|  |  |
| --- | --- |
| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 09 April 2024 |
| **Zoom details:** | 965 0758 9841 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 10.30am-11.00am | 2024 FULL 20028 | Medication Safety in Resuscitations | Dr Andrew Brainard | Mr Dominic Fitchett & Dr Nicola Swain |
| 11.00am-11:30am | 2024 FULL 19594 | MK-0616-019: A Phase 3 Extension Study of MK-0616 in Adults With Hypercholesterolaemia | Dr Michael Williams | Mrs Dianne Glenn & Ms Amy Henry |
| 11.30am- 12.00pm | 2024 FULL 20023 | Tandem Freedom Feasibility Trial #1 | Dr Martin de Bock | Ns Neta Tomokino & Ms Joan Pettit |
| 12.00pm-12.30pm | 2024 FULL 19805 | A Phase 1/2 Umbrella Substudy of MK-5684-U01 Master Protocol to Evaluate the Safety & Efficacy of MK-5684-based Treatment Combinations or MK-5684 Alone in Participants With mCRPC[MK-5684-01A Substudy] | Dr Peter Fong | Dr Maree Kirk & Dr Nicola Swain |
| **12.30pm-1.00pm** |  | **Break 30 minutes** |  |  |
| 1.00pm-1.30pm | 2024 FULL 19394 | GEO-TBI Incidence- response | Dr Giles Critchley | Mr Dominic Fitchett & Ms Amy Henry |
| 1.30pm-2.00pm | 2024 FULL 18620 | CAPTIVATE | Dr Janak de Zoysa | Mrs Dianne Glenn & Dr Nicola Swain |
| 2.00pm-2.30pm | 2024 FULL 18276  | Tailored treatment for endometrial cancer (The TAPER study) | Dr Bryony Simcock | Dr Nicola Swain & Ms Neta Tomokino  |
| **2.30pm-2.40pm** |  | **Break 10 minutes** |  |  |
| 2.40pm-3.10pm | 2024 FULL 17987 | Effects of CBD on muscle recovery and pain | Dr Matthew Barnes | Dr Maree Kirk & Ms Joan Pettit |
| 3.10pm-3.40pm | 2024 FULL 19662 | Does electrical stimulation on the skin over the spinal cord combined with exercise training improve those with chronic tetraplegia – focusing on hand and breathing function | Mrs Julia Rope | Ms Neta Tomokino & Ms Joan Pettit |
| 3.40pm-4.10pm | 2024 FULL 20065 | FASD YJ Prevalence Study | Dr Joanna Chu | Mr Dominic Fitchett & Ms Amy Henry |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Dr Devonie Waaka  | Non-lay (Intervention studies)  | 18/07/2016  | 18/07/2019  | Apologies  |
| Mr Dominic Fitchett  | Lay (the Law) (Chair) | 05/07/2019  | 05/07/2022  | Present  |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Ascc. Prof Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Mrs Carla Strubbia | Non-lay (Intervention Studies) | 03/07/2023 | 02/07/2026 | Apologies |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |

## Welcome

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

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Joan Pettit confirmed their eligibility and were co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 12 March 2024 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1**   | **Ethics ref:**   | **2024 FULL 20028** |
|   | Title:  | Improving Medication Safety in Emergency Department Resuscitations |
|   | Principal Investigator:  | Dr Andrew Brainard |
|   | Sponsor:  | Te Whatu Ora Counties Manukau |
|   | Clock Start Date:  | 28 March 2024 |

Dr Andrew Brainard, Dr Eunicia Tan, Mrs Cat Wong 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 approved the waiver of consent for patients and noted it only applies to patients as clinicians will be subject to an opt-out consent.
2. The Committee queried the expected impact of an observer reporting all errors to the hospital. The Researcher stated they would need to differentiate between standard of care errors versus research errors. The Researcher stated the severe ones would be reported the same whereas minor research errors that are not operational errors would not be reported. For example, a nurse not checking the expiration date of medicine before dispensing it is likely an error that happens daily and is not reported. The Researcher stated these would be collected as errors but not reported. The Committee queried if this was consistent with hospital policy. The Researcher stated they expected the study to identify minor errors that fly under the radar and the standard reporting for serious operational errors will remain. The Researcher stated if a clinically significant error is identified the operational staff will report it as per the regular system and not the research observer reporting it.
3. The Committee queried the scenario of clinicians opting out creating bias. The Researcher stated they did not expect clinicians to opt out as everyone wants to do a better job and the team has a supportive culture. The Researcher confirmed clinician names, specialities or any identifiable data would not be collected and there should be no employment consequences for participation, but serious errors would continue to be reported as per standard hospital policy.
4. The Committee queried how patients requiring resuscitation would be selected for inclusion in the study. The Researcher stated inclusion would be at the discretion of the research nurse on duty and all nurses are trained in resuscitation and would use their clinical judgement and prior experience. The Researcher stated they have tried to narrow the inclusion to focus on patients who would most commonly be the most common sources of error such as receiving four drugs within the first hour or who require a certain set of high-risk medications.
5. The Committee noted the letter from Dr Inia Tomas and queried the role of whānau members or natural support for patients and whether they would be informed of the research. The Researcher stated the culture at Middlemore is to include whānau in the room if at all possible and to incorporate whānau into the clinical care of patients. The Researcher stated standard practice was for clinicians to introduce them to the whānau and ensure they are not ignored in the room.

Summary of outstanding ethical issues

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

1. The Committee requested a review of the data management plan to correct references to ‘anonymous’ data collection to ‘deidentified’.

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

1. Please insert an acknowledgement in the clinician PIS that while no identifiable information on clinicians will be collected as part of the research any serious errors will continue to be reported per standard policy.

**Decision**

This application was *approved* by consensus, subject to the following non-standard conditions:

* please update the data management plan to specify deidentified information will be collected. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*
* please update the clinician information sheet to include an acknowledgement that while no identifying information will be collected and serious errors will be reported as per standard practice *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

|  |  |  |
| --- | --- | --- |
| **2**   | **Ethics ref:**   | **2024 FULL 19594** |
|   | Title:  | MK-0616-019: A Phase 3, Open-label Extension Study to Evaluate the Safety and Efficacy of MK-0616 in Adults With Hypercholesterolemia |
|   | Principal Investigator:  | Dr Mike Williams |
|   | Sponsor:  | Merck Sharp & Dohme (New Zealand) Ltd a subsidiary of Merck & Co., Inc., Rahway, NJ, USA |
|   | Clock Start Date:  | 28 March 2024 |

Dr Mike Williams, Ms Kim Huljich and Mrs Charlene Botha 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 year of birth and study code would be attached to samples sent to the Sponsor and no other identifiers would be included. The Researcher confirmed the master list with identity of participants remains with the local site only and the Sponsor will not have access.
2. The Researcher confirmed both Pacific Clinical Research Network (PCRN) and New Zealand Clinical Research (NZCR) were participating sites in the study and had minor site-specific differences in their respective information sheets.
3. The Committee noted there was no reproductive risk information for male participants and queried the risk if they had a partner of childbearing potential. The Researcher stated the medication is standard of care with an established safety profile (the trial is studying an oral formulation as opposed to injectable) and there is no risk of sperm transmission.

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 whether participants on placebo in the parent study would be unblinded before rolling over into the extension. The Researcher stated there will be a restriction on people learning what their study treatment was but when people are introduced into an open-label extension or a crossover study they will discuss all potential side-effects. The Researcher stated it was important to start from the beginning which is why information from the parent study is duplicated. The Researcher agreed to review the clauses in the parent study regarding unblinding and to add information regarding the unblinding process in the extension. The Committee suggested a line stating that while some participants were on placebo in the parent study everyone would receive the drug in the extension.
2. The Committee noted clause 20 of the information sheet (What are my choices if I don’t want to join?) includes a list of drugs that are not funded and queried why funded drugs are not included. The Researcher stated most patients would be receiving those drugs as part of standard of care. The Researcher agreed to include a line clarifying that various lipid treatments are available in New Zealand including one that is registered with Medsafe but not funded and poses a significant cost.

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

1. Please review the language on identifiable information to specify that the Sponsor will not have access.
2. Please move the statement advising participants to request an interpreter to the beginning of the sheet.
3. Please include a link to the relevant website for participants to read the industry guidelines referenced in the compensation section.
4. Please include a closing bracket in paragraph 25.
5. Please state whether a karakia will be provided at the time of tissue destruction.
6. Please state how long trial visits will take.

**Decision**

This application was *approved* by consensus, subject to the following non-standard conditions:

* 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).*

|  |  |  |
| --- | --- | --- |
| **3**   | **Ethics ref:**   | **2024 FULL 20023** |
|   | Title:  | Tandem Freedom Feasibility Trial #1 |
|   | Principal Investigator:  | A/Prof Martin de Bock |
|   | Sponsor:  | Tandem Diabetes Care, Inc.  |
|   | Clock Start Date:  | 28 March 2024 |

Associate Professor Martin de Bock, Dr Tom Wilkinson, Dr Jordan Pinsker, Dr Tom Ulrich and Ravid Katchalski, 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 response in C11 of the application form indicated the small scale of the study meant it would be unlikely to enrol Pacific participants. The Committee queried what information would be sent to clinical diabetes teams for recruitment. The Researcher stated the intention was not to exclude Pacific participants but as the study site is Ōtautahi Christchurch which does not have a large Pacific population the demographics mean the trial may not have adequate numbers. The Researcher stated they adopt a pro-equity recruitment approach and potential participants will be prioritised. The Researcher acknowledged a consequence of colonialism and previous Pharmac criteria for funding pumps resulted in fewer Māori and Pasifika on pumps which is a pre-requisite for eligibility.
2. The Committee noted the exclusion criteria contained a condition that would “put the participant or study at risk” and queried what conditions this may include. The Researcher stated it is a generic exclusion for if a potential participant has other health issues that could be raised during multi-disciplinary discussions that may preclude them or not be in their best interest. The Committee suggested transparency regarding this during the consenting process.

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 insurance certificate was not study-specific and requested the Researcher supply evidence of study-specific ACC equivalent insurance. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
2. The Committee requested the study is registered in a WHO-approved clinical trials registry.
3. The Committee noted Sponsor authorisation was not obtained on the application in EthicsRM and requested this is obtained in the response to provisional approval.
4. The Committee suggested including a link with FAQs about the PrezzyCard in the PIS so whānau can check what it may be used for (eg paying bills or not).
5. The Committee requested the Researcher update the description of the study design in the protocol to specify how outcomes (eg feasibility) will be measured. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
6. The Committee noted the Sponsor’s medical monitor could overrule the local coordinating investigator in determining whether an adverse event was study-related or not. The Committee requested if a discrepancy is noted it is reported to HDEC.

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

1. Please undertake a general revision to simplify or define technical medical terms.
2. Please differentiate between the pump, the algorithm and the sensor. Please include information explaining the pump is going to be programmed with a new algorithm which has not been tested before. Please clarify the sensor will be the same.

**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, in particular clarifying to participants that the principal investigational aspect of the device(s) is the new algorithm. *(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 supply evidence of study-specific ACC-equivalent insurance *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
5. Please register the trial on a WHO-approved clinical trials registry.
6. Please obtain Sponsor authorisation on the application in EthicsRM.

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

|  |  |  |
| --- | --- | --- |
| **4**   | **Ethics ref:**   | **2024 FULL 19805** |
|   | Title:  | MK-5684-01A Substudy: A Phase 1/2 Umbrella Substudy of MK-5684-U01 Master Protocol to Evaluate the Safety and Efficacy of MK5684-based Treatment Combinations or MK-5684 Alone in Participants With Metastatic Castration-resistant Prostate Cancer(mCRPC) |
|   | Principal Investigator:  | Dr Peter Fong |
|   | Sponsor:  | Merck Sharp & Dohme (Australia) Pty Ltd (MSD) |
|   | Clock Start Date:  | 28 March 2024 |

Dr Peter Fong, Khay Leong, Sophie Goodger and Jeny Paul 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 what lead-in and prior work there had been around dosing and treatments in previous 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 queried the NZ sample size. The Committee requested provision of some reasoning and definite numbers of participants that would be recruited and how sampling may feed into analysis of the sub-study groups.
2. The Committee requested that the note to researchers on page 3 of the Data Management Plan be removed.

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

1. Please clarify on page 3 that the reference to “your breast cancer” is in relation to the genes.
2. Please clarify that there is potential for drug exposure through semen. If this is the case, there should be inclusion of a more general description of risk for men and advice on condom use for all intercourse rather than focusing on risk of pregnancy.
3. Please provide a lay title.
4. Please make it clear that no karakia will be available at the time of tissue destruction.
5. Please describe and address the risks of germline and genome-wide genetic analysis. This needs to be clear to participants.

**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).*

|  |  |  |
| --- | --- | --- |
| **5**   | **Ethics ref:**   | **2024 FULL 19394** |
|   | Title:  | GEO-TBI incidence - An international, prospective observational study on traumatic brain injury epidemiology |
|   | Principal Investigator:  | Professor Giles Critchley |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 28 March 2024 |

No one from the research team was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee requested clarification as to the conflicting answers in sections S5 and D9 of the submission. The Committee requested clarification as to whether participants would be able to give consent and in what aspects may these people need supported decision making.
2. The Committee requested clarification as to the age range that will be included in this study as this is not clear in any of the study application documentation. *National Ethical Standards* para *9.7a & 9.8*
3. The Committee noted that there was no inclusion of transgender/nonbinary under the gender collection. This was raised by the peer reviewer but has not been included. The Committee recommend that this advice is taken and actioned.
4. The Committee requested clarification as to how clinician/researcher influence will be mitigated. *National Ethical Standards* para *9.7a*
5. The Committee noted the significant capacity for consent issues for this research in a vulnerable population and raised the following with the Researcher *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.6-6.12, 6.20-6.30, 7.59-7.74)*:
	1. Those 16 and above should be assessed for capacity to provide their own consent, but those 10-15 should also be assessed for their capacity to provide their own consent and seek paired consent with the parent and guardian as well (especially as they are also participants).
	2. 18-year-olds have limited options for someone consenting on their behalf, as the study involves more than minimal risk. While it would be acceptable for 18-year-olds to provide consent with supported decision making, if someone is unable to consent with that support, they should be excluded.
	3. The assessment of capacity needs to be documented in the participant’s study notes to detail that someone with appropriate experience and training has undertaken that assessment of capacity to determine whether they should provide assent or consent.
	4. Please provide a simplified version of the main participant information form for younger participants or participants who may require a simplified version of the PIS.

The Committee requested the following changes to the Participant Information Sheet and Consent Forms (PIS/CF) (*National Ethical Standards* para *7.15 & 16*):

Main PIS/CF:

1. Please ensure that on page 1 there is reference to the number of pages in the PIS/CF per the [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).
2. Please ensure that it is clear that some health data will have to be kept for 10 years after the youngest participant turns 16.

Assent Form:

1. Please ensure that on page 1 there is reference to the number of pages in the PIS/CF per the [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).
2. Please make it clear that the parent/guardian will have to provide their consent alongside the assenting process.
3. Please include the space for parents/guardians to sign as per the HDEC [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).
4. Please ensure that alongside this form there is an adapted version of the Main PISCF for the parents/guardians that addresses them and states clearly their child will be participating.

**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:**   | **2024 FULL 18620** |
|   | Title:  | The Chronic kidney disease Adaptive Platform Trial Investigating Various Agents for Therapeutic Effect. |
|   | Principal Investigator:  | Associate Professor Janak de Zoysa |
|   | Sponsor:  | Te Whatu Ora Waitemata |
|   | Clock Start Date:  | 28 March 2024 |

Dr Ben Varley, Ms Enmoore Lin and Dr Sradha Kotwal 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 role of Bayer and the access they would have to the dataset. The researcher noted that this data would only be provided once the study had concluded. The Committee noted that due to this, amongst other factors, the study is considered investigator initiated.
2. The Committee queried if there would be cross-over opportunities for participants should another arm of the study prove to be more effective than another. The Researcher noted that this would not be possible but that should there be proven efficacy from one of the study arms, this would prompt the study to end, and a process undertaken to then state that the efficacious drug should be standard of care. The researcher clarified that should there be futility in certain tests, those arms will be closed and that follow up would occur depending on efficacy.
3. The Researcher clarified for the Committee that there is no data as to whether the study drug transmits to semen.

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 there was a clear understanding that withdrawal can occur by any means per the National Ethical standards. The form provided should not be the only means of withdrawal.
2. The Committee queried the lack of reimbursement. The Researchers noted that there would likely be no additional visits as part of the study and that the visits should align with the regular (non-study) appointments. The Committee requested that if there are additional visits that travel costs at the minimum must be covered.
3. The Committee requested that there be some clarity as to what standard of care is in New Zealand, specifically where concerning the drug transporters. The Researcher noted that there was an addendum that details this. Please provide this to the Committee for review.
4. The Committee queried the exclusion of people of child-bearing age. The researcher explained that one of the main study drugs is teratogenic and that the requirement for monthly pregnancy tests to be provided to researchers would be overly onerous to participants. The Committee noted that this is an overly paternalistic approach. The Committee suggested opening the study to this group as while this may be onerous, it would provide a better outcome for these participants long-term. The inclusion group would be much greater for this as the willingness to do so many pregnancy tests is likely to exclude far fewer potential participants as opposed to just excluding all people of this population. The Committee suggested including these participants and being incredibly clear in the PISCFs as to why there is so much risk for pregnancy and what forms of contraception should be used.
5. The Committee noted that the study may not be stopped for purely commercial reasons.

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

1. Please amend the wording around stopping/terminating the study per the business interests of the sponsor on page 3 in accordance with the Committee’s comment above.
2. Please advise that all males should use condoms given there is no data on possibility of risk of the drug exposure through semen.
3. Please insert the statement at the start that an interpreter may be available, rather than at the start of the consent forms.
4. Please note that advising a GP of participation is a mandatory part of participation. It is not truly an option given the medical record will pass things to the GP should an adverse effect occur.
5. Please make it clear that karakia will not be available at the time of tissue destruction.
6. Please address the risks of sending health data overseas per the HDEC [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).
7. Please distinguish approved medications (“treatment”) from investigational (use “study drug” or “study product”, “investigational drug”).

**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 Mrs Dianne Glenn and Dr Nicola Swain.

|  |  |  |
| --- | --- | --- |
| **7**   | **Ethics ref:**   | **2024 FULL 18276**  |
|   | Title:  | Tailored adjuvant therapy in POLE‐mutated and p53‐wildtype early stage endometrial cancer (TAPER) |
|   | Principal Investigator:  | Dr Bryony Simcock |
|   | Sponsor:  | Australia New Zealand Gynaecological Oncology Group |
|   | Clock Start Date:  | 28 march 2024 |

Dr Briony Simcock 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 clarified the extent to which discussions around specific molecular classifications, and one specific subset for the Aotearoa part of the trial, would inform current treatment.

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 why the submission stated different statistics and none with great certainty whereas there was a definite number given in the participant information sheet/consent forms (PIS/CFs) as to the decrease in risk of harm. The Researcher noted that the personalised risks to radiation therapy and recurrence would be discussed with all participants on a case-by-case basis. The Committee requested that the 1% figure be amended to something along the lines of “extremely low” as citing actual numbers may be misleading.
2. The Committee requested that koha be considered for people as part of an Aotearoa specific appendix to the study. This is commonly done as part of NZ specific components of global trials.
3. The Committee requested that the relevant tumour mutations as found in the screening are made clearer in the protocol in terms of how this will be determined through pre-screening.
4. The Committee queried what follow up would be undertaken around the mental health questionnaires. The Committee suggested that there be a safety plan to detail when and how the researchers will follow up should distress be disclosed.
5. The Committee noted that there were 2 PIS/CFs uploaded. The Researcher clarified that the one involving the sending of tissue to Canada is the correct version and that the other PIS/CF was uploaded in error. The Committee requested that only the accurate version be uploaded in the response.
6. The Committee requested that the Data and Tissue Management Plan (DTMP) include information per the transport of tissue to Canada.
7. The Committee requested that the researcher ensure that the contents of the protocol and PIS/CF are the same where withdrawal is concerned.

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

1. Please clarify the risk of using the molecular classification to direct treatment and the potential benefit as opposed to the standard of care approach. Specifically, this should be approached through the lens of radiation risk versus the risk of recurrence.
2. Please create a lay title that is meaningful for people.
3. Please amend the wording on the section mentioning the potential for creation of new drugs etc., as this is not relevant to this study specifically.
4. Please clarify on page 6 the section “How will you tolerate the study treatment and side effects” given there is less treatment this may need to be removed for relevancy.
5. Please clarify recurrence and how this is treatable or surgically manageable on page 6 where mentioning “there’s a small risk that it’s not as good as usual”.
6. Please amend the future unspecified use and specify that this would be related to cancer research specifically and ensure that this is reflected in the DTMP.
7. Please ensure that the information pertaining to follow up till death is clear and consistent between the PIS/CF and DTMP. This should include that withdrawal should also involve removal of the dataset.
8. Please reference the number of pages in the PIS/CF on page 1 per the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).

**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 Nicola Swain and Ms Neta Tomokino.

|  |  |  |
| --- | --- | --- |
| **8**   | **Ethics ref:**   | **2024 FULL 17987** |
|   | Title:  | The effect of cannabidiol (CBD) on recovery from contusion injury in healthy males |
|   | Principal Investigator:  | Dr Matthew Barnes |
|   | Sponsor:  | Massey University |
|   | Clock Start Date:  | 28 March 2024 |

Dr Matthew Barnes 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 with the Researcher that the genetic marker being tested is validated for this use.
2. The Committee clarified with the Researcher that this study hasn’t gone to SCOTT. This is an approved product for use and is on the Medsafe website.
3. The Committee noted the exclusion of females as model has not been tested on females. The Researcher clarified that when they got ethical approval to develop this model, it was specifically for males. While females get the same injuries, this is a starting point.
4. The Committee clarified the role of Eqalis, which is just supplying the investigational product and has no sway over the conduct and design of the study or interpretation of data. The Committee is satisfied this is an investigator-initiated study and therefore ACC will apply.

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 risk of creating the contusion injury being outweighed by the potential benefit of the study, and asked why the Researcher isn’t seeking out individuals who already have contusion injuries. As the research is looking at CBD and recovering from pain, why not recruit people who have these like recruiting from local sports clubs. The Researcher explained that there is no control, the amount of force and injury and timing would differ (“There are confounding factors that I want to eliminate to ensure the intervention was the actual cause”). The Committee stated that this justification is missing from the protocol. Adequate scientific basis for the risk imposed should be highlighted, and assurance that the Researcher is doing everything they can to minimise risk needs to be documented clearly in the protocol.
2. The Committee queried what happens to information if the person takes part in the screening with genetic testing and isn’t able to participate. The Researcher responded that they would still get their test information and then their information will be kept. The Committee requested this is clear in the protocol and also to these people. The Committee should also see the letter that people would get explaining their results to them.
3. The Committee noted that no measurements to evaluate pain have been provided. The Researcher responded that there will be physical evaluations of pain and pressure. The Committee noted that this needs to be added in protocol and participant information sheet.
4. As this is an intervention, this will need to be registered on a WHO approved clinical trials registry before it commences.
5. The Data Management Plan has some errors on the contents page that should be reviewed and amended.

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

1. The language is too complex and technical, i.e. "experimentally induced contusion injury" means "we're going to drop a 7.2kg weight on your leg to create an injury...”. The Committee suggested providing a diagram of the person lying on his side and how the injury will be created.
2. Please clarify if the CBD will show up on workplace testing (i.e., clarify that it doesn’t meet the level of THC content and is non-psychoactive and should be fine.)
3. On page 5, please make it clear that no karakia will be available at time of tissue destruction.
4. More information about the CBD product would be useful, including a link to the Medsafe website about it. Please provide this.
5. Please suggest use of rescue medication sooner than 72 hours, i.e. if pain levels are high, treat it sooner with anti-inflammatories etc.
6. Remove the yes/no tick boxes in respect of use of information collected prior to withdrawal as this is 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 study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Maree Kirk and Ms Joan Pettit.

|  |  |  |
| --- | --- | --- |
| **9**   | **Ethics ref:**   | **2024 FULL 19662** |
|   | Title:  | Get A Grip: Spinal stimulation for upper limb and respiratory function in tetraplegia |
|   | Principal Investigator:  | Mrs Julie Rope |
|   | Sponsor:  | The Catwalk Spinal Cord Injury Trust |
|   | Clock Start Date:  | 28 March 2024 |

Julie Rope and Claire Boswell-Ruys 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.

Ms Neta Tomokino declared a potential conflict of interest and the Committee decided to include Ms Tomokino in the discussion as it was deemed minor and to have no impact on the decision-making process.

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 one of the exclusion requirements include a history of autonomic dysreflexia in response to electrical stimulation. The Committee also noted there is a plan in place for participants who may experience autonomic dysreflexia due to the intervention, but queried if they remain in the study. The Researchers confirmed they will remain in the study but with plan in place to terminate the session, determine if the autonomic dysreflexia was caused by the intervention and offer to reschedule the visit. If the participant has an AD response related to the intervention then they will be monitored and if stopping criteria is met and it is deemed no longer safe for their continued participation, then participation for the individual will cease.

Summary of outstanding ethical issues

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

1. It was clarified that the investigational device is different to the one used in standard care in that its marketed for research purposes only and goes to a slightly higher frequency than what is marketed as standard. The Committee stated that it would be helpful to provide that information and assurances from clinical engineers surrounding the safety and test before use in the study documentation.
2. The Researchers clarified that the hypothesis of the study is that the response is the same from the muscles using the standard frequency and this higher one, so people can buy standard off the shelf frequency device versus this more expensive one. The Committee requested this is made clearer in your protocol and comment on the safety of each frequency level.
3. The Committee noted that the submission form’s defined good outcome is inconsistent with the protocol. Please review and amend for consistency.
4. The protocol and participant information sheet (PIS) states the effect of TSS on training but must mean TSS *and* training. Please correct.
5. The Committee requested the Researchers unpack the consideration for travel time, preparation time and travel costs for getting to and from sessions. Participants should not be paying for participation and the Committee encouraged that it be looked into how this can be provided for either by the study or by another agency arranged on their behalf, or it is upfront to participants to account for. The Committee accept this could result in a mixed method solution to help accommodate this, and a koha for their time like food could also be provided.
6. The Committee noted that Sponsor authorisation needs to be ticked off (If part of a University, then it should be the institution).
7. A data and tissue management plan is required, as what has been provided doesn’t comply with the standards. Please see [the HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates) as an example of how much detail, which can either be used for a new one, or used as a guide.
8. The Committee noted that the submission form indicated that the study is using Kaupapa Māori methodology, but it isn’t.

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

1. Clarifications around device and safety should be summarised in PIS.
2. Clarify that exercise regiment is the same that would be used in standard of care.
3. On page 8 under Māori data sovereignty, please correct ‘kanahi ki te kanahi’ to – ‘kanohi ki te kanohi’
4. Please state how long each visit will be in total.
5. Please state if the participants can remain in their chair or will have to move onto a bed or other.
6. Remove tick box for informing the participants GP of significant abnormal events, as this is not optional.
7. Note participants can withdraw from the study orally and do not have to complete the attached form. The form can be filled in by the Researchers for their records if required.
8. The CF says karakia won’t be available at time of tissue destruction, but this should also be explained in the main body of PIS.

**Decision**

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

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

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

|  |  |  |
| --- | --- | --- |
| **10**   | **Ethics ref:**   | **2024 FULL 20065** |
|   | Title:  | The need for FASD intervention: Prevalence and Knowledge in Youth Justice |
|   | Principal Investigator:  | Dr Joanna Chu |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 28 March 2024 |

Dr Joanna Chu and Holly Wilson 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 they had checked the statistics since the last submission surrounding potential participant demographics and confirmed that there is currently no one over 18 at the moment that would be able to be recruited as part of this study, and only one individual residing within a youth justice facility in which Oranga Tamariki has legal guardianship.
2. The Committee confirmed with the Researchers that the comments raised by the peer reviewer were addressed.

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 capacity for consent issues for this research in a vulnerable population and discussed the following with the Researcher during the last submission, which is included here for transparency *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.6-6.12, 6.20-6.30, 7.59-7.74)*:
	1. Confirmed that capacity to consent for research participation will be assessed by the Researchers through conversation with the person but also liaising with their case managers.
	2. Those 16 and above should be assessed for capacity to provide their own consent, but those 10-15 should also be assessed for their capacity to provide their own consent and seek paired consent with the parent and guardian as well (especially as they are also participants).
	3. 18-year-olds have limited options for someone consenting on their behalf, as the study involves more than minimal risk. While it would be acceptable for 18-year-olds to provide consent with supported decision making, if someone is unable to consent with that support, they should be excluded.
	4. The assessment of capacity needs to be documented in the participant’s study notes to detail that someone with appropriate experience and training has undertaken that assessment of capacity to determine whether they should provide assent or consent.
	5. Those persons aged 18 years who independently consent to study participation should not require additional parent or guardian consent in order to take part in the study. In these cases, parental consent should be limited to their own participation in the study.
	6. Oranga Tamariki is involved as a Sponsor for the study. Where the young person’s legal guardian is the Chief Executive of Oranga Tamariki, any potential participant where whānau opinion cannot be ascertained should be excluded from participation due to this significant conflict of interest.
	7. Please provide a simplified version of the main participant information form for younger participants or participants who may require a simplified version of the PIS.
2. It was confirmed with the Researchers that the above discussed prior was taken into account, however the Committee re-iterated the following that had not been addressed fully:
	1. In order to be able to give consent on behalf of an over 18 year old who doesn’t have capacity, it would need to be a property manager appointed by the Court or an EPOA. They are the only options there. A parent or normal guardian would not be able to provide that consent.
	2. The resubmission implies that parental consent with a dual consent process is required for those over 18 who do provide their own consent, which the Committee stated is not appropriate.
	3. Responses in cover letter differs from protocol, where the protocol says all young people under 16 will provide assent only, but cover letter and discussed last time was that a young person under 16 that can provide their own consent should do so. Please correct the discrepancy.
3. Queried how FASD will be explained to these young people. Confirmed that there are clinicians very well trained and experts in providing this diagnosis and information. It was noted this was under addressed in your protocol how you are going to address this with the youth and how it will be addressed with the whānau due to the very strong emotional reactions. This needs to be thought out and the consultation and plans around it should be documented as this is a risk of the study.
4. Concerned that the science to establish prevalence will not be met as you are not testing everyone, so will you be able to reach your objective? After discussion, the goal ultimately is to get prevalence data but for now is to get cohorts with representative data. This should be outlined in the protocol.

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

1. The 10-16 and the 16-18 information sheets are not very different from one another. The full PIS (16-18) should be the one for young people able to provide their own informed consent, and either use the read-easy version for those who can’t provide their own consent and need dual-consent with a parent or guardian and create an intermediate version between the two for those who fit in the middle.
2. The consent form should only follow the full PIS and assent form should follow the simplified versions and be kept separate.

**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 forms, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 14 May 2024 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

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

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

The meeting closed at 4.10pm