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| **Committee:** | NTA Health and Disability Ethics Committee |
| **Meeting date:** | 15 July 2025 |
| **Zoom details:** | 812 7953 3520 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12.00-12.30pm |  | Committee Welcome |  |  |
| 12.30-1.00pm | 2025 FULL 23158 | TERN-701-1012 - Participants with Chronic Myeloid Leukaemia (CML)/Phase 1 | Professor Peter John Browett | Dr Catriona McBean / Dr Kate Parker |
| 1.00-1.30pm | 2025 FULL 22549 | RASolve 301: Phase 3 Study of RMC-6236 in Previously Treated NSCLC Patients with RAS Mutation | Dr Laird Cameron | Ms Kate O’Connor / Dr Andrea Forde |
| 1.30-2.00pm | 2025 FULL 23377 | TRX-100-0002: A Study to Evaluate Different Oral Doses of TRX-100 and Standard of Care in Participants with Influenza | Dr James Stanley | Mr Jonathan Darby / Dr Kate Parker |
| 2.00-2.30pm |  | *Break (60 mins)* |  |  |
| 3.00-3.30pm | 2025 FULL 22585 | A pilot implementation study of a telehealth intervention aimed at improving adolescent outcomes following acquired brain injury | Associate Professor Kelly Jones | Ms Kate O'Connor / Dr Katrina Gibson |
| 3.30-4.00pm | 2025 FULL 22169 | Using Empathic Characters for Virtual Cognitive Rehabilitation | Professor Mark Billinghurst | Dr Catriona McBean / Dr Andrea Forde |
| 4.00-4.30pm | 2025 FULL 23439 | REPORT Study (REducing the PrOgression of diabetic kidney disease) | Dr Kalpa Jayanatha | Mr Jonathan Darby / Dr Kate Parker |
| 4.30-5.00pm | 2025 FULL 23330 | LTG-32-013: Phase 1 Single and Multiple Ascending Dose Study of LTG-321 in Healthy Participants. | Dr Cory Sellwood | Ms Kate O'Connor / Dr Malisa Mulholland |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Kate O’Connor | Lay (Ethical/Moral reasoning) (Chair) | 09/06/2025 | 8/06/2030 | Present |
| Dr Kate Parker | Non-lay (Observational studies) | 09/06/2025 | 08/06/2029 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies) | 09/06/2025 | 08/06/2030 | Present |
| Ms Catherine Garvey | Lay (the Law) (Chair) | 09/06/2025 | 08/06/2030 | Apology |
| Dr Malisa Mulholland | Non-lay | 09/06/2025 | 09/06/2028 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Dr Katrina Gibson | Non-lay | 09/06/2025 | 08/06/2029 | Present |
| Dr Catriona McBean | Lay | 03/03/2025 | 02/03/2030 | Present |

## Welcome

The Chair opened the meeting at 12:00 and welcomed Committee members, that apologies had been received from Catherine Garvey

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 17 June 2025 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **FULL 23158** |
|  | Title: | A Phase 1 Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of TERN-701 in Participants with Chronic Myeloid Leukaemia |
|  | Principal Investigator: | Professor Peter Browett |
|  | Sponsor: | Terns, Inc. |
|  | Clock Start Date: | 3 July 2025 |

Peter Browett and Vaidehi Chaporkar 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 Researchers clarified that participants who derive benefit from the study drug will be offered continued access after the trial. The sponsor has committed to provide the drug in an extension study or on compassionate grounds until an alternative treatment becomes available, ensuring no participants are left without therapy if the investigational treatment is helping them. This extension study will be submitted as an amendment to the study once protocolised.

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 a study in New Zealand cannot be terminated for commercial reasons. Please ensure the sponsors are aware of this and revise the Participant Information Sheet as necessary.
2. The Committee noted the significant commitment required from participants. While expenses are reimbursed, there is no provision for compensation for time. The Committee requested that the sponsor consider providing further compensation to acknowledge the burden on participants.
3. The Committee requested written confirmation from senior officials from the Sponsor that there is no United States government funding for this study.
4. The Committee questioned whether such frequent pregnancy testing is warranted for this study, especially if participants are competent to consent to participation in the study, well advised around contraception, and the risks to a pregnancy, and hence the importance of the avoidance of a pregnancy. The requirement and frequency of this testing needs to be properly justified, reduced, or removed to acknowledge the participants’ competence, ensure respect for participants’ autonomy and privacy while still acknowledging the risks associated with a pregnancy.

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

1. Please revise the Participant Information Sheet (PIS) to ensure that the study treatment is not suggested to be a potential ‘treatment’ for chronic myeloid leukaemia. Explain that this is a Phase 1 study with an investigational medicine and should not indicate that the study medicine is a treatment option
2. Please update the wording in the PIS for clarity around dose levels for each part of the study and how they are determined. Currently the PIS states that part one of the study is being done to determine the dose levels and then goes on to indicate that part two of the study already has the dose levels determined.
3. Please clarify the sites that will be involved in the study, and whether primary care sites will be involved.
4. Please remove the statement in the PIS that advises participants to ‘ask the study doctor to explain any payments for which you may be responsible.’ As participation in this trial will not incur any charges to the participant
5. Please include information on what the potential maximum study duration could be.
6. Please include in the PIS what a participant should do if a participant forgets or misses a dose of the study medication. Currently, instructions about missed doses are unclear and only found in the draft diary and not in the main information sheet. Please revise the information provided in the diary and include the same information in the PIS.
7. Please add a specific line in the consent form for participants to indicate whether they consent to genetic testing
8. Please add an option in the consent form for participants to indicate if they wish to receive study results.
9. Please revise the section in the PIS about genetic testing to clearly explain that any genetic tests performed in this study are only looking at specific mutations related to the study and will not be looking at any hereditary diseases. Please also revise to address any cultural concerns that participants may have as well.
10. Please revise the reference to medication storage being out of reach from children to be in a standalone section for clarity.
11. Please revise the tables referring to dosing to align with instructions and instructions for what to do if a dose is forgotten.
12. Please revise for the New Zealand context, references to the EMA and FDA can be replaced with Medsafe or by clarification that the investigational medicine is not licensed by any regulator including Medsafe.
13. Please ensure that it is clear where the 22 previously treated patients received the investigational medicine.
14. Please remove reference to ‘coin flip’
15. Please clarify or describe what ‘local rules’ are in the PIS and ensure that this is customised to the New Zealand context.
16. Please revise contraception section to include any expectations for male participants, and the partners of male participants and ensure that gender neutral language is used in this section.
17. Please ensure that the contraception and pregnancy sections explain what participant obligations are if they are part of this study, including the duration that contraception measures are expected for.
18. Please revise the references to ‘drug’ or ‘study drug’ to ‘investigational medicine’
19. Please revise references to ‘side effects’ to ‘adverse events’
20. Please revise the contraception advice to remove unnecessary contraceptive measures as the consent form currently requires condom use in addition to other highly effective forms of contraception. The Committee noted this may be unnecessary for certain individuals. For instance, a participant who has had a tubal ligation or has an hormonal implant or IUCD does not need to use condoms for pregnancy prevention.
21. Please remove references to the Medicines New Zealand guidelines if Terns is not a member of Medicines New Zealand. Please ensure any references to the guidelines are kept as brief as possible.
22. Please ensure the Future Unspecified Research form is reviewed for typographical and grammatical errors
23. Please review the PIS for repetition. For example, the voluntary nature of participation is provided multiple times within the document. Additionally, the statement ‘you will not take part in the study after withdrawal’ is self-evident and can be removed.
24. Please revise statement ‘tissue destruction’ to ‘tissue disposal’.
25. Please revise the PIS to ensure that it is clear that New Zealand participants will only be included in part two of the study. References to part one of the study can be removed to avoid confusion.

**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 Catriona McBean and Dr Kate Parker.

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| **2** | **Ethics ref:** | **FULL 22549** |
|  | Title: | RASolve 301: A Phase 3 Multicenter, Open Label, Randomized Study of RMC-6236 versus Docetaxel in Patients with Previously Treated Locally Advanced or Metastatic RAS[MUT] NSCLC |
|  | Principal Investigator: | Dr Laird Cameron |
|  | Sponsor: | Revolution Medicines Inc |
|  | Clock Start Date: | 3 July 2025 |

Dr Cameron Laird and Azmeena Sajid 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 clarified that the exclusion of pregnant or lactating individuals from this trial is in line with the same exclusion criteria from standard care. This is due to safety concerns for both the standard chemotherapy and that the investigational drug could harm an unborn child or nursing infant.
2. The Researcher clarified that participants will continue to take the study drug indefinitely as long as it is providing benefit. The ‘end of treatment visit’ is only for participants who need to go off the treatment for a specific reason.

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 study design does not include a crossover or guaranteed post-trial access for participants randomised to standard therapy (docetaxel). The Committee requested that a plan be provided, such as an open label extension trial, for post-trial access so both arms can access the investigational treatment if it shows clear benefit.
2. The Committee noted that the pre-screening information sheet/consent form is overly detailed for permission to review health records and possibly perform a KRAS test. The Committee requested that if a pre-screening consent is used, it be significantly shortened to cover only the necessary record review/test, omitting full study details. If routine practice renders this pre-screening unnecessary, the Committee suggested removing the separate pre-screening consent step entirely.
3. The Committee requested official confirmation from senior executives of the sponsor that no U.S. federal funding is involved in this study.
4. The Committee requested clarification on the types of petrol and meal vouchers that will be offered to participants. The Committee noted that fast-food vouchers could be inappropriate and recommended using grocery or general food vouchers to better support participants’ well-being.
5. The Committee noted the expectation that a trial conducted in New Zealand should lead to an application for local licensure so that successful experimental medicines, trialled upon NZ participants, become available to New Zealand patients.
6. The Committee requested clarification on whether the information provided in the main PIS regarding future unspecified research of tissues is separate from the information provided in the separate FUR information sheet and consent form.
7. The Committee noted that the unspecified use of data can be included as an option in the main PIS and consent form but for tissues a separate form would be needed.
8. The Committee noted that the protocol tests for pregnancy every 21 days for participants of childbearing potential and questioned whether such frequent testing is necessary since participants will be thoroughly advised of the risks and cautioned against becoming pregnant and as noted by the researcher, this frequency is not standard in routine care. The Committee requested that the sponsor reconsider the pregnancy test schedule to reduce unnecessary burden on participants noting that participants of child bearing potential are competent to consent, are advised of contraceptive measures, and also of the potential risks to a pregnancy.
9. The Committee requested assurance that the sponsor will cover any additional medical costs or needs arising from trial participation. For example, if the investigational drug causes side effects like skin rash that require specific treatments or products, the Committee expects the sponsor to provide or pay for these, rather than having participants or the publicly funded health system bear the cost.

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

1. Please review the PIS for any typos and repetitive content and remove any duplicate or unnecessary information. [The HDEC intervention study template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/PISCF-template-intervention-studies-1.docx) can be used as a resource for PIS revisions.
2. Please update to reflect that this is a single-site study.
3. Please remove any statements that indicate the study could be stopped for commercial reasons as this is not permitted in New Zealand.
4. Please clarify the description of the treatment schedule in the PIS. Ensure the diagram clearly states that one group will take an oral investigational tablet daily, while the other group receives an IV chemotherapy once every 3 weeks, so that participants understand the different regimens.
5. Please revise the PIS to clarify what benefits or aspects of care a participant would forfeit by withdrawing from the study, and what they would not lose. It should be clear that choosing to withdraw will not affect the participant’s standard medical care or rights
6. Please use the term ‘investigational medicine’ instead of ‘investigational drug’
7. Please ensure that it is clear that this investigational medicine is not yet approved by Medsafe or any other regulatory authority.
8. Please consider updating the dietary advice in the PIS to include other food such as dragon fruit as well.
9. Please ensure the PIS is clear that docetaxel is an approved ‘medicine’ in New Zealand as opposed to an approved ‘drug’
10. Please revise the section about COVID-19 and pandemics. If required, a brief statement that study activities will continue as per standard of care even in the event of pandemics, epidemics or outbreaks can be included.
11. Please revise the contraception and pregnancy statements for clarity. Participants who cannot become pregnant, for instance, those who have had a hysterectomy or tubal ligation, should not be asked to use barrier contraception like condoms. However, consideration as to whether male participants should use condoms to protect any sexual partners from potential medicine exposure, not just to prevent pregnancy, if the medicine, its metabolites or excipients, or chemotherapy could be present in bodily fluids such as seminal fluid should be included.
12. Please remove the paragraph referencing the Medicines New Zealand Code of Practice if the sponsor is not a member of Medicines New Zealand.
13. Please inform participants that the researchers will check vital records to determine a participant’s status if they are lost to follow-up.
14. Please remove the yes/no tick box next to notification of GP of participation in study as this is mandatory.
15. Please clarify in the PIS that any counselling or support services offered to participants will be arranged at no cost to the participant.
16. Please use the ‘disposal of tissue’ rather than ‘destruction of tissue’
17. Please reword the phrase ‘unborn baby toxicity’ for clarity and without reference to unborn baby’.
18. Please clarify the information about tumour biopsies in the PIS. It should be made clear that providing a tumour sample is a required part of the study if an existing biopsy sample is not sufficient for the study’s needs. In this case participants will be asked to undergo a new biopsy, paid for by the sponsor, as a condition of continuing in the trial.
19. Please correct the description of the CT scan schedule in the PIS. Currently, the PIS suggests that the amount of radiation or number of scans is the same as normal care, but in this trial participants will receive CT scans every 6 weeks, which is more frequent than standard of care for patients who are stable.

**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 Andrea Forde.

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| **3** | **Ethics ref:** | **FULL 23377** |
|  | Title: | TRX-100-0002: A Multicenter, Open-Label, Randomized Phase 2a Study to Evaluate the Safety and Efficacy of Different Oral Doses of TRX-100 and Standard of Care in Participants with Influenza |
|  | Principal Investigator: | Dr James Stanley |
|  | Sponsor: | Trawsfynydd Therapeutics AU Pty Ltd (On behalf of Traws Pharma, Inc.) |
|  | Clock Start Date: | 3 July 2025 |

Charlene Botha, Eugenia Ezhova, David Pauza, Ali Davies, James Stanley and Kate Dokukina 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 Andrea Forde declared a potential conflict of interest related to this application however the Committee resolved that the member did not need to be excused from discussion for this review.

Summary of resolved ethical issues

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

1. The researchers clarified that any patient in hospital care for the influenza will **not** be enrolled in the study.
2. The Researchers clarified that they do not intend to do viral culture in this study. The Committee recognised this, however, highlighted that this can cause issues in influenza studies.

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 significant challenges in recruiting acutely ill patients within 48 hours of symptom onset who are then identified as having influenza infection and raised concerns about the risk of such participants spreading respiratory infections when coming into the clinic as currently proposed in the study protocol. The Committee requested a detailed plan to address these practical issues, for avoiding harm to the community. For example, guidance on safe transportation, procedures for coming into the clinic, or the possibility of home visits before the study proceeds *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.1-8.3; 9.7-9.8)*.
2. The Committee queried issues around diagnosis of influenza, the influenza season, and requested further detail such as which Rapid Antigen Test was going to be used and what the positive predictive value is for this test.
3. The Committee noted that seasonal influenza is not a notifiable disease in New Zealand while both Highly Pathogenic Avian Influenza or a new strain of influenza are . This would also need to be addressed in the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
4. The Committee requested that the finalised advertisements be provided (noting the plans for community safety in relation to the confirmatory RAT), and the advertising include a statement indicating that the ethical aspects of the study have been approved by HDEC *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12)*.
5. The Committee requested that the participant compensation be re-evaluated and revised for consistency across advertisements and the information provided in the PIS. Currently the advertisements indicate a lump sum will be paid, however the PIS indicates that there is no payment offered to participants. The Committee highlighted the demanding study schedule, including a 16-hour clinic visit when the person is ill and noted that food would not be provided (although reimbursed), further increasing the risk of spreading respiratory illness. The Committee noted that this is a substantial burden on sick volunteers and asked the sponsor to consider providing appropriate compensation and benefits. Additionally, a revised reimbursement plan needs to have the requirement of receipts and sponsor review to be removed *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.21)*.
6. Please review the Data and Tissue Management Plan for typos and missing links *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17)*.
7. The Committee requested a clearer justification for excluding pregnant and breastfeeding individuals from the trial. Given that influenza infection during pregnancy can pose serious risks and outcomes, to both the pregnant person and the pregnancy, the Committee noted that it is important to explain why these participants are excluded. The investigators should clarify if this is due to unknown safety data for the investigational drug and if the risks of influenza during pregnancy have been assessed against the risks of the investigational drug *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8;9.19).*
8. The Committee noted that the study refers to vaccines from 2020 and 2021 and requested information on whether these are the trivalent or quadrivalent vaccines, the inactivated or live attenuated, cell or egg based, and Southern versus Northern Hemisphere vaccines, as this can impact the study and the results of the study if conducted in NZ *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please correct and streamline the participant documents for clarity and consistency. Fix all typos and broken links, and ensure terminology is used consistently, for example, use either “avian influenza” or “bird flu”.
2. Please remove any irrelevant references, such as mentions of insurance company billing procedures that do not apply in the New Zealand context.
3. Please refer to the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) for guidance on the PIS wording for sections on insurance and contraception.
4. Please ensure the PIS is revised for plain language.
5. Please remove paragraph on page 3 of the PIS about collecting a urine sample for pregnancy testing. This information is explained later in the document in the proper context.
6. Please remove the requirement for an alcohol breath test at screening, as this was noted to have been an error.
7. Please remove references providing that study could be stopped for commercial reasons as this is not applicable in New Zealand.
8. Please provide more information about how incidental findings will be handled when reporting to GPs and what incidental findings could be during this study.
9. Please clarify the screening process, the statement that screening “may take up to 72 hours” could be misinterpreted as continuous observation. Please explain instead that screening may involve up to two visits over a few rather than confinement for 72 hours.
10. Please use the ‘disposal of tissue’ rather than ‘destruction of tissue’
11. Please update the PIS to indicate that the study will assess the safety and efficacy of the investigational influenza medicine, rather than to “confirm” safety and efficacy.
12. Please ensure that it is clear that licensed medicines for influenza such as neuraminidase inhibitors are excluded from the study.
13. Please revise PIS for consistency when referring to ‘drug’ and ‘medicine. Instead refer to ‘licenced medicines’ and ‘investigational medicines’.
14. Please provide clear guidance on what medications participants can or cannot take during the trial. For example, let participants know that they may use paracetamol (acetaminophen) for fever or pain, but should avoid other anti-inflammatories like ibuprofen or aspirin unless the study doctor says it’s okay
15. Please ensure the PIS is clear that participants will not be hospitalised as part of the study, unless deemed clinically necessary for care, and revise PIS where necessary.
16. Please clarify what will happen with the virus samples collected in the study. Please clearly state if the samples will only be used for measuring viral load and not for culturing. Ensure the PIS doesn’t suggest any procedures that are not actually going to happen in this study.
17. Please provide clear instructions to participants about eating and drinking recommendations. If there are specific times, participants need to fast or avoid specific fluids when taking the study medication, outline those clearly, otherwise, reassure participants that they should continue to follow standard of care i.e bed rest and the drinking of clear non-alcoholic fluids while sick.
18. Please revise wording ‘father a child’ to state ‘getting a partner pregnant’ as this encompasses the broader range of possibilities.
19. Please provide guidance on what medications participants can or cannot take during the trial. For example, let participants know that they may use paracetamol (acetaminophen) for fever or pain, but should avoid other anti-inflammatories like ibuprofen or aspirin
20. Please adjust the injury compensation statement in the PIS. If the sponsor or site is not a member of the Medicines New Zealand organisation, remove the reference to the Medicines NZ guidelines. Ensure that the PIS clearly explains the process for compensation in the event of study-related injury in line with HDEC requirements.
21. Please clearly outline the pregnancy testing schedule and method. State when pregnancy tests will be done and whether they will be urine or blood tests as current indication is that there will be two pregnancy tests within 3 days.
22. Please clarify what ‘PK analysis’ is for participants especially for lay perspective.
23. Please review for the use of plain English. For example, the use of “concomitant use” on p3.

**Decision**

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

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| **4** | **Ethics ref:** | **FULL 22585** |
|  | Title: | A pilot implementation study of a telehealth intervention aimed at improving adolescent outcomes following acquired brain injury |
|  | Principal Investigator: | Associate Professor Kelly Jones |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 3 July 2025 |

Kelly Jones 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 confirmed that this project is an observational study evaluating the implementation of an existing Teen Online Problem Solving (TOPS) program rather than a new intervention trial. The Researchers clarified the study’s nature, as TOPS is already offered as part of standard care and the research will only observe its use and outcomes. As such the Committee noted that the review and decision made for this study is with the understanding that this is an observational study.
2. The Researchers explained that treating therapists will not directly recruit patients into the study, preventing any perceived pressure on families. Instead, families already using the TOPS program will learn about the research through a link or notice on the program’s website that they can choose to click.
3. The Researcher confirmed that, if a family is using TOPS, then they will already be eligible for participation in the study and that therapists will not be involved in any screening aspects of the study.
4. The Researcher described how the TOPS program was adapted for New Zealand with input from experts and feedback from Māori reviewers. Appropriate usage and New Zealand relevant scenarios have been included in the adapted version to ensure cultural suitability

Summary of outstanding ethical issues

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

1. The Committee requested that the researchers provide any wording or posters that will be used for the purposes of recruitment notice and an invitation that will be shown to potential participants on the TOPS website.
2. The Committee noted that each participating service provider involved in implementing the TOPS program will require locality approval for the study. The Researchers must confirm institutional sign-off and research governance approval from sites.
3. The Committee requested a more detailed Data Management Plan, outlining exactly how data will be collected, handled, and protected. This plan should clearly identify all sources of data, including information entered by families into the TOPS software, therapist-administered questions at discharge, and the short demographic survey, and who will have access to each type of data. It should clearly explain the differences distinguishing study data and its sources from regular uses, outline exactly which data is going to be used in the study, and the data flow and storage of study data. An explanation that a designated ‘TOPS champion’ at each site will extract de-identified data and send it securely to the research team, who will not have access to any identifiable data. Any involvement of external IT support, such as Triple Orbits in the U.S or Cheeky Monkey in New Zealand, who maintain the TOPS platform, does not need to be included in study documentation as they are involved on the standard operating of the platform. A diagram outlining these different data interactions can be included.
4. The Committee queried the necessity of the brief capacity assessment questionnaire and requested that this aspect be removed given the context of the study (i.e. this is an observational study and participants already have to have enough capacity to be able to use the TOPS program).
5. The Committee requested that the notification of the participant’s care provider in the case serious concerns are raised for a participant’s safety and wellbeing be mandatory.
6. The Committee recommended that the proposed koha of a $20 petrol or supermarket voucher for each participating family be revised and potentially increased

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

1. Please clarify the distinction between the therapy and the study in the PIS. It should explicitly state that taking part in the research is voluntary and separate from receiving the TOPS. Ensure it is clear that withdrawing from the study will not affect care in any way.
2. Please put more study structure in the header and include the providers.
3. Please ensure that the PIS is clear about what taking part in the study means for participants and what taking part in TOPS entails. Please include a diagram or timeline outlining what the therapy is, what the research is and at what points these intersect to provide clarity to participants.
4. Please remove the ACC injury compensation statement from the PIS as this is not applicable to this study.
5. Please remove the reference to contacting HDEC with complaints or concerns about aspects of the study
6. Please ensure that only the PIS for adult participants mentions the availability of AUT counselling services, as AUT’s counselling is only provided for adults
7. Please adjust the child assent forms for younger children version and an older children version
8. The Researcher explained that any conflict arising is part of the normal therapeutic process and is handled by the trained therapists and not managed as part of the study.
9. Please simplify the separate service provider consent letter or form. This document should be shortened to cover only the essential points such as allowing access to de-identified data or staff cooperation, and assurances about how client safety, security and confidentiality will be protected.
10. Please revise the PIS for typos and repetition.
11. Please ensure that there is support for alternatives to phone conversations such as a contact email address and that these options for support are provided in the PIS.
12. Please ensure that it is clear that HDECs approve only ethical aspects of the study

**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 9.7-9.8)*.
4. Please update the data management plan, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).

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 Katrina Gibson.

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| **5** | **Ethics ref:** | **FULL 22169** |
|  | Title: | Using Empathic Characters for Virtual Cognitive Rehabilitation |
|  | Principal Investigator: | Professor Mark Billinghurst |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 3 July 2025 |

Researchers were not present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee noted that early-stage activities such as focus groups, co-design and testing with healthy volunteers would fall under institutional ethics committee (IEC) review and do not require HDEC approval.
2. The Committee requested that, once the study protocol has been developed to include patients with traumatic brain injury, this be submitted to HDEC to address the ethical issues for including this population. At this point this should include a review of the participants’ capacity to consent, outline how voluntary informed consent will be obtained, and ensure comfort and convenience for participants throughout the study. Recruitment strategies must also be clearly described *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*
3. The Committee requested clarification on the inclusion of a Quality of Life questionnaire in the study. It was unclear why this survey was needed for a primarily VR rehabilitation study. If quality of life is not a central outcome, the Committee suggested removing the QoL survey to reduce participant burden. If it is included because of concerns about participant well-being, its results must be incorporated into the safety plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.1-8.3; 9.7-9.8)*.
4. The Committee requested a comprehensive safety monitoring plan for the intervention. They questioned how the researcher will identify if the VR tool is causing any harm or undue stress and noted that clear criteria to halt the study or an individual’s participation are needed if adverse effects occur or if the study is proving not feasible *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
5. The Committee noted that some of the proposed questionnaires and assessments may be overly long or complex for participants with brain injuries. For example, the application included very detailed surveys which the Committee considered could overwhelm or stress participants. It is also unclear if these instruments have been validated for use in traumatic brain injury populations. As such, the Committee requested that engagement with clinical experts be sought to determine what is appropriate on questionnaires to get meaningful information for the research while not putting undue stress and pressure on participants *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
6. The Committee noted that greater clinical oversight in the project is advised, as there are no clinicians listed as investigators, which is a concern given the medical needs and origins of the participant group. The Committee recommended adding a clinician to the research team or as a supervisor, to provide guidance on medical aspects of the study. A peer review by a clinical expert, in addition to the VR specialist, is also advised to vet the study design from a healthcare perspective. Additionally, the Committee noted that participants’ GPs should be informed of their patient’s involvement in the study and that the protocol should include a plan for notifying the participants’ GP or other relevant healthcare providers, as appropriate, to ensure continuity of care and safety monitoring outside the research setting *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
7. The Committee noted that the applicant stated there was no commercial interest in the study, but found this point needed clarification. It should be explicitly confirmed whether any commercial or proprietary software/hardware is involved and whether there are any conflicts of interest. In a resubmission, the researcher should clearly state the presence or absence of commercial interests or sponsorship, to ensure transparency *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.23)*.
8. The Committee requested a more thorough consideration of participants’ mental health and any psychiatric or psychological comorbidities from the submission.
9. The Committee noted that the application’s response regarding Kaupapa Māori did not align with the rest of the information provided for this application.
10. The Committee noted that the application did not adequately address how the study will accommodate participants with disabilities, cognitive or physical, resulting from their brain injuries. This population may have special needs in terms of communication, comprehension, mobility, or use of the VR equipment. The researcher must ensure that all study procedures are accessible and tailored to participants’ abilities *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 5.11; 5.13; 9.7-9.8)*.

**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:** | **FULL 23439** |
|  | Title: | REducing the PrOgression of diabetic kidney disease: A cluster Randomised Trial (REPORT Study) |
|  | Principal Investigator: | Dr Kalpa Jayanatha |
|  | Sponsor: | Te Whatu Ora Counties Manukau |
|  | Clock Start Date: | 3 July 2025 |

Dr Kalpa Jayanatha, Viliami Tutone, Tanya Poppe and Sumudu Ranasinghe 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 raised concerns about seeking a waiver of consent, or an opt out consent model when conducting an interventional study. It was clarified that this study follows a service optimisation model whereby any intervention measures occur only at the practice level. This can include adjusting clinic workflows or adding a study-funded nurse for support, to ensure patients receive standard of care as opposed to the current usual care, which tends to fall well below the recommended standard of care thereby ensuring patients are better looked after. With confirmation that patients will not receive any new treatments only enhanced usual care to reach the recommended standard of care, the committee agreed the project effectively functions as an observational study and therefore a waiver of consent was acceptable for using de-identified patient data.
2. The Committee queried why practices needed to be randomised to intervention vs. usual care instead of using historical data as a control. The Researchers explained that standards of diabetic kidney care have changed in recent years, for example, new medications and criteria have been introduced, so historical comparisons would not give reliable information for this study.
3. The Researchers clarified that the different PHOs and their Kaimanaaki have different models of care, such as doing home visits. This further clarified that any additional services offered by some PHOs as a result of being in this study still fall within the standard of care model.
4. The Researchers clarified that not all of the additional tests or procedures associated with extra clinic resourcing will result in additional cost to patients, for example, GPs will have access to specialists, follow ups can occur via phone, or additional blood tests have no additional associated costs.
5. The Researchers clarified that no identifiable patient information will leave the participating general practices. All research data will be de-identified and transferred through secure, routine PHO processes.
6. The Researchers confirmed that all PHOs will have access to Care Plus patient support pathways regardless of which arm the practices are randomised into.

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 participants in the sites that are randomised into the intervention practices might face additional GP visit costs due to the enhanced follow-up care, and requested that the researchers analyse potential financial barriers, for example, Care Plus funding use by PHO and any missed appointments due to cost, as part of the study’s outcomes to ensure cost does not prevent participants from receiving optimal standard of care.
2. The Committee noted that the justifications for the need for a waiver of consent for the use of data in this study are rendered moot by the provision of the possibility of participants opting out. As such, the Committee recommended removing the information around opting out from the poster and from the study leaflet.

**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:** | **FULL 23330** |
|  | Title: | A Sequential, Randomized, Double-Blind, Placebo-Controlled, Phase 1, Single and Multiple Ascending Dose Study of LTG-321 Administered Orally to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics in Healthy Male and Female Participants 18 to 55 Years of Age. |
|  | Principal Investigator: | Dr Cory Sellwood |
|  | Sponsor: | Latigo Biotherapeutics, Inc. |
|  | Clock Start Date: | 3 July 2025 |

Dr Cory Sellwood, Chris Wynne, Kayla Malate, Julia O’Sullivan and Samantha Nie 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 Researchers are as follows.

1. The Researchers assured the Committee that the scientific literature supports the assertion that pain perception varies significantly throughout the menstrual cycle. The exclusion of females from part C was therefore justified to reduce variability in results in this early-phase trial.
2. The Researchers clarified that the study is structured in multiple parts. Where in the first stages the safety and efficacy of the investigational medicine is tested then followed by the cold pressor test as a low-risk way to induce pain in healthy volunteers for an early efficacy signal. This pain test will only proceed if the investigational medicine is found to be safe in the earlier parts. The Researchers noted that the cold pressor test causes temporary pain without lasting harm, allowing efficacy data without enrolling actual patients at this stage.
3. The Researchers clarified that Wellington is included only in Part C as this part will require more participants than part A and B. The Wellington site will assist in meeting the recruitment targets for Part C.
4. The Committee inquired about non-English-speaking participants and how, if there is a requirement for an interpreter for the consenting process, but not to explain or instruct in study procedures, they will be able to be included in the study. The Researchers highlighted that the need for an interpreter to assist during the consent process to fully explain risks may be necessary, while the level of comprehension and understanding to actually participate and follow instructions in English is much lower and would not require the use of an interpreter.
5. The Researchers clarified the study will not be storing tissue for future unspecified research.
6. The Researchers clarified that, while there is a specified discontinuation review scheduled in part C, the patients are checked for any reason for discontinuation at every visit.
7. The Committee queried the provision that “abstinence” is only accepted as a method of contraception if it is in ‘line with the participant’s usual lifestyle’. The Researchers clarified that in the case of abstinence, it has been found that it is only a reliable form of contraception it if does already align with someone’s lifestyle, not for those who indicate that they will become abstinent for the duration of the study.
8. The Researchers clarified that requiring condom or barrier contraceptive use even when a female partner has had a tubal ligation is in line with international research guidelines since tubal ligation, while highly effective, is not absolutely 100%, is reversible, and is treated as still having a risk of risk. The Committee expressed its surprise at this and queried whether clinicians recommending and performing tubal ligations and people who have had tubal ligations are aware of this approach by other colleagues and researchers.
9. The Committee queried the need for multiple pregnancy tests during screening, followed by another relatively quickly, including one after a 16-day inpatient stay. The Researchers indicated that the additional timepoints give reassurance that participants are not pregnant coming into the trial as a pregnancy might not be detectable at the first test. The Researchers noted that participants who are confident they are not pregnant have, in past experiences, occasionally had unexpected positive tests. Further, the Researchers clarified that menstrual history, and reproductive history comes before the pregnancy testing.
10. The Researchers clarified that the wording around male participants discussing contraception with female partners has been updated to include a provision that the participant is responsible for informing their partners of the risks and implications as well as contraceptive expectations for those on the study.
11. The Researchers confirmed that participants are ruled out from re-participation in subsequent cohorts.
12. The Researchers confirmed that the PIS for each of the stages of the study include information about travel, related logistics, and as a separate reimbursement and can be discussed with study staff in more detail if required.

Summary of outstanding ethical issues

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

1. The Committee requested that the study advertisement and participant materials be corrected to state that the cold pressor test “may be used” instead of "will be used." This clarifies that the cold pressor portion will only occur if the trial progresses to Part C. Additionally, the Committee requested that all study materials make it clear that the cold pressor test portion is limited to male participants only to avoid any confusion for potential female volunteers.
2. The Committee requested that recruitment materials clearly communicate that the cold pressor procedure will cause pain. So that potential participants are fully aware of what it entails and can self-select after seeing the advertisements.
3. The Committee requested screening for participants COVID-19 vaccination status be removed from this study.
4. The Committee requested the removal of the need for participants to keep bus ticket receipts for reimbursement and that the petrol rate be updated.
5. The Committee requested clarification regarding of the signatory’s position within the company from the sponsor’s support letter included with the application.

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

1. Please check the formatting for withdrawal statement in PIS.
2. Please remove the broad data sovereignty statement from the consent form that ‘allows Māori organisations access to data.’
3. Please add a statement to clarify that any blood or tissue samples collected will not be returned to participants, even if requested. Include an explanation as to why these samples cannot be returned.
4. Please ensure that there is a clear explanation of “blinding” in the Part C Participant Information Sheet/Consent Form as explained in other parts of the study.
5. Please ensure that it is clear to participants that, if the use of condoms is required then the use of lube is also recommended for use with barrier contraception.
6. Please ensure site location is explicitly stated in the diagram for part B.
7. Please ensure it is clear that all inpatient stays and dosing will occur at the Christchurch site regardless of whether recruitment occurs in Wellington

**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).*
* 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).

## General business

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

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| **Meeting date:** | 19 July 2025 |
| **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.