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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 10 September 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10.30-11.00am | 2024 EXP 19890 | Delivery and evaluation of a health and wellbeing programme for young people experiencing psychosis | Dr Matthew Jenkins | Ms Dianne Glenn and Dr Nicola Swain |
| 11.00-11.30am | 2024 FULL 20970 | RIN-PF-305, TETON-PPF | Dr Michael Epton | Mr Dominic Fitchett and Dr Amy Henry |
| 11.30am-12.00pm | 2024 FULL 19744 | STORM-PE | Associate Professor Andrew Holden | Dr Maree Kirk and Dr Patries Herst |
|  | *Break (30)* |  |  |  |
| 12.30-1.00pm | 2024 FULL 18621 | A study testing a new pharmacist-led service to improve medicine use in older adults. | Mr Lisheng Liu | Ms Neta Tomokino and Dr Nicola Swain |
| 1.00-1.30pm | 2024 FULL 20939 | Sutra Hemi-Valve FIH study | Dr Sanjeevan Pasupati | Mr Dominic Fitchett and Dr Amy Henry |
| 1.30-2.00pm | 2024 FULL 20631 | Warfarin patient portal and self-testing | Dr Miriam Wheeler | Dr Maree Kirk and Dr Patries Herst |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Dr Devonie Waaka  | Non-lay (Intervention studies)  | 18/07/2016  | 18/07/2019  | Present  |
| Mr Dominic Fitchett  | Lay (the Law) (Chair) | 05/07/2019  | 05/07/2022  | Apologies |
| Dr Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | 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 |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Present  |

## Welcome

The Chair opened the meeting at 10.00am and welcomed Committee members, noting that apologies had been received from Dr Devonie Waaka.

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 confirmed their eligibility and were co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 13 August 2024 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 EXP 19890** |
|   | Title:  | Moving with psychosis: Delivery and evaluation of a health and wellbeing programme for young people experiencing psychosis |
|   | Principal Investigator:  | Dr Matthew Jenkins |
|   | Sponsor:  | The University of Otago |
|   | Clock Start Date:  | 10 September 2024 |

Dr Matthew Jenkins, Dr Victoria Chinn, Mr Alex El Amanni 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 the participants would be recruited through existing services and clinician support was available.
2. The Committee queried maximum numbers of participants as this was unclear. The Researcher stated 15 participants (with up to 15 support people) will fulfil the research project but if capacity allows more participants may join the activities. Additional participants will not have data collected for the research purposes.

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 advertising is updated to include the University of Otago logo and the HDEC approval number (2024 EXP 19890). Please state whether sessions are expected to be longer than two hours so participants are aware of the time commitment.
2. The Committee requested the protocol is updated to include more detail on clinician support for the participant and follow-up after the study. Please include a statement on the underlying cause of psychosis.
3. The Committee requested the data management plan is updated to specify what data is collected from the phone app and how it is managed distinct from other study data.
4. The Committee requested the information sheet is updated to include information about the smartphone app or separated into an optional sheet as participants cannot consent now and receive information about it at a later date. If details regarding the app have not been finalised yet this may be submitted via the amendment pathway.
5.

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

1. Please include the University of Otago logo at the top of the sheet.
2. Please amend the incomplete sentence “This may lead to us knowing.”
3. Please revise the retaining data paragraph to be more specific on what will or will not be destroyed. Please change 5 years to 10 years. Please state where data will be kept and in what form.
4. Please include contact information for the HDC advocacy service, the HDECs and a number for Māori cultural support.
5. Please revise the ‘What will I do’ section to clearly state one session per week for around two hours so participants understand what their participation involves.
6. Please state that participants will be in a group setting with other participants and their support people (up to 30 in total).
7. Please state at the beginning of the sheet to let the study team know if an interpreter is required.
8. Please state how much money is available for travel/parking expenses and koha available.
9. Please include more information on what participation involves (eg focus group interviews, physical activities).
10. Please specify what components whānau or friends may attend and how many may attend.
11. Please include a statement informing participants to maintain the privacy of others in the group.
12. Please revise the statement that it will not be possible to identify individual contributions due to the use of pseudonyms as this cannot be guaranteed and depending on what a participant discloses it may still be possible to identify them.
13. Please include a statement advising if a participant withdraws whether they can withdraw their data (eg focus group contributions) or at what point this will not be possible.
14. Please include a statement regarding what information whānau or support people may disclose about participants.
15. Please clarify if service providers will complete focus group surveys or interviews.
16. Please amend anonymous information to deidentified.
17. Please include information on ownership rights of images and how they may be used. Please specify photos will be of spaces and places and not participants or people.
18. Please clarify the app will collect location (and how to turn it off).
19. Please clarify that audio recordings will be destroyed once transcribed.

**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).*
4. Please update the advertising.

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Dianne Glenn and Dr Nicola Swain.

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| **2**   | **Ethics ref:**   | **2024 FULL 20970** |
|   | Title:  | A Randomized, Double-blind, Placebo-controlled, Multinational, Phase 3 Study of the Efficacy and Safety of Inhaled Treprostinil in Subjects with Progressive Pulmonary Fibrosis (TETON-PPF) |
|   | Principal Investigator:  | Dr Michael Epton |
|   | Sponsor:  | United Therapeutics Corp. |
|   | Clock Start Date:  | 29 August 2024 |

Dr Michael Epton and Ms Malina Storer 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 Researcher confirmed there are no restrictions on rescue medications if required.
2. The Committee advised that it is not permitted to terminate a study solely for commercial reasons in New Zealand. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.37)*

Summary of outstanding ethical issues

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

1. The Committee requested someone who is not the participant’s clinician is involved at some part of the consenting process to give them the opportunity to say no to someone who is not their treating clinician.

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

1. Please include a short lay-friendly title (eg a brief explanation of what the study is for).
2. Please remove the reference to Medsafe and state the nebuliser device is not approved in New Zealand.

**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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| **3**   | **Ethics ref:**   | **2024 FULL 19744** |
|   | Title:  | STORM-PE: A Prospective, Multicenter, Randomized Controlled Trial Evaluating Anticoagulation Alone vs Anticoagulation plus Mechanical Aspiration with the Indigo® Aspiration System for the Treatment of Intermediate High Risk Acute Pulmonary Embolism |
|   | Principal Investigator:  | Dr Andrew Holden |
|   | Sponsor:  | Penumbra Inc |
|   | Clock Start Date:  | 29 August 2024 |

Dr Andrew Holden was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee queried how mental distress caused or discovered through the questionnaires would be addressed. Please detail a safety protocol surrounding this and the timely follow up of suicidality or mental distress indicated as part of the study. Please include details on this in the PISCF as well.

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

1. Please include some details of the potential side effects of the study.
2. Please include the auditors access of information in the information sheet prior to mentioning it in the consent form.
3. Please include the lay title.
4. Please clarify that participants not recruited to the Indigo system intervention arm will still receive standard treatment. This is not clear.
5. Please remove the tick box for informing the GP of significant abnormal results.
6. Please clarify the statement, “you may be treated with the Penumbra, Inc. Indigo Aspiration System even if you don’t participate in this study” and whether this is true in New Zealand.
7. Please clarify “If participants provide optional additional consent, de-identified data and tissue will be made available for future research as specified above and may be added to data from other sources to form larger datasets”. If this will occur say so clearly.

**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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| **4**   | **Ethics ref:**   | **2024 FULL 18621** |
|   | Title:  | A cluster randomised controlled trial to evaluate a pharmacist-led intervention addressing inappropriate polypharmacy and its impact on medication use outcomes in older adults |
|   | Principal Investigator:  | Mr Lisheng Liu |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 29 August 2024 |

Mr Lisheng Liu 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 queried if the study was testing the tool that identifies the patients. The researcher noted that the tool would identify the patients, but this was part 1 of 4 where there would be review of those patients and then provision of feedback, planning and follow up.
2. The Committee queried how feedback would be given based on the use of the tool. There would be feedback from the pharmacist to the primary physician of the patients identified within the study as well as later on with those patients in the practice not in the study with the goal of reducing inappropriate prescription. The appropriateness of the prescription would not be specifically due to one reason but would be determined by a panel that considered a range of potential issues that may occur for older adults and potential for harm.

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 what reason control participants would want to participate as there is no clear direct benefit. The researcher clarified that whilst during the study they would largely be doing this altruistically that there would be review of their medicines after the study to also gain a portion of benefit from the intervention. Please include this in the participant information sheet/consent form (PIS/CF).
2. The Committee requested that the adverts provided contain the HDEC application number and the University of Auckland logo.
3. The Committee requested how the questionnaires would be administered. Please clarify this in the PIS/CF and the data management plan (DMP). Please note that this needs to address how it will be administered as well as how addresses will be gained and consent to send questionnaires will be obtained.
4. The Committee requested some detail in the Protocol as to how the 16 regions will be selected out of the 19 regions in Te Whatu Ora. The Committee suggested some thought into how this may be available to rural communities.
5. The Committee noted that translation will need to take into account dialects and differences between areas in the study.
6. The Committee queried how reimbursement for services offering sign language or other disability services indicated in the PIS/CF will be managed and requested more information for participants around this reimbursement.
7. The Committee requested the wording in the adverts be reviewed for clarity.
8. The Committee requested the following changes to the DMP:
	1. Please review and remove sections that are not related to this study such as CROs, international sponsors, future use and identifiable information.
	2. Please separate out the data streams (i.e. pharmacist data, GP data, etc.) and detail who will do the interviews and how each dataset will be managed.
	3. Please remove the note to researchers from page 3 as this is template information only.

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

 **All PISCFs**

1. In addition to points noted above:
2. Please state that at the end of the study the participants clinician will receive information from the study that they may act on.
3. Please note that the data bank registry is specifically referring to the keeping of a national scale database to be used for future secondary use. This is not the case and what the researcher appears to have interpreted this as registering the trial. This can be removed from the PISCF. This does not need to be in the consent form as it is not required.
4. Please reword the statement “you will be helping people in our community/will be helping clinics improve quality” to “you *may*” as this is not a guarantee.
5. Please state how long participants will be in the trial.
6. Please be clear about what data will be collected as current statements are vague.

**Patient PISCF**

1. Please remove the tick box from the GP notification part of the consent as it is a compulsory part of participation.
2. Please recognise in this document the giving of time by patients as there is no koha. Some recognition of whānau time still needs to be given as koha is about reciprocity not payment for time. Please justify why this is not possible.

**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 advertisements, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).
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).
5. Please update the data management plan to ensure the safety and integrity of participant data *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Neta Tomokino and Dr Nicola Swain.

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| **5**   | **Ethics ref:**   | **2024 FULL 20939** |
|   | Title:  | First in Human Study of the Sutra Hemi-Valve to Assess Safety and Performance in Patients with Mitral Regurgitation  |
|   | Principal Investigator:  | Dr Sanjeevan Pasupati |
|   | Sponsor:  | Sutra Medicals Inc. |
|   | Clock Start Date:  | 29 August 2024 |

Dr Sanjeevan Pasupati, Mrs Simi Christudas Jayakumari, Ms Liz Low, Ms Barbara Lindsay, Mr Wei Sun Ms Caitlin Martin and other members of the research and sponsor team 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 requested that for future applications please ensure that all study procedures are correctly detailed in the submission form.
2. The Committee clarified that the selected option in the submission that states participants have already given consent is incorrectly ticked.
3. The Committee clarified that the selected option in the submission that states identifiable tissue will be sent overseas is not correct.

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 an updated insurance certificate listing the protocol number and New Zealand as a region covered by the insurance.
2. The Committee requested that whether tissue will be sent overseas be clearly detailed in the protocol and the data tissue management plan (DTMP).
3. The Committee requested clarification in the protocol if there will be a stand down period after the study intervention to assess impact of the intervention. If the intent is to do one participant first to see how they go before continuing with more participants, please detail this.

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

1. Please include in the black box that this is a first in human trial.
2. Please ensure that participants are aware that the intervention contains products derived from bovine.
3. Please provide a lay summary of the listed risks. These need to be easily understandable and the Committee would prefer that they are separated out by likelihood of occurring. Please include numbers of occurrence in a 1 in 100 format.
4. Please clarify what collected data will become study data versus what will become part of their clinical medical record.
5. Please state what imaging will be sent overseas (and in what form this will be sent) in the PIS rather than first introducing this in the consent.
6. Please remove the paragraph related to “Loss of Confidentiality” in the risks section (page 8), as this is covered in the information section on page 12.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Dr Amy Henry.

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| **6**   | **Ethics ref:**   | **2024 FULL 20631** |
|   | Title:  | Warfarin self-testing and use of a patient web portal for individuals living with rheumatic heart disease and mechanical valve replacement |
|   | Principal Investigator:  | Dr Miriam Wheeler |
|   | Sponsor:  | Auckland Hospitals Research and Endowment Fund of Te Toka Tumai Auckland |
|   | Clock Start Date:  | 29 August 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 vague answers to the HDEC application made it difficult to ascertain what the study involved without referring to the protocol and requested the Researcher be mindful of this for future submissions.

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 clarification on how many participants would be enrolled.
2. The Committee queried whether interviews were optional or mandatory.
3. The Committee requested good quality ethnicity data is collected for final reporting to HDEC. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.10.*
4. The Committee queried how often participants would use the portal and how often they would test normally. The Committee queried how often portal data will be checked and when and how it will be analysed.
5. The Committee queried if portal data will be compared across participants and with non-portal using participants.
6. The Committee queried how a participant with a health issue would be identified.
7. The Committee requested confirmation as to whether there was any ability for the researchers to provide internet access where individuals may not currently have it but would wish to participate.

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

1. Please include more information about the interviews for participants.
2. Please include detail on training required.
3. Please fix the logo as it bleeds into the text.
4. Please clarify what happens to the audio recording once transcribed on page 3.

**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 Maree Kirk and Dr Patries Herst.

## General business

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

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| **Meeting date:** | 08 October 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 1.40pm