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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 01 October 2024 |
| **Zoom details:** | 965 0758 9841 |

| **ime** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11:30am - 12:00pm | 2024 EXP 19716 | National Breast Cancer Analysis- Density, Access, and Outcomes | Dr. Nicholas Knowlton | Kate / Patries |
| 12:00 - 12:30pm | 2024 EXP 21064 | Impact of AI Fracture Detection on Turnaround Time and Accuracy | Radiologist and Chef Medical Officer (Dr. / Profes Martin Gunn | Dianne / Nicola |
| 12:30 - 1:00pm | 2024 FULL 20723 | Exploring How Older Adults with Memory Issues or Concerns Feel About Using Technologies for Better Brain Health | Professor Elizabeth Broadbent | Joan / Barry |
| 1:00 - 1:30pm | 2024 FULL 21236 | The Early AID Trial | Associate Professor Martin de Bock  | Kate/ Amber |
| 1:30 - 2:00pm |  | BREAK (30 mins) |  |  |
| 2:00 - 2:30pm | 2024 FULL 20464 | Dynamic prediction of postoperative complications using integrated data and multi-task artificial intelligence | Dr Chris Varghese | Kate / Barry |
| 2:30 - 3:00pm | 2024 FULL 21162 | HB0056-HV-01-01: A Study to Evaluate HB0056 in Healthy Adults | Dr Cory Sellwood | Joan / Nicola |
| 3:00 - 3:30pm | 2024 FULL 21349 | A study comparing two formulations of R-107 under fasting conditions. | Dr Noelyn Hung | Dianne / Amber |
| 3:30 - 4:00pm | 2024 FULL 19012 | SURFSUP | Dr Vinayak Kodur | Kate/ Patries |

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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 | Apology |
| 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 | Apology |
| 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 |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Apology |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Dianne Glenn | 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 Mrs Leesa Russell, Ms Maakere Marr, and Ms Alice McCarthy.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Patries Herst, Dr Nicola Swain and Ms Dianne Glenn confirmed their eligibility and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 03 September 2024 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 EXP 19716** |
|   | Title:  | From Detection to Disparity: Employing AI and GIS to Investigate Breast Cancer Outcomes in Aotearoa New Zealand's DiversePopulations. |
|   | Principal Investigator:  | Dr. Nicholas Knowlton |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 19 September 2024 |

Dr Nicholas Knowlton, Dr Alex Trevarton and Dr Annette Lasham 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 research team noted that the model may have clinical use further down the track specifically relating to breast density. There would be no commercial issues for a transition to use by Health NZ as the model is entirely open source.
2. The Committee noted that extended future use of the data suggested in the Data Management Plan would not be covered by the waiver granted as part of this application.

Summary of outstanding ethical issues

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

1. The Committee queried the funding. The Committee noted that consultation (to be undertaken as part of the activity funded by the Royal Society MBIE grant) was needed prior to the study being undertaken as the consultation is required for a waiver of consent to be granted for the study itself. The research team noted that the establishment of a advisory rōpū group was underway.
2. The Committee noted that there was no supporting documentation for the arm of the study concerning the community led development of resources. The researcher must provide this for any approval to be given and as this currently is not provided within the current submission, the Committee suggested taking this component out of the study a this qualitative arm separate from the aspects of the study for which documents have been provided. The Committee suggested the components concerning the development of resources could be reviewed by the university IEC.
3. The Committee queried where the GIS data would be coming from and how this would be linked. The researcher noted that the data would be coming from Stats NZ but that the research team would like to get specific data that would not be individually identifiable but would have a 100-household geographical area. Stats NZ requires a waiver for this. Please detail this succinctly in the protocol.
4. The Committee queried what data would be included in what was being requested from Stats NZ. The researcher noted that ethnicity and age would be included for people who had breast cancer in that 100-household area. The Committee noted this is still quite identifiable and queried what protections would be in place to ensure that nobody could link this data with other datasets and re-identify as this would be easily re-identified. The Committee asked if there would be any masking of the dataset to reduce the linkage, but the researcher noted that the linkage was needed for the research but that the storage access management would be the main security measures taken. This data would not be used in the AI part of the study. Please distinguish this in the protocol.
5. The Committee requested that a study schematic, detailing inputs and linkages, data cycles, security measure checks (‘human in the loop’), and outputs for the AI component and the parallel GIS stream.
6. The Committee noted that the peer reviewer had made a distinction between training baseline models and developing a new one. The researcher noted that they are validating a model that has already been developed for the New Zealand context. This model and the validation and training data set would not be going to the developer of the model.
7. The Committee queried why the images needed to be identifiable when entered into the model. The researcher noted that this was so that the outcomes could be associated with the input and ensure that there was actual validation. This needs to be included in detail in the protocol and the schematic.
8. The Committee queried what would be passed on to breast cancer Register. The researcher noted that this would be scores, not images and the Committee requested that this be clarified in the study documentations. Specifically, this needs to distinguish what future use will entail and what is meant at each step when “data” is to be shared.
9. The Committee requested that the rōpū as part of the work conducted by Dr Trevarton be consulted around the upload of data to the register. If the linked dataset will go to the register, if this is done at a later stage this could be done after the main research had received ethical approval.
10. The Committee requested that the Register use of data collected and linked for this study be referenced in the resubmission of this application.
11. Revise the Data Management Plan, removing extended future use and sharing.

**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 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 Patries Herst and Ms Kate O’Connor.

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| **2**   | **Ethics ref:**   | **2024 EXP 21064** |
|   | Title:  | Impact of AI Fracture Detection Software on Turnaround Radiology Report Turnaround Time. |
|   | Principal Investigator:  | Professor Martin Gunn |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 19 September 2024 |

No researcher was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted this study may not be quality assurance (QA) but that it is possible that it could be framed as such. Please refer to the guidelines set by the relevant institutions (university or Te Whatu Ora) the [National Ethical Standards](https://neac.health.govt.nz/national-ethical-standards) and the HDEC Standard Operating Procedures to determine if this research may actually be QA. In the event this is QA the application should be withdrawn.

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 to receive a waiver of consent as required for use in this study the applicant must provide documentation detailing the level of consultation and approval for use of the tool as characterised in the submission. Please provide the evidence of this and refer to the [National Ethical Standards relating to waivers of consent](https://neac.health.govt.nz/national-ethical-standards/part-two/12-health-data) para *12.28-12.30*, and what is required to obtain this.
2. The Committee queried how the research was intending to address inequity or differential diagnosis and outcomes for Māori when the study design as submitted does not have provision for the analysis of outcomes by ethnicity. Please provide a sufficient answer to how ethnicity will be collected and represented and modelled in this study in a more detailed data management plan.
3. The Committee noted that the researcher must identify a suitable person who will be responsible for the approval of the research at the locality (Chairperson or CEO or other).
4. The Committee requested assurance that the data would not be further utilised for machine learning or in training or use for an artificial intelligence.
5. The Committee queried why the study population is proposed to be 18 and over and the justification for this.

**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 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 Nicola Swain, Ms Dianne Glenn and Ms Kate O’Connor.

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| **3**   | **Ethics ref:**   | **2024 FULL 20723** |
|   | Title:  | User Feedback on the Use of a Virtual Human and Social Robots to Enhance Cognitive Health in Older Adults with Mild CognitiveImpairment |
|   | Principal Investigator:  | Professor Elizabeth Broadbent |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 19 September 2024 |

Professor Elizabeth Broadbent, Dr Ngaire Kerse, and Ms Yuan Gao 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 origin/ ownership of the social robots and virtual human as used in the research. This was discussed as part of an explanation of who could stand to commercially gain from this research.
2. The Committee clarified that rest homes may not be a good group to recruit from as the target of the research are community dwelling.
3. The Committee discussed the safety and appropriateness of group discussions (rather than one on one) and encouraged locating these in the community where possible to reduce participant inconvenience.

Summary of outstanding ethical issues

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

1. The Committee queried the recruitment strategy via advertising, and the use of the initial screening test, that could potentially indicate more than mild cognitive decline which would make the potential participant ineligible for the research (and potentially unable to consent for themselves) and how this process would be managed. The Committee requested some documentation as to how the recruitment will be designed to ensure that any potential distress that could be caused from the screening dementia test is adequately managed and any abnormal results followed up with. This should be noted in the Participants Information Sheet (PIS) and in the protocol. The Committee suggested that an abbreviated consent to screen would also be required, this could be verbal.
2. The Committee requested that the consent to screening be separate from the study PISCF.
3. The Committee noted that the research team was clearly very capable of conducting the research and was able to exemplify the practice requested by the Committee in terms of ensuring the safety of participants and determining capacity to consent and that the demonstration of knowledge and experience working with this population provided to the Committee needs to be translated to the protocol.
4. The Committee noted that sections 8.5 and 11.2 of the Data Management Plan (DMP) did not appear to be relevant to the study or match up with the protocol. Please review.
5. The Committee requested a researcher safety plan for home visits.

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

1. Please disclose from the outset, the potential commercially benefitting entities whose software etc., is being used in this study, as well as any interests members of the research team have in these.
2. Please simplify the language for the intended audience.

**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 provide a safety plan addressing the concerns raised by the Committee (National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).
3. 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).*
4. 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 Joan Petit and Mr Barry Taylor.

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| **4**   | **Ethics ref:**   | **2024 FULL 21236** |
|   | Title:  | Early Automated Insulin Delivery to improve equity in type 1 diabetes (The Early AID Trial) |
|   | Principal Investigator:  | Associate Professor Martin de Bock |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 19 September 2024 |

Associate Professor Martin de Bock, Antony Watson, Ramai Haeta, and Kelly Tikao were present via videoconference for discussion of this application.

Potential conflicts of interest

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

Dr Amber Parry Strong declared a potential conflict of interest and the Committee decided to exclude her from discussion.

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 comparators are non-Māori and non-pacific children with type-1 diabetes. This is through the national database previously approved under another application with the university.
2. The Committee clarified the process and flexibility around teaching the young people how to finger prick and the steps towards getting young people on board into the trial.

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 the protocol mention the benchmark data and the university approval for that application.
2. The Committee noted that the study protocol doesn’t describe the intent of the study. It appears to address the efficacy where the study itself is more about usability and how people are using the technology under study. Please clarify this by amending the protocol.
3. The Committee clarified that the researchers can no longer rescind the intervention from participants as of October 1st and that those benefitting from the system will be able to stay on it and have the choice as to whether they would like to continue with it post-study. Please include this in the information sheets, and address whether the smart phone with the installed app can be kept.
4. The Committee noted that the PI cannot be the responsible person for sign-off for the University as the sponsor and that they will need someone else to conduct the sponsor sign off at the research and innovation office.
5. The Committee noted that the qualitative sections of the study needed to be clarified with more detail in the protocol. Given that this component is the key research goal, the qualitative aspects should not be optional.
6. The Committee queried the process for assent and the collection and use of qualitative data from the family of the youngest participants. The researcher noted that the assent would be used from around 2 or 3 and simplified for that age group as required. The Committee pointed out that the child being unable to read was in the exclusion criteria and requested that this be protocolised in more detail and corrected where necessary to be clear as to what ages would be assented and how.

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

1. Please include that the phone may be kept depending on clarification from the provider.
2. Please remove the tick-boxes that would indicate that informing the participants general practitioner (GP) of participation or incidental findings optional. This should be mandatory.
3. Please include a cultural contact for Pasifika peoples as well as Māori 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 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 Kate O’Connor and Ms Joan Petit

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| **5**   | **Ethics ref:**   | **2024 FULL 20464** |
|   | Title:  | Dynamic prediction of postoperative complications using integrated data and multi-task artificial intelligence |
|   | Principal Investigator:  | Dr Chris Varghese |
|   | Sponsor:  | Te Whatu Ora – Waitaha Canterbury |
|   | Clock Start Date:  | 19 September 2024 |

No researcher 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 suggested that the researchers consider the [National Ethical Standards relating to waivers of consent](https://neac.health.govt.nz/national-ethical-standards/part-two/12-health-data) para *12.28-12.30*, and what is required to obtain this as this will be required to progress this application.
2. The Committee noted that the hospital is not the sponsor of the activity, just the locality. The University would be the sponsor of this study.
3. The Committee requested that as part of the locality approval process that Māori consultation be undertaken and that this specifically address the potential for cultural harm with artificial intelligence (AI).
4. The Committee requested more information concerning the process of accessing the data warehouse and queried if this was a supplementary process to obtaining locality approval from the hospital. Please clarify the stages to this and the security measures undertaken as well as any governance information or protocolisation of how access may be managed from the holders of the data warehouse. *National Ethical Standards* para *9.7, 9.8 & 12.31-12.39.*
5. The Committee noted that the protocol and the submission both speak in the past tense in stating that the aim “was therefore to utilize” and request assurances that this study has not already begun as per the Declaration of Helsinki para 23, ethical approval cannot be given retrospectively.
6. The Committee requested that the researchers utilize and submit the [HDEC AI/New technology supplementary form](https://ethics.health.govt.nz/guides-templates-and-forms/health-data-and-new-technologies-supplementary-form) with the resubmission. Particularly to provide the Committee context as to whether the study intends to develop or validate a pre-existing model/algorithm. This should also address whether there is potential for commercial gain/implications surrounding intellectual properties and by whom should the research prove beneficial in some manner. *HDEC Standard operating procedure* para *144.*
7. The Committee requested the provision of more clarity and information concerning the “local integration development environment”, and who the person responsible for security and managing access will be. *National Ethical Standards* para *9.7, 9.8, 12.15 & 12.31-12.39.*
8. The Committee requested clarification as to who was funding the study and how. *HDEC Standard operating procedure* para *144.*
9. The Committee queried how the HRC was involved in the study as the protocol utilizes the HRC logo.
10. The Committee requested evidence of the response to the points raised by the peer reviewer. *National Ethical Standards* para *9.25-9.32.*
11. The Committee requested clarification as to how the researcher will account for inequalities and systemic racism in terms of outcomes of surgery. As part of this please explore the practicalities of the bias inherent in the algorithm and provide details around how the bias will be managed. *National Ethical Standards* para *9.7, 9.8 & 12.31-12.39.*
12. The Committee queried what the researcher believes the translation of this algorithm to clinical practice may be.
13. The Committee noted that the Data Management Plan did not have the correct title and there are a lot of details retained from the template that are not accurate or should not pertain to this study, such as the return of results to participants (this is a non-consented study). *National Ethical Standards* para *9.7 & 9.8.*
14. The Committee noted that the HDEC is not the appropriate body to approve release of the data for that length of time from the data holders. As such the Committee suggests that the researcher proves the methods prior to this proposed study through a pilot that would need to be sufficiently protocolised and there must be detailed documentation of the data flow and who the persons responsible for this will be and how the data will be analysed. Stating vaguely that analysis will occur is not sufficient. The pilot would help determination of valuable data points for analysis in a broader study and ensure the safety of the people’s data given how broad the current proposal is on a population who would not be consented.

**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:**   | **2024 FULL 21162** |
|   | Title:  | A Phase 1a, Randomized, Double-blind, Placebo-controlled, Single Dose-escalation Study to Evaluate the Safety, Tolerability andPharmacokinetics of HB0056 in Adult Healthy Subjects |
|   | Principal Investigator:  | Dr Cory Sellwood |
|   | Sponsor:  | Shanghai Huaota Biopharmaceutical Co., Ltd. |
|   | Clock Start Date:  | 19 September 2024 |

Dr Cory Sellwood, Lucy Druzianic, Julia O’Sullivan, and Kayla Malate 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 the e-consent was uploaded but not mentioned elsewhere. The Researcher confirmed that this is just in case, but there is preference for consent in person.

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 regarding the protocol:
	1. Some language may be templated for trials in patient populations, but this is all healthy volunteers. Please review and amend.
	2. Further, there is a sentence saying if required there would need to be access to participant medical records before pre-screening. This is not explained anywhere else and needs to be clear if this is occurring.
	3. Page 7 of the protocol and D9 of the submission form notes an effort made to recruit as many Asian participants as possible, with a concrete outline defined of what this descent looks like. After discussion around the justification, the Committee requested this justification be explained properly in documentation.
2. The Committee noted the advertisement says women must be using copper IUD which is very restrictive. Please ensure the updated version with this removed is provided to the HDEC.

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

1. Please ensure the complete prohibition of over-the-counter medications and vitamins is noted higher up in the PIS and should be more prominent. Please also highlight if dietary supplements are included.
2. Technical language used regarding the protein interaction. This could be helped with a simplified or lay explanation around the technical description to aid understanding.
3. “Side effects are similar to an approved drug…” Define more about what ‘similar’ means and provide a little clarifying statement.

**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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| **7**   | **Ethics ref:**   | **2024 FULL 21349** |
|   | Title:  | A single dose, randomized, two period, two sequence, crossover, relative bioavailability study comparing R-107-H with R-107-P inhealthy participants under fasting conditions. |
|   | Principal Investigator:  | Dr Noelyn Hung |
|   | Sponsor:  | Douglas Pharmaceuticals Ltd |
|   | Clock Start Date:  | 19 September 2024 |

Dr Noelyn Hung, Linda Folland, Dr Jason Long, and Rhona Macdonald 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. It was clarified that the novel product is an extended slow-release tablet which reduces its abuse potential with little dissociation. After discussion, it was noted that there are no observed abuse cases from this formulation, and a few cases of side effects from discontinuation.
2. The Researchers confirmed there is a psychiatrist on site and on call after hours.
3. The Researchers confirmed mixed gender quarters are monitored for safety, and staff will also be in the room.

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 screening for ketamine is an important safety step for this protocol, and requested the Researchers investigate performing this.
2. The Columbia suicide scale is noted to also be done post-dose. The Committee requested a safety plan for how to handle concerning results.
3. Additionally, page 18 of protocol says this scale will be done to exclude those with suicidal thoughts and behaviour, but if this is done post-dose, the Committee queried if they would be excluded. The Researchers clarified they will monitor them and arrange for their care. The Committee noted that the Researchers may want to modify that section and explain what would happen at screening, pre-dose and post-dose with how each situation would be handled.
4. Both ketamine products are investigational, but page 22 has a sentence that says the purpose is to test the formulations for abuse potential. This does not appear to be the main aim pitched for this study but is written in the protocol. After discussion, it was clarified it was one of the aims, but the main purpose is the bioavailability of both formulations given these are healthy participants. This needs to be made clearer what the purpose of this study is.
5. The Committee requested to give some kind of food to participants in the morning for breakfast before they leave.

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

1. Please clarify that if someone for cultural or religious purposes wishes to be in a different room of not mixed gender, they can request that.
2. Please provide a link or information for the Medicines NZ guidelines mentioned.
3. Clarify if someone uses their personal card, they can be reimbursed by filling in a form.
4. At beginning, please advise whether an interpreter can be available.

**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 Dianne Glenn and Dr Amber Parry Strong.

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| **8**   | **Ethics ref:**   | **2024 FULL 19012** |
|   | Title:  | SURFactant Administration by SUPraglottic Airway (the SURFSUP Trial)  |
|   | Principal Investigator:  | Dr Vinayak Kodur |
|   | Sponsor:  | Te Whatu Ora – Waikato & Monash University |
|   | Clock Start Date:  | 19 September 2024 |

Dr Vinayak Kodur 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 Researcher clarified this intervention is used in this context already, and doctors know what they are doing as these are two approved devices.
2. The Researcher confirmed Māori consultation has already been undertaken.
3. The Committee noted the use of the assent form, and its intention will not work in New Zealand. The scenario of obtaining oral assent in the event of parents not having enough time to consider means there is not written informed consent for the intervention. The limitations for this in New Zealand means that the study can only enrol babies who have a full signed written informed consent from parent/legal guardian. This assent is not to be used in New Zealand, which the Researcher confirmed.

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 Researcher clarified the timeframe for parents to think about taking part in this study is more than 48 hours before birth so can be approached about the study, then after birth if baby is pre-term and needs the medicine, can be approached again. The Committee was in favour of this approach and requested this be confirmed in the study documentation.
2. The Committee noted it was inappropriate to ask parents in distress to consider videos being available wider than the study purpose. Please remove this. If the Researcher wants it for teaching purposes, they can be contacted again a month later to ask with a different consent. This should be submitted as an Amendment if this occurs.

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

1. Please include that the doctors have experience using the device and it is approved for use in New Zealand.
2. Please clarify more about the airway access. The picture provided was not super helpful, and perhaps a diagram of what it looks like inside would be useful.
3. The PIS should state this research is being conducted at Monash, and other hospitals in Europe as well.
4. Replace HREC information with Ministry of Health contact for HDEC as per the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
5. Please add advocacy contact details as per the HDEC template.
6. Please include the ACC statement from template.

**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 Kate O’Connor and Dr Patries Herst.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 5 November 2024 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 4.00pm.