|  |  |
| --- | --- |
| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 02 July 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 11.30am-12.00pm | 2024 FULL 20554 | Randomized, Controlled Trial Comparing GenIcular Artery EmbOlization Using Embosphere Microspheres to Corticosteroid iNjections for the Treatment of Symptomatic Knee Osteoarthritis: MOTION Study | Dr Rahul Bera | Ms Catherine Garvey and Dr Devonie Waaka |
| 12.00-12.30pm | 2024 FULL 18155 | Psilo Feasibility Study | Dr Valerie Tan | Ms Catherine Garvey and Dr Amber Parry-Strong |
| 12.30-1.00pm | 2024 EXP 20626 | Cognitive disorders research clinic | Dr Campbell Le Heron | Ms Maakere Marr and Mr Barry Taylor |
| *Break (10)* |  |  |  |  |
| 1.10-1.40pm | 2024 FULL 20155 | M22-128: Relapsed or Refractory Diffuse Large B-Cell Lymphoma: Phase 3 Study to Evaluate the Safety and Efficacy of Epcoritamab Plus Lenalidomide Compared to Rituximab Plus Gemcitabine and Oxaliplatin | Dr Sophie Leitch | Ms Catherine Garvey and Ms Joan Pettit |
| 1.40-2.10pm | 2024 FULL 20591 | Paracetamol and Ibuprofen in Kids Intervention (PIKI) Study | Dr Eunicia Tan | Ms Maakere Marr and Dr Devonie Waaka |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Kate O’Connor  | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Apologies |
| Mrs Leesa Russell | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Apologies |
| 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 |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Catherine Garvey  | Lay (the Law) (Chair) | 11/08/2021  | 11/08/2024 | Present  |

## Welcome

The Chair opened the meeting at 11:00am and welcomed Committee members, noting apologies had been received from Ms Kate O’Connor, Mrs Leesa Russell and Ms Alice McCarthy.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Catherine Garvey confirmed her eligibility and was co-opted as acting Chair of the Committee for the duration of the meeting. Dr Devonie Waaka confirmed her eligibility and was co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 04 June 2024 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1**   | **Ethics ref:**   | **2024 FULL 20554** |
|   | Title:  | Multi-centre, Prospective, Randomized, Controlled Trial Comparing Genicular Artery Embolization Using Embosphere Microspheres to Corticosteroid injections for the Treatment of Symptomatic Knee Osteoarthritis: MOTION Study |
|   | Principal Investigator:  | Dr Rahul Bera |
|   | Sponsor:  | Merit Medical Systems, Inc |
|   | Clock Start Date:  | 20 June 2024 |

Dr Rahul Bera and Mr Hector Gonzales were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the number of participants intended to be recruited in New Zealand. The Researcher noted the complications in this recruitment pool and how the referral and recruitment process would occur.
2. The Committee clarified that this device is already in use in other joint replacement interventions.
3. The Committee clarified the way in which the microspheres influence pain by working directly to reduce blood flow to areas of inflammation believed to be the drivers of the pain response.
4. The Committee clarified the selection of arteries that would be suitable for treatment via angiogram to reduce off-target or incorrect application of the intervention. The researcher noted that there were multiple methods through which the team could prevent off-target embolization.

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 insurance certificate reflect the number of anticipated participants. Amend as necessary.
2. The Committee requested that the researchers ensure that the PI was not the person responsible for the recruitment of participants and that the first approach to potential participants be made by someone not directly responsible for their clinical care.
3. The Committee queried why a standard hospital consent form is being utilized in addition to the study participant information sheet/consent form (PIS/CF), as the study information forms should be comprehensive enough to cover every aspect of the study. The Committee queried why this was the case and after some discussion recommended that the legal team at the hospital be consulted as to why this is required. The Committee went on to note that if the information and consent forms for the hospital are required as part of the study then these need to be provided for review.
4. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
	1. In section 3, please reference the applicable data governance policies for the lead site.
	2. In section 7.3, either specify what anonymous data may be collected and used or amend to “does not apply”.
	3. In section 11, please amend the statement concerning return of safety and screening results to participants to note that this will be done as they become available rather than “after the study” as is currently stated.

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

1. Please clarify the process for participants if the intervention is not able to be completed once the surgery is underway.
2. Please provide more information about what the study intervention does and the way it works for participants.
3. Please provide likelihood of risks as a number out of 100 or 1000 etc., please group these by rarity of risks.
4. Please ensure that the approval of the intervention is clear as FDA clearance does not mean much to New Zealand participants. Please contextualise and make this clear.
5. Please clarify that this is an investigational product.
6. Please clarify what this study hopes to achieve as it is currently unclear what the potential benefit to participants may be compared to standard of care.
7. If contraception is required, please include contraceptive advice per the [HDEC PISCF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).
8. Please include the approximate number of New Zealand participants who will be included in the trial.
9. Please avoid the use of the terms “treatment” or “treatment group” for avoidance of misconception about the investigational nature of this intervention.
10. Please clarify the additional angiogram during the screening period and please ensure that the time of this angiogram is clearly defined.
11. Please review and replace jargon with lay language.
12. Please include a table for summary of assessments for participants to know what is required of them and when.
13. Please state approximately how long each visit will take.
14. Please include an approximation of the radiation that will be received in the study comparative to background radiation experienced day-to-day.
15. Please include the [HDEC PISCF template statements](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) around access to and amendment of data as well as privacy breach.
16. Please remove the section in the consent form relating to pregnant partner risk.
17. Please include the information as to what anaesthetic may be used and what this process will entail.

**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 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 Dr Devonie Waaka.

|  |  |  |
| --- | --- | --- |
| **2**   | **Ethics ref:**   | **2024 FULL 18155** |
|   | Title:  | Feasibility study of the effect of psilocybin in response to brief psychological input with psychological flexibility as a mediating factor |
|   | Principal Investigator:  | Dr Valerie Tan |
|   | Sponsor:  | The University of Otago |
|   | Clock Start Date:  | 20 June 2024 |

Dr Valerie Tan and Professor Paul Glue were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researcher confirmed an application to SCOTT would be made.
2. The Researcher confirmed trial registration was in progress.
3. The Researcher confirmed this was an investigator-initiated trial with no commercial sponsor.
4. The Committee queried if someone with relevant medical experience would be in the room to monitor the participant’s vital signs at all times. The Researcher confirmed the study site was fully equipped for resuscitation and Professor Glue would be present in the room to monitor participants post-dose. The Researcher confirmed the site was connected to Dunedin Hospital with access to the Emergency Department if serious medical problems occurred. The Researcher stated serious life-threatening responses to psilocybin have not yet been reported in the literature though some participants may feel anxious.

Summary of outstanding ethical issues

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

1. The Committee queried how the study would recruit participants. The Researcher clarified recruitment would not involve direct referrals from student health, but advertisements would be in the building and interested participants could contact the study team. The Committee requested any advertisements or posters are supplied for approval prior to use. *National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.10-11.13).*
2. The Committee queried if feedback from the scientific peer review had been incorporated such as restricting participant age to 25 and above. The Researcher confirmed this. The Committee noted the documentation submitted had not been updated to reflect this and was missing other things such as information about con-meds and ensuring a responsible adult was present in the house after the dosing. The Committee requested the protocol and participant information sheet are updated to reflect the peer review changes. *National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17; 9.7).*
3. The Committee queried if this was a feasibility study or would measure efficacy. The Researcher stated it would also calculate power for a full-scale study and assess the mechanism for any changes observed. The Committee noted as people would be dosed and effects observed, equipoise is relevant and suggested the Researcher amend the answer to B9 in the application form.
4. The Committee queried where the psilocybin would be sourced from. The Researcher stated this is likely to be from a research group in Australia. The Committee noted the source would need to be confirmed, with a Certificate of Analysis for the product, in order to grant approval.
5. The Committee noted a pregnancy test would be performed during screening and suggested another is performed on the day of dosing.
6. The Committee requested GP notification is a mandatory component of participation.
7. The Committee suggested updating the protocol to include information on the handling of psilocybin and the legality of working with a Class A drug.
8. The Committee requested the data safety charter is included in the protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
9. The Committee noted section 5.4 of the protocol discussed participant withdrawal but not safety-based stopping rules and requested this is updated. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7; 11.35).*

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 include the risk of urinary incontinence, rare adverse events such as psychosis and any other potential side effects not covered in the PIS (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8883979/>).
2. Please revise use of ‘off-label’ as psilocybin is an unapproved drug. Please state it is not approved for use in New Zealand and clarify its legal status.
3. Please state whether psilocybin may show up in drug tests and the expected timeframe it would be present.
4. Please explain the screening visit and what participants can expect.
5. Please explain in lay language how ‘brief psychological intervention’ is defined for eligibility purposes.
6. Please correct the age of participants from 18 to 25 years.
7. Please include a statement referring to SCOTT approval.
8. Please include details for Māori cultural support.
9. Please amend the HDEC contact number to the Ministry of Health general enquiries number (0800 400 569).
10. Please remove the HDEC approval statement on page 2 and retain the one on page 7.
11. Please revise the eligibility criteria and other changes to study conduct as per the peer reviewer’s recommendations.
12. Please state where the psilocybin is sourced from.
13. Please include more information on the post-dose environment (music will be played, participants will wear eye shades and headphones).
14. Please provide more information about potential extension of time at the research site depending upon when the effect of the drug wears off.
15. Please provide more information about how to contact regarding adverse events following the dosing.
16. Please remove any ‘yes / no’ tickboxes from the consent form unless they are truly optional (ie the participant can answer no and still participate).
17. Please review the consent clause regarding partner pregnancy as the PIS does not contain information about this.

**Decision**

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

|  |  |  |
| --- | --- | --- |
| **3**   | **Ethics ref:**   | **2024 EXP 20626** |
|   | Title:  | Establishing a translational cognitive disorders research clinic |
|   | Principal Investigator:  | Dr Campbell Le Heron |
|   | Sponsor:  | The University of Otago |
|   | Clock Start Date:  | 20 June 2024 |

Dr Campbell Le Heron and Miss Lee-Anne Morris 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 Secretariat noted COG is an acronym for the Children’s Oncology Group and advised any references to COG on HDEC forms / documentation would not be applicable to this study.
2. The Committee noted Māori words in the application were lacking a tohu toa (macron) and requested the Researcher be mindful of this for future applications.
3. The Committee noted significant others would be asked to complete questionnaires and queried if they would provide information about themselves or the primary participant only. The Researcher confirmed the questions are related to the primary participant’s functioning and no data on the significant other would be collected.
4. The Committee queried if genetic tests are validated or research tests. The Researcher stated it would involve both, though the implications of research tests are not fully known. The Researcher confirmed these nuances would be explained.

Summary of outstanding ethical issues

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

1. The Committee requested the data management plan is updated to include interview data. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
2. The Researcher confirmed information sheets would be staggered and dependent upon previous consents. The Committee suggested the blood sample could be an addendum to the data sheet to avoid repetition. The Committee suggested removing duplicated information from later information sheets so participants can read new information and refer back to an existing sheet.

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 clarify if there is any risk of people being re-identified by cross-matching through DNA databases in any sheets that involve genetic testing.
2. Please address concerns regarding the tapu nature of the head and how this will be respected in the EEG sheet.
3. Please include information to explain that a participant’s continuing capacity to consent will be assessed as the study progresses.
4. Please state how long participant data will be kept for.
5. Please include information on what data participants may withdraw and how long they will have to do so.

**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 data management plan to include interview data *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
* 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).*

|  |  |  |
| --- | --- | --- |
| **4**   | **Ethics ref:**   | **2024 FULL 20155** |
|   | Title:  | M22-128: A Phase 3, Multicenter, Randomized, Open-Label Study of Epcoritamab Plus Lenalidomide Compared to Rituximab Plus Gemcitabine and Oxaliplatin in Participants with Relapsed or Refractory Diffuse Large B-Cell Lymphoma |
|   | Principal Investigator:  | Dr Sophie Leitch |
|   | Sponsor:  | AbbVie Ltd |
|   | Clock Start Date:  | 20 June 2024 |

Ms Francisca Reed and Ms Sarah Foster 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 outstanding ethical issues

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

1. The Committee requested the Researcher collect good quality ethnicity data at a site-level based on the New Zealand census categories. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20).*
2. The Committee requested an update to Section 6.1 of the data management plan to notify participants of any breach of privacy, not just those notifiable to the Privacy Commissioner. This should be included in the information sheet. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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 the page numbering as it resets after page 13.
2. Please explain the purpose of the recommendation to drink more water, namely to minimise the risk of an adverse immune response.
3. Please state 1,300 people have taken the study drug when discussing that Phase 3 is the last stage on page 3.
4. Please mention the risk of allergic reaction to the dye.
5. Please include information regarding what approved drugs are available as part of standard care in New Zealand and their funding status so participants understand what their alternative choice is if they do not wish to participate.
6. Please state how many participants in New Zealand will be recruited.
7. Please undertake a plain language revision to use lay-friendly language and simplify the information, particularly the contraception section.
8. Please remove any repetition.
9. Please simplify the lay title and replace efficacy with effectiveness.
10. Please remove spoon and cup measurements for blood volumes and state millilitres.
11. Please explain biomarker, DNA and PBMC in lay language the first time they are referenced, and state whether the participant's entire genetic code will be sequenced / analysed.
12. Please significantly simplify the schedule of assessments; this looks to have been almost cut and pasted direct from the protocol.
13. Please delete 'also called the AIDS virus'
14. Please clarify why the participant's 'images, photos, video, and voice recordings' are being collected / accessed for the study, or delete if the statement is not applicable.
15. Please delete 'with your consent' from the bullet point regarding GP notification of study participation; this should be mandatory for a study of this nature.
16. Please make it clear that a number of study tests and assessments will be included in the participant's general (non-study) medical records.
17. It is stated that the study may be stopped if the drug is being shown to work and does not need further testing. Please clarify what would happen to New Zealand participants on-study and judged to be receiving therapeutic benefit if that situation arises.
18. Please include a consent clause with optional tick box for participants to indicate whether they wish to be informed of the results of the study.
19. Please clarify whether the participant's entire genetic code will be recorded / analysed, and whether there is any risk of DNA matching across genetic databases (e.g. with law enforcement databases) in the Future Unspecified Research PIS.

**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 data management plan to notify participants of any privacy breach *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
* please ensure good quality ethnicity data is collected at a site level *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20).*

|  |  |  |
| --- | --- | --- |
| **5**   | **Ethics ref:**   | **2024 FULL 20591** |
|   | Title:  | The PIKI study: A randomised controlled trial of paracetamol versus ibuprofen for fever and pain in children under 2 years of age. |
|   | Principal Investigator:  | Dr Eunicia Tan |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 20 June 2024 |

Professor Stuart Dalziel, Dr Eunicia Tan and Mrs Georgia Doyle 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 queried if the peer reviewer recommendations were actioned. The Researcher stated some were actioned and the feedback on dosing was discussed with the steering group. It was decided to maintain the original dosing in the protocol.
2. The Researcher confirmed participants would have access to data collected about them during the study.
3. The Researcher confirmed the protocol would be updated to include stopping rules once these have been determined and this would be submitted as an amendment.

Summary of outstanding ethical issues

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

1. The Committee requested the trial is registered in a WHO-approved clinical trials registry prior to commencement.
2. The Committee noted Sponsor authorisation was not obtained and the form incorrectly selected that it was not required. The Committee requested Sponsor authorisation is obtained from the University of Auckland in the EthicsRM system.
3. The Committee requested the following changes to the video script:
	1. Please amend the sentence 'and then decide if the children are feeling better'. The Committee suggested ‘see’ if the children are feeling better.
	2. Please temper the call to action ('NEED your help', 'global breakthrough' etc).
	3. Please make it clear that if the parent says yes but decides not to continue, an abbreviated data set will need to be kept for safety reasons.

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 delete repeated information.
2. Please delete bullet-pointed eligibility criteria - these are not useful given they were assessed prior to the parents being given the PIS/CF.
3. Please state what happens if ongoing consent is not provided, i.e. what information is retained, how long it will be kept for, and why.
4. Please state whether participants can find out which intervention they received after the study is completed.
5. Please delete the optional tick-box for GP notification of significant abnormal results.

**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 obtain Sponsor authorisation from the University of Auckland.
4. Please update the video script.
5. Please ensure the trial is registered in a WHO-approved trial.

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

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 6 August 2024 |
| **Zoom details:** | 965 0758 9841 |

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 2:00pm.