00pm.