|  |  |
| --- | --- |
| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 01 April 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 11:00am-11:30am |  | Committee Welcome |  |  |
| 11:30am-12:00pm | 2025 FULL 22135 | (Duplicate) Ketamine Sedation In Acute Traumatic Brain Injury: A Randomized Pilot Feasibility Study | Dr Jonathon Taylor | Ms Kate O’Connor / Dr Amber Parry-Strong |
| 12:00pm-12:30pm | 2025 FULL 22080 | ASCEND EV Study | Dr Matthew Daly | Ms Maakere Marr / Mrs Leesa Russell |
| 12:30pm-1:00pm | 2025 FULL 22523 | A study testing MAR001 that may help lower triglycerides and leftover cholesterol in blood | Dr Joanne (Jo) Finlay | Ms Catherine Garvey / Mr Barry Taylor |
| 1:00pm-1:30pm |  | *Break (30 mins)* |  |  |
| 1:30pm-2:00pm | 2025 FULL 22477 | A randomised trial of WET therapy for PTSD comparing 5 sessions over 5 weeks or 2.5 weeks | Professor Bruce Arroll | Ms Kate O’Connor / Mr Barry Taylor |
| 2:00pm-2:30pm | 2025 FULL 22083 | Fully automated artificial pancreas in adults with previously above-target type 1 diabetes | Professor Benjamin Wheeler | Ms Catherine Garvey / Mrs Leesa Russell |
| 2:30pm-3:00pm | 2025 FULL 22370 | AROAPOC3-3006: An Open-Label Extension Study Evaluating Long-Term Safety and Effectiveness of Plosiran in Adults with High Triglycerides (SHASTA-10 study) | Professor Russell Scott | Ms Maakere Marr / Dr Amber Parry-Strong |
| 3:00pm-3:15pm |  | *Break (15 mins)* |  |  |
| 3:15pm-3:45pm | 2025 FULL 22564 | BI1378-0023: A study to test whether vicadrostat in combination with empagliflozin helps people with Chronic Kidney Disease | Dr Andrew Edwards | Ms Catherine Garvey / Mrs Leesa Russell |
| 3:45pm-4:15pm | 2025 FULL 22145 | Growing Screws for SCFE | Doctor Andrew Kim | Ms Kate O'Connor / Dr Amber Parry-Strong |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 | Present  |
| 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 | Apologies |
| 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 | Present |
| Dr Joy Panoho | Lay  | 03/03/2025 | 02/03/2030 | Present |
| Ms Catherine Garvey  | Lay (the Law)  | 11/08/2021  | 11/08/2024  | Present  |

## Welcome

The Chair opened the meeting at 11.00am and welcomed Committee members, noting that apologies had been received from 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. Ms Catherine Garvey confirmed their eligibility and were co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair welcomed Dr Joy Panoho as a new member of the Committee.

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 04 March 2025 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1**   | **Ethics ref:**   | **2025 FULL 22135** |
|   | Title:  | Ketamine Sedation In Acute Traumatic Brain Injury: A Randomized Pilot Feasibility Study |
|   | Principal Investigator:  | Dr Jonathan Taylor |
|   | Sponsor:  | Monash University |
|   | Clock Start Date:  | 20 March 2025 |

Dr Jonathan Taylor and Dr Colin McArthur 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 the rationale for doing this study in this population is well-made that the use of ketamine sedation needs further evidence to support clinician’s choice in using it.
2. The Committee noted that participants will also be enrolled in the precision TBI study and inquired about the link between the two studies. The Researcher explained that the precision TBI study is an observational study using clinical records, which has been approved by HDEC. The rationale for linking the two studies is to reduce the data acquisition burden. The Committee emphasised the importance of keeping the consent processes separate, even if the discussions occur simultaneously.

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 discussed the best-interests argument for unconsenting participants under Right 7(4) of the Code of Rights. The Researcher suggested in the cover letter that there will be additional monitoring and a greater focus on certain aspects of treatment and care. It is essential to clearly outline the inclusion benefits and the specific extra checks and monitoring in the protocol to satisfy this requirement. This information is summarised only in the cover letter and should be included for any other co-investigator on the study in the study documents. It must also be clearly communicated in the letter to whānau, explaining the decision to continue and why it is in the participants' best interests to be included. Additionally, there should be a provision to document the clinician's decision for each participant, explicitly stating they as the doctor believe it is in their patient’s best interest to participate.
2. The Committee discussed the extended future use of data in the data management plan (DMP), noting that this involves unconsented data for unspecified future uses. The Committee asked whether a distinction would be made between data obtained with consent and data without consent, suggesting that some confinement be placed around the latter. The Researcher responded that since this is not a compulsory component of participation, it can be made optional for those who consent to the study-specific collected data. The contingency planning document could include this refinement.

**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 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).*
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 Amber Parry Strong.

|  |  |  |
| --- | --- | --- |
| **2**   | **Ethics ref:**   | **2025 FULL 22080** |
|   | Title:  | Assessment of a Chronically Implanted Parasternally Delivered EV-ICD Lead (ASCEND EV) Study |
|   | Principal Investigator:  | Dr Matthew Daly |
|   | Sponsor:  | AtaCor Medical, Inc. |
|   | Clock Start Date:  | 20 March 2025 |

Dr Matthew Daly 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 that the Investigator's Brochure (IB) provided for this submission offers substantial context and assurance. The Sponsor demonstrates reasonable engagement with New Zealand ethical standards, and the additional peer review by a New Zealand expert is very helpful.
2. The Committee and Researchers discussed that the cases potentially being enrolled involve serious but not life-threatening conditions, and there is no need for quick decision-making. Defibrillators are offered only to those who have recovered sufficiently to ensure their heart will not fail, or to those born with a condition that predisposes them to cardiac arrest. Currently, these devices are not being used in the paediatric population, but that is the potential direction in which the research is heading.
3. The Committee inquired whether the study is specifically targeting Māori and Pacific populations or if it is expected to include a larger population. The Researcher confirmed that the conditions being studied are anticipated to be more prevalent in these populations. The Committee noted that the exclusion criteria based on BMI could limit inclusion, especially if these conditions have a high incidence in these populations. The Researcher explained the required margin and noted that being very overweight would reduce these margins. The Committee was assured however that the study would eventually be more inclusive of higher BMI populations.

Summary of outstanding ethical issues

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

1. The Committee asked whether there is any federal US funding involved that could potentially be at risk. The Committee requested confirmation from the Sponsor to ensure that the study will not be abruptly terminated.
2. The Committee requested to ensure notification to GP about participation is mandatory, not optional.
3. The Committee inquired about the provision of identifiable data to the sponsor. The Data Tissue Management Plan (DTMP) states in section 8.4 that the data is identifiable. If this is not the case, please amend the DTMP. If the data is only identified by a study ID, please clarify that.
4. The Committee inquired about what happens if the device stops working. The Researcher explained that the defibrillator generator is standard and not experimental, and clinic visits, along with X-rays, will monitor its functionality. If the device fails, the patient will revert to the standard of care (SOC). The Committee requested that this information be clearly stated in the Participant Information Sheet (PIS), including the assurance that patients will receive a new standard device if necessary.
5. The Committee discussed the intent of marketing-purpose photos taken of clinical trial participants, noting that photos of the implant site could include identifiable tattoos. The Committee suggested making the use of such photos optional or avoiding photography where there are obvious identifiers. This should be clearly stated in the Participant Information Sheet (PIS), explaining that the photos could be used for marketing purposes and participants have the option to decline if they do not want their photos used.
6. The Committee reminded that C4 of the application form is designated for Māori data only and emphasised the need to be more specific in these sections regarding cultural issues. Please provide further clarification for this submission via the cover letter.

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

1. Please review and amend the PIS to ensure it is easy to understand, especially the sections that describe procedures. Including some diagrams would be helpful to make the information clearer.
2. Some parts of the document are complicated and should be simplified. The photos included have been very helpful.
3. For the Transesophageal Echocardiogram (TEE) that some people may need, the risks are listed, but the procedure itself is not described. Please add a description of the procedure to make it clear for everyone.
4. Regarding the reimbursement on page 13, there are two options available. However, it was suggested to stick with petrol or grocery vouchers as they are tax-free. The word 'NOT' is quite extreme; please change it to 'not'.
5. Review all Māori words for correct macron usage.
6. When listing reasons for removing participants from the trial, please consider softening the language.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data and tissue 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, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Maakere Marr and Mrs Leesa Russell.

|  |  |  |
| --- | --- | --- |
| **3**   | **Ethics ref:**   | **2025 FULL 22523** |
|   | Title:  | Phase 2b Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study of MAR001 in Patients with Elevated Triglycerides and Remnant Cholesterol (TYDAL-TIMI 78) |
|   | Principal Investigator:  | Dr Joanne Finlay |
|   | Sponsor:  | IQVIA |
|   | Clock Start Date:  | 20 March 2025 |

Dr James Stanley, Charlene Botha, Simon Carson, Mark Joing, Rebecca Juliano, Ethan Weiss, and Andrew Lane 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 inquired about StudyHub and the use of videos for medication compliance, noting that this is a new approach they haven't seen before. They acknowledged the benefit of allowing participants to stay at home and avoid travel but expressed concerns about the intrusiveness of video surveillance. The Sponsor explained that the videos provide visual confirmation that the proper dose was administered correctly and clarified that the video meetings are not recorded.
2. The Committee asked whether there is any US federal funding tied up with this application that could potentially endanger the research. The Sponsor confirmed that no federal funding is involved in the study.
3. The Researcher confirmed registration on clinical trials registry before starting.
4. The Committee discussed the exclusion of pregnant and lactating women, inquiring whether they would normally be treated for this condition. The Researcher explained that they potentially would be, but since this is an early-stage study, there could be risks involved. The Committee asked for an update on the assessment of reproductive risks when available and noted that the exclusion is out of an abundance of caution.

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 final advertisements need to be submitted. When creating social media ads, please ensure that comments are moderated or turned off.
2. The Committee noted concerns about the follow-up procedure from the Sponsor for participants withdrawing from the study, describing it as quite intrusive. The Committee requested a review to ensure that the follow-up is conducted appropriately and through the New Zealand sites. Additionally, if there is to be any additional follow-up, it must be ensured that participants have consented to this.
3. The Committee noted that there is a lengthy section on data linking on pages 13 and 14 of the participant information sheet, but this information is not included in the Data Management Plan (DMP). The Committee requested clarification on what data is being linked and asked for this to be clearly specified in the DMP.

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

1. The Committee noted that the Participant Information Sheet (PIS) needs a review. There are several places with double words, typos, and it needs more spacing
2. Please ensure measurements for fluids are written in millilitres, not teaspoons.
3. On page 6, please list the options for the sites will have for karakia.
4. If Sponsor is committed to Medicines NZ guidelines, please state this definitively or delete.
5. The Committee requested to state that notification to the GP is mandatory, not optional.

**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 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 Catherine Garvey and Mr Barry Taylor.

|  |  |  |
| --- | --- | --- |
| **4**   | **Ethics ref:**   | **2025 FULL 22477** |
|   | Title:  | A Randomised Controlled Trial to Compare five sessions of Written Exposure Therapy for PTSD given weekly for five weeks or twice weekly for 2.5 weeks  |
|   | Principal Investigator:  | Professor Bruce Arroll |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 20 March 2025 |

Professor Bruce Arroll 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 confirmed that this therapy technique has been applied in practice and that participants will not be required to pay to receive it for participation. If participants decide to join the study, the five sessions will be free.
2. The Committee confirmed with the Researcher that participants with reduced literacy will receive information verbally and have a conversation to ensure understanding. Additionally, those who cannot provide their own consent will be excluded from the study.

Summary of outstanding ethical issues

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

1. The Committee noted that the notice/advertisements need to be clearer that the therapy is already on offer and that the study aims to determine if it is more effective when administered once a week or twice a week, with the frequency being randomised. The notice should specify who you are looking for, what is involved, and the duration of the study.
2. The Researcher confirmed that most participants live close by, so increased frequency will not be an extra burden. If someone needs a taxi, it can be paid for. The Committee requested that this information be included in the Participant Information Sheet (PIS).
3. The Committee noted that the research question is stated on page 4 of the PIS, but it should be more upfront. Additionally, the research question should be included on the recruitment poster, clearly stating that the study aims to determine if doing the procedure more frequently will result in a better outcome.
4. The Committee requested that a safety plan or contingency be provided to give participants more tools rather than just the helpline card. It was suggested to include a takeaway safety plan for participants.

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

1. The Committee suggested that the details of what will happen at visits could be summarised in a table rather than being written out in paragraphs.
2. The Committee suggested reviewing the document for any repetition of information.
3. The Committee noted that there are still references to "WET" in the document. Please review and consider using a different acronym for participants.
4. The Committee suggested that the benefits should distinguish between those receiving the therapy normally and those participating in this research. The focus should be on the potential benefit of receiving the therapy more frequently.
5. The Committee suggested that the PIS should be framed to address someone who has just had their first session.
6. Please be clearer that information from the sessions will be kept and reviewed before it is destroyed or given to the participants. The Committee also noted that the university may have its own policy on sensitive data, so please ensure compliance with their data governance.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Mr Barry Taylor.

|  |  |  |
| --- | --- | --- |
| **5**   | **Ethics ref:**   | **2025 FULL 22083** |
|   | Title:  | Closing the loop with the FLIP-IT trial – Fully automated insulin delivery and patch pumps in adults with type 1 diabetes and abovetarget glycaemia |
|   | Principal Investigator:  | Professor Benjamin Wheeler |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 20 March 2025 |

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.

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

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 role of the distributor, noting that while they are not involved in the analysis, the balance of benefit to the distributor is unclear. If the distributor receives the dataset, even if de-identified, it tips the balance. The involvement of a co-investigator working for the distributor further complicates matters. Additionally, informing participants that they can purchase the device after the trial introduces another layer of concern. The Committee questioned what benefits the participants would receive, emphasising that it is unfair to offer something superior to other market options only to take it away. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.19.d, 11.23, 12.15a)*
2. The Committee noted that the app used requires a proper security review. The Participant Information Sheet and Consent Form (PIS/CF) should clearly state what information the app might take from the Android phone. Additionally, any risks associated with using open-source technology need to be highlighted. There should also be reassurance regarding the algorithm's use, specifying that it does not consider factors such as ethnicity to make decisions and will only adjust the clinical indication.
3. The Committee inquired whether the Data Tissue Management Plan (DTMP) includes keeping identified video recordings of interviews and questioned the rationale behind this. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
4. The Committee noted that the recruitment seems to be targeting Māori and Pacific participants, which while can be justified, there needs to be transparency about this. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.6c, 9.9a, 11.5).*
5. The Committee inquired about the PIS/CF section in the application that mentions "setting realistic expectations about the system with participants." Please clarify this.

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. The Committee noted that it is not explained to participants that they do not usually use what is involved in the study. While the side effects are explained, this information is not made clear upfront.
2. The PIS should be clearer about what the BMI standard deviation means in lay terms.

**Decision**

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

|  |  |  |
| --- | --- | --- |
| **6**   | **Ethics ref:**   | **2025 FULL 22370** |
|   | Title:  | A Phase 3 Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Plozasiran in Adults with Hypertriglyceridemia (SHASTA-10 study) |
|   | Principal Investigator:  | Professor Russell Scott |
|   | Sponsor:  | IQVIA RDS Pty. Ltd |
|   | Clock Start Date:  | 20 March 2025 |

Dr Jane Kerr, Julia O’Sullivan, Kayla Malate, and Lucy Druzianic 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 that the cover letter clarifies that the study will not be affected by any US federal funding issues.
2. The Committee inquired about the protocol for when the open label extension ends. The Researcher explained that participants will be transferred to the standard of care (SOC).

Summary of outstanding ethical issues

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

1. The Committee requested clarification on the parent study from which the New Zealand participants are coming, as the current information is too general and not applicable to these participants.
2. The Committee suggested rewording the alternative treatments section to state that there are other options available and to discuss these with your GP. Additionally, please remove niacin if it is not available in New Zealand. Some other things mentioned, such as fish oils, are not publicly funded.
3. The Committee suggested allowing participants to choose between petrol or grocery vouchers.
4. The Committee requested a review of the document to ensure correct spelling and macron usage for Māori words.
5. The Committee noted that there is a repeated sentence on page 12 of the document.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Maakere Marr and Dr Amber Parry Strong.

|  |  |  |
| --- | --- | --- |
| **7**   | **Ethics ref:**   | **2025 FULL 22564** |
|   | Title:  | A Phase II randomised, double-blind, parallel-group, multicentre, international trial to investigate the safety and efficacy of vicadrostat and empagliflozin administered with simultaneous vs staggered initiation in participants with chronic kidney disease at risk of kidney disease progression. |
|   | Principal Investigator:  | Dr Andrew Edwards |
|   | Sponsor:  | Boehringer Ingelheim |
|   | Clock Start Date:  | 20 March 2025 |

Dr Andrew Edwards and Dr Richard Stubbs 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 confirmed that sufficient cultural considerations have been addressed as part of the locality approval.

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 insurance certificate does not specify New Zealand as a covered territory. They requested that a memorandum be sought from the insurer to confirm that New Zealand is covered.
2. The Committee requested a description of the broad scope of the Future Use of Research (FUR) in the Data Tissue Management Plan (DTMP) as it differs from the Protocol.
3. The Committee queried the sponsor's practice of surveying participants about the conduct of the investigator, specifically the 'patient trial experience survey' which involves sending contactable data back to the sponsor. While this would be acceptable if conducted at the site, the sponsor-initiated aspect tied into the study is problematic. If it is part of the study, it needs to be protocolised. If it is not, the Committee questioned why it is being included. Additionally, it is not good Good Clinical Practice (GCP) to encourage participants to identify themselves to the sponsor. This should also be addressed in the Participant Information Sheet (PIS).

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

1. Please ensure measurements for fluids are written in millilitres, not teaspoons.
2. The Committee suggested that the reference to the stipend should include the actual figure in all the information sheets.
3. The Committee suggested that the phrase "Do not participate in another research study" should be clarified to specify that it refers to clinical trials.
4. If Sponsor is committed to Medicines NZ guidelines, please state this definitively.
5. The Committee requested that the contraception and risks section be revised to use gender-neutral language.
6. The Committee noted that the data section from the HDEC PIS template is laid out better than the sponsor’s wording. It is suggested to use the HDEC PIS template for clarity and consistency.
7. The Committee noted that the Biobanking Participant Information Sheet (PIS) references individual consent restrictions but does not explain what this entails. Please provide a clear explanation of what individual consent restrictions are and how they apply to 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 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 data and tissue 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, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Catherine Garvey and Mrs Leesa Russell.

|  |  |  |
| --- | --- | --- |
| **8**   | **Ethics ref:**   | **2025 FULL 22145** |
|   | Title:  | Static Versus Free Gliding Screws in Slipped Capital Femoral Epiphysis: A Randomised Controlled Trial |
|   | Principal Investigator:  | Dr Andrew Kim |
|   | Sponsor:  | Te Whatu Ora Health New Zealand - Waikato |
|   | Clock Start Date:  | 20 March 2025 |

Dr Andrew Kim 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 how much time potential participants would have to consider joining the study. The Researcher said in many cases it is an acute scenario that requires treatment as soon as possible and they may only have a couple of days to decide.
2. The Researcher confirmed the screws are supplied by the hospital and have been used before.

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 confirmed each site has supervisor consultant paediatric surgeons with experience of the equipment and condition. The Committee requested this is made clear in the information sheet.
2. The Committee requested a photograph or diagram of the screws and their placement with a visual explanation of how the old screws and new screws are different.
3. The Committee requested the data management plan is updated to remove prompts from the HDEC template which are not applicable (e.g. the CRO, a commercial sponsor and potential commercial use of data, future unspecified research). Please remove anything that is not relevant to this study.
4. The Committee queried if something went wrong and a screw had to be removed if there is a difference in risks between the old and new screws. Please include this information in the information sheet.
5. The Committee requested the protocol is updated to include information on the study sponsor (Te Whatu Ora Health New Zealand Waikato), the name of the investigators, the manufacturer of the device and information about the screws.
6. The Committee noted the 5 – 9 year and 9+ year group assent forms did not contain many differences and the language of the younger sheet could be simplified further. The Committee noted the sheets are not firm categories and depending on each individual’s understanding and literacy they may benefit from a simpler sheet or one with more comprehensive information.

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

1. Please remove ‘yes / no’ tick boxes unless they are truly optional (i.e. the participant can answer NO and still participate).
2. Please include a statement advising parents that the surgeons have used the screws before and have sufficient training.
3. Please amend the sentence ‘one stops you from growing’ in the assent form as this may be misinterpreted.
4. Please include a statement advising that both arms of the study are going to fix the immediate problem (i.e. the pain) but the screws might perform differently over time and the study will determine how the new screws work long term.
5. Please amend the continued participation form to specify what information has been collected and its purpose so participants can make an informed decision when they turn 16.
6. Please state any known rates of removal due to screws breaking (e.g. X in 100 screws will fail and require removal).

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

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 Amber Parry-Strong.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 06 May 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 4.15pm with a karakia.