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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 20 February 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12.30-1.00pm | 2024 FULL 19409 | MK-7240-001: Phase 3 Program to Evaluate MK-7240 for Moderate to Severe Ulcerative Colitis | Dr Sriharan Selvaratnam | Ms Jessie Lenagh-Glue & Dr Andrea Forde |
| 1.00-1.30pm | 2023 FULL 18347 | WHIRI TB: Towards tuberculosis elimination for Māori | Professor Philip Hill | Ms Catherine Garvey & Ms Jade Scott |
| 1:30-2:00pm | 2024 FULL 18421 | PACE-NODES:A randomised trial of 5 fraction prostate stereotactic body radiotherapy (SBRT) versus 5 fraction prostate and pelvic nodal SBRT | Dr Jerusha Padayachee | Mr Jonathan Darby & Dr Kate Parker |
| 2.10-2.40pm | 2024 EXP 19306 | AI for assessment of noncontrast CT study | Dr Ben McGuinness | Ms Jessie Lenagh-Glue & Mr Derek Chang |
| 2.40-3.10pm | 2024 FULL 19582 | A Phase 3 Study of Nemtabrutinib vs Ibrutinib or Acalabrutinib for 1L Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma | Dr Merit Hanna | Ms Catherine Garvey & Dr Sotera Catapang |
| 3.10-3.40pm | 2024 FULL 19501 | MOTION Study | Dr Rahul Bera | Mr Jonathan Darby & Dr Andrea Forde |
| 3.50-4.20pm | 2024 FULL 18446 | The C-POS Questionnaire Study | Dr Gemma Aburn | Ms Jessie Lenagh-Glue & Ms Jade Scott |
| 4.20-4.50pm | 2024 FULL 18651 | Measuring vaccine induced protection against tuberculosis in blood | Dr Gergely Toldi | Ms Catherine Garvey & Dr Kate Parker |
| 4.50-5.20pm | 2024 FULL 19577 | Aquablation Therapy in Prostate Cancer patients | Professor Peter Gilling | Mr Jonathan Darby & Mr Derek Chang |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mr Derek Chang  | Non-lay (Intervention studies)  | 08/07/2022 | 08/07/2025 | Present  |
| Dr Kate Parker  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present  |
| Dr Andrea Forde | Non-lay (Intervention studies)  | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey  | Lay (the Law) (Chair) | 19/03/2019  | 19/03/2022  | Present  |
| Dr Sotera Catapang  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present  |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The meeting was opened at 12.00pm with a karakia, and the Chair welcomed Committee members, noting that no apologies had been received.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Jessie Lenagh-Glue 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 23 January 2024 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 FULL 19409** |
|   | Title:  | A Phase 3, Randomized, Double-Blind, Placebo-Controlled Program to Evaluate the Efficacy and Safety of MK-7240 in Participants with Moderately to Severely Active Ulcerative Colitis |
|   | Principal Investigator:  | Dr Sriharan Selvaratnam |
|   | Sponsor:  | Merck Sharp & Dohme (New Zealand) Limited |
|   | Clock Start Date:  | 08 February 2024 |

Dr Sriharan Selvaratnam, Warde Elias, Esther Ji, and Smita Boban 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 exclusion of Crohn’s Disease affected individuals was due to there being another study to look at Crohn’s. There is intent by the sponsor to do feasibility studies on this other group adjacent to this study.
2. The Committee noted that the exclusion of HIV, Herpes Zoster, CMV and Hepatitis B and C affected individuals was due to high potential for biological medications, such as those used in this study, to cause reactivation of viral diseases.

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 approach for participation be made by someone who is not their treating physician by default.
2. The Committee queried why Herpes Simplex Virus had not been included in the exclusion criteria. Please clarify this.
3. The Committee requested clarification as to the ability to receive live vaccines during participation. This is listed as an exclusion in the protocol, but this should be clarified for participants in the Participant Information Sheet/ Consent Form.
4. The Committee requested that there be rewording to the statement inferring that there may be some attribution of Covid 19 and Covid-pneumonia to the study medicine.
5. The Committee noted that the submission stated that there would be no additional ionising radiation included in this study but that there would be an x-ray to exclude tuberculosis. Please reword this section to include this procedure.
6. The Committee explained that in New Zealand the sponsor may not terminate the study purely for commercial reasons. This should be reflected by the study documents.
7. The Committee requested that there be clarification as to how many participants are going to be recruited.
8. The Committee requested clarification as to why the study is collecting productivity data from participants. Please clarify with the sponsor why this is necessary.

The Committee requested the following changes to both Participant Information Sheet and Consent Forms (PIS/CFs):

1. Please specify how many New Zealand participants there will be as this currently is confused between the submission and the PIS/CF.
2. Please clarify the variability to the number of visits required in participation.
3. Please include a table or flow chart to show the procedures and schedule of visits for participants to more easily see what is required of them at what point.
4. Please clarify why there will be a genital or breast check for those participants under 18. This requires some cultural consideration as well as sensitivity in the way that this is discussed and conducted. Please clarify if a support person or gender-matched clinician will be permitted for this and acknowledge what cultural significance this may have to people, in particular, the issue of whakamā.
5. Please create a safety plan detailing the timeline for follow up and analysis of questionnaires that track quality of life. Please detail how people may reach out and who will be arranging and paying for a referral if required.
6. Please clarify if answering all the questions to the quality-of-life survey is mandatory.
7. Where discussing the identifiable information, please refer back to the Data Management Plan and ensure that explanation of who may have access to that identifiable information is clear and correct. Sponsors should not be receiving identifiable data.
8. Please clarify what the urine and blood samples are taken for.
9. Please clarify what the “local lab safety sample” is.
10. Please consider using a more general cultural statement that is broader and not just for samples taken.
11. Please include numeric quantification of risks e.g., 1 in 10 etc.
12. Please consider making reimbursement a blanket amount covering expenses rather than requiring participants to keep receipts as this is extremely onerous for participants.
13. Please clarify that should the participants become unblinded that they will only be followed up for monitoring for any long-term effects with their consent.
14. Please note that reporting of blood test results to General Practitioners should be mandatory and this should be detailed in the PIS.
15. Please specifically state that de-identified data will be sent to Singapore, the US and the UK.
16. Please amend the access and correction of information section. Please refer to the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for guidance on what is expected of this section.
17. Please amend the optional extension statement regarding withdrawal or declining to participate to ensure it is clear to participants that they may continue with the main trial even if they decline to participate in the extension trial.
18. Please specify if after the study is unblinded whether there is the opportunity for placebo participants to be reassessed and placed on the study treatment.
19. Please include a Māori data sovereignty statement in both the optional extension and main PIS.
20. Please address the issues of whakamā and tapu as they may relate to the study.
21. Please directly address the collection and refrigeration of stool samples and whether there is an alternative to keeping this in the participant’s fridge with food.
22. Please refer to the study intervention as a medicine rather than a “drug”.
23. Please clarify if there will be ongoing access after the study for those who have received therapeutic benefit from the intervention. An exclusion due to the treatment not being a “registered medicine” is not a valid reason nor a true statement.
24. Please specify what hepatides are notifiable in New Zealand.

**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 Jessie Lenagh-Glue and Dr Andrea Forde.

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| **2**   | **Ethics ref:**   | **2023 FULL 18347** |
|   | Title:  | Towards elimination of tuberculosis (TB) for Māori in Aotearoa New Zealand (WHIRI TB) |
|   | Principal Investigator:  | Professor Philip Hill |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 08 February 2024 |

Professor Philip Hill and Dr Sue McCallister 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 age-group of participants.

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 clarified that this study is concerning the elimination of tuberculosis (TB) in Māori populations. The researchers noted that this requires a Māori-led approach that must serve those who have not been served by the system and current response. Please include this in the Protocol. (*National Ethical Standards for Health and Disability Research and Quality Improvement* para *9.7a & 9.8)*
2. The Committee queried how the contacts identified in a household who had not been able to engage with the system would be contacted and who would be doing the first approach. This should be included in the Protocol. *(National Ethical Standards* para *9.7a & 9.8)*
3. The Committee noted that in New Zealand you cannot gain consent by proxy. There could be supported consent for individuals who may require additional aid or a simpler information sheet, but the proxy-consent model is not legal. Please re-word this to reflect that this is supported decision making, and participants who are not capable of giving informed consent will be excluded. *(National Ethical Standards* para *7.20-7.21*, *9.7a & 9.8)*
4. The Committee requested that the protocol and participant information sheet/consent form (PIS/CF) reflect that a study staff member would be coming into the participants home, how long this would be for and how frequently. This will also require a safety plan for researchers to be included in the protocol. *(National Ethical Standards* para *9.7a & 9.8)*
5. The Committee suggested separating groupings for young people who may be presented with a PISCF into younger and older children’s groups. These could be labelled as “Tamariki” and “Rangatahi”. (*National Ethical Standards* para *6.25-6.27)*
6. The Committee queried if there would be te Reo versions of the PIS/CFs. The researcher noted that there were a number of study staff that are fluent and that there had been prior consultation as to what would be the preference of the community in this case.
7. The Committee noted that study data will need to be kept for participants who are under 16 for 10 years from the point that those participants turn 16.
8. The Committee requested consent forms and PIS for policy-makers, public health workers and any other professionals that may be involved in this study as they would also be participants. Means of recruitment of these participants also needs to be described.
9. The Committee requested an information sheet for parents consenting for their child. This will need to include the details surrounding the data collection and retention.
10. The Committee requested the start date of the study be clarified and amended as it states 01 January 2024.
11. The Committee requested that a statement noting that all interviews will be recorded is added into all PIS/CFs. *(National Ethical Standards para 7.15 – 7.17)*
12. The Committee queried if non-Māori whānau would be included in the study. The Researcher noted that in terms of the scientific aims of the study there may be issues around excluding non-Māori but that there would be a decision made on a household-by-household basis. Please clarify this in the study protocol. *(National Ethical Standards* para *9.7a & 9.8)*
13. The Committee noted that there may be potential for further stigmatisation of whānau based on the potential to identify historic genealogy links to TB in Māori. Please comment on this in the protocol and specifically how stigmatisation may be avoided in the dissemination of results. (*National Ethical Standards* para *9.7a & 9.8)*

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

1. Please include how long it would take for participants to have blood results returned to them and in what form those results will be given to them.
2. If there will be focus groups, please specify this and please include details as to what may be required for those participants in these groups.

**Decision**

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

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| **3**   | **Ethics ref:**   | **2024 FULL 18421** |
|   | Title:  | PACE-NODES: A phase III randomised trial of 5 fraction prostate SBRT versus 5 fraction prostate and pelvic nodal SBRT. |
|   | Principal Investigator:  | Dr Jerusha Padayachee |
|   | Sponsor:  | The institute of Cancer Research |
|   | Clock Start Date:  | 08 February 2024 |

Dr Jerusha Padayachee 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 that the participants would all already be aware that they have a high-risk profile.
2. The Committee requested clarification as to the consenting process and the opportunities given to participants to speak to someone who is not their treating clinician. The Research nurse’s details would be given to participants and the research team would be taking as much initiative as possible to give the participants time to consider participation as well as being able to ask questions if needed.

Summary of outstanding ethical issues

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

1. The Committee requested an independent peer review per the [HDEC peer review template](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx).

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

1. Please rewrite the information sheets as the fragmentation into two parts means relevant sections are not obviously linked to the first part, and it is missing sections that HDEC require. The Committee recommended use of the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) for guidance.
2. Please use consistent terminology when referring to and describing the radiotherapy component of the study.
3. Please move the section on cultural data significance to the data section.
4. Please make clear what support is available to participants and who will provide this and that there will be no cost to applicants in receiving support.
5. Please include the New Zealand specific information concerning the data usage per the [HDEC PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
6. Please address the issues of whakamā and tapu as they may relate to the study where sexual function and that these questions could cause distress.
7. Please include whānau and other professionals where noting that participants may ask them questions before consenting.
8. Please use the contraception wording in the [HDEC Reproductive Risks template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-v.4.0-april2023.docx) for the use of contraception. The combination of a diaphragm plus Highly Effective Hormonal contraception, both used by a female sexual partner, places an undue burden on the female partner. Please do not put the emphasis on female contraception. Please do place emphasis on the risk of conception and exclude the risk of exposure of sexual partners to radiation.

**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 Dr Kate Parker and Mr Jonathan Darby.

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| **4**   | **Ethics ref:**   | **2024 EXP 19306** |
|   | Title:  | Is an AI neural network able to be trained to discriminate CT scans that are normal or with common age-related changes from seriouspathology? |
|   | Principal Investigator:  | Dr Ben McGuinness |
|   | Sponsor:  | Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland |
|   | Clock Start Date:  | 08 February 2024 |

Dr Ben McGuiness, Davina McCallister and Genevieve Morris 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 noted that this was largely an undertaking to better understand the use of Artificial Intelligence (AI) in this field so that in the future, the researcher is better prepared to deal with trials and new modes of 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 requested that the researcher justify the request for a waiver of consent in accordance with Chapter 7 of the National Ethical Standards. Please include the practical, ethical and scientific justification of this as well as the mitigation of risk and consideration of cultural issues that may arise. Alternatively, if the researcher decides to use open-source data sets, please include this in the Protocol.
2. The Committee requested that the researchers conduct specific Māori consultation on the use of AI with Māori data. (*National Ethical Standards* para *13.6)*
3. The Committee requested clarification as to the AI model being used. The researcher noted that he has no expertise in AI but that this would be part of the process of his sabbatical. Please clarify the process of selection and development for use of the AI model once this has been decided. There should be adequate detail concerning the AI in the protocol prior to commencement of this proposed study. *(National Ethical Standards para 13.1-13.5)*
4. The Committee queried if there had been any historic use of this AI in practice and the researcher noted that the AI has previously been used to generate models of cranial injury or stroke incidence. This has been used to pre-diagnose stroke incidence in the US.
5. The Committee queried the plans should a data-breach occur. The researchers noted that there would be de-identification between the images and data and there would be no linking back or coding kept to re-identify. Please make this clear in the Data Management Plan and Protocol.
6. The Committee suggested referring to the [Data.govt.nz toolkit for Data Ethics](https://data.govt.nz/toolkit/data-ethics/government-algorithm-transparency-and-accountability/algorithm-impact-assessment-toolkit/) to ensure that this study is adequately considering all factors required for an AI project.
7. The Committee queried the appropriateness of the individual used to scientifically peer review the application. Please organise review by someone who works with the type of AI model that will be used or a neuroradiologist external to New Zealand.
8. The Committee noted that it is a requirement in New Zealand to collect good quality ethnicity data when doing research. This can be obfuscated to prevent identification, but it should be collected if possible.
9. The Committee noted that training AI algorithms requires access to vast amounts of underlying data while the use of the tools creates a risk of exposure of such data either because the tool memorizes and retains the information or because third-party vendors may be exposed to data breaches. If any data is going anywhere or if the AI will be linked into a larger project now or in the future this must be included as a risk in the protocol. (*National Ethical Standards* para *13.1-13.18)*

**Decision**

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

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| **5**   | **Ethics ref:**   | **2024 FULL 19582** |
|   | Title:  | A Phase 3, Randomized Study to Compare Nemtabrutinib Versus Comparator (Investigator’s Choice of Ibrutinib or Acalabrutinib) inParticipants With Untreated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BELLWAVE-011) |
|   | Principal Investigator:  | Dr Merit Hanna |
|   | Sponsor:  | Merck Sharp & Dohme LLC |
|   | Clock Start Date:  | 08 February 2024 |

No Researcher was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of 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 around recruitment, specifying that there should be assurance of separation of clinician role.
2. The Committee requested clarification on the number of participants in New Zealand as it states different numbers across the study documentation.
3. The Committee asked for more information on how the study presents Kaupapa Māori as indicated in the application form. This is not currently evident in the submission and may have been selected in error.
4. Please address ongoing access to study medication for participants after the conclusion of the study. The fact that the medicine is not registered in New Zealand is not an adequate reason. The Committee expect it to be available if participants are receiving therapeutic benefit.
5. The Sponsor cannot stop study for only commercial reasons. Please ensure this is made clear across documentation.
6. The Committee required confirmation that SCOTT has approved both comparators and that either they are publicly funded in New Zealand or that they’re being provided and funded by the sponsor.

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

Main PIS:

1. The statement – “If you need an interpreter, please tell us” should be at the beginning of the PIS, not the end.
2. Please ensure that the visit schedule is in an easy-to-read form like a table.
3. Clarify how many people will be recruited in New Zealand.
4. Please clarify risks for comparators, quantifying this verbally and numerically.
5. Studies should not require receipts for reimbursements, either provide a set fee or that reimbursements can be discussed with the site.
6. Please remove the exclusion of insurance cover for the comparator medicines. ACC equivalent insurance should cover injury of participating in trial regardless of what medicine they take as ACC does not cover participation in the trial.
7. Please remove the statement that participants will not be shown the privacy policies for apps that they are required to use when participating in the study. Participants ought to have access to this information in a timely manner.
8. Please review for Americanisms – “inside cell” instead of “inside of”
9. Please refrain from using ‘treatment’ and use “investigational medicine” instead.
10. Ensure that any reference to what “may not be approved in your country for your type of cancer” is specific to New Zealand.
11. Reportable diseases are reported to the Medical Officer of Health, not Ministry of Health.
12. Page 7 only lists two CYP450 inhibitors. Please clarify if there are any more examples that the participants should know about.
13. In the contraceptive statement, please combine reproductive risks for sperm and pregnancy in one section (as you already have a vasectomy as a method of sterilisation). Please also clarify if a barrier method is required due to secretion of investigation medicine or metabolites in body fluids, or whether you are just trying to prevent pregnancy as that should be specified. If highly effective contraception has been used (like vasectomy), clarify why a barrier method should be used or remove.
14. Please provide more information about the quality-of-life questionnaires, such as what sort of questions they will be asking and information on what to do if the questions are triggering or upsetting.
15. The Committee expressed preference that the Auckland cultural statement is used for the PIS.
16. Please clarify whether there will be the option of a karakia at the time of tissue destruction.
17. Please change “you will not be penalised or lose any benefits” to “you will continue to receive appropriate care for your cancer”.
18. Please change the wording of “you must do so by contacting the trial doctor or staff” to “you should do so”.
19. Please remove reference to trials being stopped for commercial reasons in New Zealand.
20. Under Section 24, please remove duplicate paragraphs.
21. Identifiable information should not be available to the Sponsors, their representatives, or vendors other than for the reasons noted in the HDEC template.
22. Data is destroyed after (usually 10) or 15 years and should not need the sponsor’s permission to do so.
23. The Sponsor should only be transferring health information overseas if it is de-identified.
24. The ethical aspects of the trial have been approved by HDEC – SCOTT has approved the scientific validity of the trial. Please amend.
25. Please explain ‘tumor lysis syndrome’ in lay terms.
26. In the CF, please add item that reminds participants they understand they will be tested for certain diseases that may require mandatory disclosure to the relevant health authorities (as in section 8 of the PIS)

Future Unspecified Research PIS/CF:

1. Please change “you will not be penalised or lose any benefits” to “you will continue to receive appropriate care for your cancer”.
2. The Committee expressed preference that the Auckland cultural statement is used for the PIS.
3. Please clarify whether there will be the option of a karakia at the time of tissue destruction.

**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 Catherine Garvey and Dr Sotera Catapang.

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| **6**   | **Ethics ref:**   | **2024 FULL 19501** |
|   | Title:  | Multicenter, PrOspective, Randomized, Controlled Trial Comparing GenIcular Artery EmbOlization Using Embosphere Microspheres toCorticosteroid iNjections for the Treatment of Symptomatic Knee Osteoarthritis: MOTION Study |
|   | Principal Investigator:  | Dr Rahul Bera |
|   | Sponsor:  | Merit Medical Systems, Inc. |
|   | Clock Start Date:  | 08 February 2024 |

Dr Rahul Bera and 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 queried the limited study enrolment cap imposed by the FDA for participants in the US. It was clarified after discussion that this is so it can be tested globally via multi-centre trials.
2. The Committee queried the recruitment target in New Zealand. The Researchers responded that it depends on uptake as patients they want to see for the study are patients the standard of care referral pathway is rejecting. Uptake will depend on whether the Researchers can work out the referral pathway to send participants to the study.
3. The Researchers confirmed no direct clinical care is being provided by the Researchers.
4. The Committee queried why the lower age limit was 21. The Researcher responded that knee osteoarthritis is highly unusual in those aged under 21.

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 peer reviewer has described themselves as an interventional cardiologist, but the Researchers clarified that they are an interventional radiologist. For completeness, the Committee requested to have the peer reviewer clarify this, and their institution affiliation on the peer review.
2. The Committee noted throughout the use of “subjects” which should be “participants”, and the use of gendered binary language which could be exclusionary of trans or non-binary potential participants. Please review all documentation and amend where possible, such as in the participant information sheet (PIS) i.e., removing “woman of child-bearing age” to “if you can become pregnant”.
3. The Committee noted the following for the application form submitted:
	1. C18.2 of the app form states 'no other medical, social, or psychological problems that, in the opinion of the investigator, preclude them from receiving this treatment, and the procedures and evaluations pre- and post-treatment.' After discussion, it was clarified that this can be as simple as the investigator determining the participant cannot fully commit. Please make that clear in the PIS to potential participants that if they aren’t prepared to participate as required, they should not enrol.
	2. S6. should be yes – identifiable health data will be accessed, reviewed, and collected.
	3. B15.1 - there are publishing restrictions placed on the study as outlined in B15.
	4. E.6.1 – The sponsor should only be allowed access to de-identified participant data and not their entire health records. Privacy law requires that they only be granted access to information directly related to the question being investigated.
4. The Committee requested clarification of why those planning a pregnancy are excluded for 3 years. The Researcher clarified that while there can be some short-term interaction with radiology imaging, this may be attributed to a conservative American approach. The Committee suggested reviewing how this is outlined in the PIS and its inclusion in the study.
5. The Committee queried why the top of every page of the PIS has a place for Te Whatu Ora patient identification labels. The Researchers explained that this is considered a legal document, so every page should be identified so it can be filed with the site and onto their medical records. After discussion, the Committee stated that for research, he labels should not be affixed The Committee requested that the Data Management Plan contains detail as to how confirmation of consent is de-identified and connected to study data at a site-level.
6. The Data Management Plan (DMP) requires further details regarding organisational governance. Template data that is not relevant to the study such as reference to under 16s can be removed.
7. The Committee requested New Zealand specified or clarified as a named territory for the insurance for the trial. This can be done via a clarification letter from the insurance company.

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

1. Please review for grammatical errors and typos.
2. Review for Americanised language.
3. Please specify that there are a number of arteries in the groin. The investigator will determine on clinical grounds which is the best to be used at the time of the intervention.
4. Please note that the trial cannot be stopped by the Sponsor for commercial reasons in New Zealand.
5. “If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.” The document should specify the data that may be collected and ensure that this is limited to what is relevant.
6. Pleas amend the compensation section to remove reference to the Medicines NZ Industry Guidelines as these do not cover devices.
7. Please specify that this device is licensed for use in New Zealand and other countries, but not for the use being studied in this trial.
8. The Protocol refers to arthroplasty as an exclusion which should be in the PIS.
9. The Committee suggested a stipend for reimbursement, with expenses beyond any stipulated figure to be discussed with the site manager. The committee also suggests a koha of a supermarket voucher as a token of appreciation for participation. Please clarify the difference between what is being given as a koha and what is reimbursement.
10. Remove 0800 4 ethics number and replace with number on [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
11. Please include some kind of diagram to explain the procedure.
12. Section 6 could be condensed to avoid repetition.
13. A Māori cultural statement is required, one for use can be found in the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
14. The Committee requested that advising the GP of participation was mandatory and 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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Jonathan Darby and Dr Andrea Forde.

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| **7**   | **Ethics ref:**   | **2024 FULL 18446** |
|   | Title:  | The Children’s Palliative Outcome Scale Validation Study |
|   | Principal Investigator:  | Dr Gemma Aburn |
|   | Sponsor:  | King’s College London |
|   | Clock Start Date:  | 08 February 2024 |

Dr Gemma Aburn 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 targeted recruitment for Māori and Pasifika. The Researcher responded that with the small number of participants in New Zealand this is difficult, but they intend to address this with future research as the tool is adapted for use.
2. The Committee commended the quality of the submitted documents and comprehensive submission.

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 Protocol states information will be kept for 8 years, but any health data collected in New Zealand needs to be kept for period of 10 years following participant turning 16.

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

1. Please remove specific age ranges on the assent forms. The Researcher can instead adopt a guide for the study team to assign the planet names used on the forms to an age-range for comprehension.
2. For the Mercury group, the Committee encouraged use of simpler language so the participants can read it themselves.
3. There is not enough information about the study such as who is doing the research and why it is being done in the Mercury assent form.
4. In the Saturn and Neptune assent forms, the child will not be giving consent, but assent. Please change the language.
5. The Committee noted that in New Zealand, those who turn 16 can consent for themselves.
6. The Neptune PIS can include an item from the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) about information being taonga.
7. Please remove the language that “no one will mind” if the young person does not want to participate; the PIS can reflect that there is no need to take part if they do not want to.
8. Please include the full reference to King’s College in the PIS for health professionals as a site to which data will be sent.
9. In the PIS for health professionals, there is reference to a parent or guardian. This is not relevant for this group, please remove.
10. Those participants who are aged 16-17 years can use the same PIS as the document prepared for parents/guardians with language amended to state “you or your child”.
11. Please include an option for participants to receive a summary of their results.
12. Please ensure that all consent forms include provision for the researcher to counter sign these.
13. Please consider replacing the phrase ‘email ID’ with email address.
14. Please include the HDEC contact details [from the template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) and ensure the HDEC email is corrected.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| **8**   | **Ethics ref:**   | **2024 FULL 18651** |
|   | Title:  | Elucidating patterns of BCG vaccine-induced resistance to Mycobacterium tuberculosis strains in peripheral blood |
|   | Principal Investigator:  | Dr Gergely Toldi |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 08 February 2024 |

Dr Gergely Toldi and Riya Shajumon 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 peer review provided states that it would be better to do single cell RNA sequencing than group batch testing of samples. The Committee queried if the Researchers have been able to increase their budget to do this. The Researcher clarified that samples will be tested individually.

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 clarified the association with the other named investigator in the PIS but not the Protocol. The Committee stated that the investigators should all be named and any relationship with other research should be acknowledged in the Protocol and the data management plan. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
2. The Committee queried the timing of recruitment at the two sites, and whether participants’ parents/guardians would have adequate time to provide informed consent. The Researcher clarified that the BCG vaccine is not part of the routine vaccine schedule, and it is offered to newborns and very young infants based on identified risk-factors; this means that eligible infants and whānau are given information about the vaccine and self-register and request an appointment at the BCG clinic. This can be typically 4-6 weeks of age and up until 1 year of age. The Committee requested the Researcher to plan a process whereby potential participants receive information about the study ahead of that scheduled appointment. Regarding participants in the control group, the Researcher clarified that information can be provided ahead of a planned appointment. The Committee requested that the protocol be updated to include this detail. The Committee also requested that the researcher ensure that the peer review adequately addresses the recruitment of the two groups. The protocol currently is not adequate and needs to address key aspects of the study such as background, scientific rationale, aims, inclusion criteria, data analysis, etc. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7 & 9.26).*
3. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP) (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17*):
	1. There is conflicting information on who the sponsor is as the University of Auckland is named in the application form, but University of Otago is named in the DTMP. Please clearly identify the Sponsor\, and the sites to which data is being sent and stored. including relevant organisational data governance details.
	2. The DTMP states that tissue may be analysed overseas but there is no information in the PIS about this. Please make sure this is clarified and consisten across the documentation.
	3. The DTMP states there is no data linking, but the participant information sheet (PIS) mentions there is. Please align both to what is correct.

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 control group is not referred to in the PIS provided. They should be included either within the existing PIS or a new PIS created.
2. Information from the mother is also being collected, so they are also participants, and it should be clearly stated as such in the PIS and consent form.
3. Please include a description of the wider study in the PIS as well as identifying all investigators.
4. Please include New Zealand statistics on TB incidence.
5. Please clarify the reimbursement policy, and whether participants will be fully reimbursed for travel and parking for the study visits.
6. Please ensure that the consent form specifies what participants are agreeing to do, especially surrounding whose samples are being taken.
7. Please remove 0800 4 ETHICs number and replace with number on [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
8. Please review and amend for simple and plain language.

**Decision**

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

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| **9**   | **Ethics ref:**   | **2024 FULL 19577** |
|   | Title:  | Aquablation theraPy outcomes in pRostate Cancer patienTs |
|   | Principal Investigator:  | Prof Peter Gilling |
|   | Sponsor:  | PROCEPT BioRobotics Corporation |
|   | Clock Start Date:  | 08 February 2024 |

Margaret Ross, Professor John Rewcastle and Wikus Vermeulen 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 the investigators are familiar with the device, and participation in the trial is an offer to those with prostate cancer to relieve their urinary tract symptoms only. This is not available in private practice at this stage.
2. The Researchers clarified that ‘additional intervention’ referenced relates to managing symptoms that can develop such as urinary urgency so at most would be a catheter that would be placed.
3. The Committee confirmed with the Researcher that there is adequate separation between clinical care and the way participants receive information and consent to enrol in 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 queried if the follow-up for the study differs to standard of care (SOC). The Researchers responded that there is more than SOC for follow-up, such as checking quality of life and more frequent contact with participants. The Committee stated that the PIS should clearly distinguish what is SOC and what is required as follow-up for the study.
2. The Committee requested further Peer Review as the peer reviewer states they work as a consultant for the Sponsor of the study. The Committee advised the Researchers to obtain a New Zealand based peer review from an independent reviewer.
3. Please ensure that relevant organisational governance policies and New Zealand legislation are included in the Data Management Plan (DMP). The Sponsor may also have guiding documents that can be included.
4. The Committee requested correction of the study start date and timeframe in the application form.
5. The Committee noted that the evidence of CI’s indemnity has elapsed, please ensure current evidence is uploaded.
6. The Committee noted that Insurance Cover is worldwide, not New Zealand-specific.

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

1. Please revise the language “You will not be penalised or lose benefits” such as to state “you will still receive standard of care regardless of whether you decide to participate”.
2. The participant does not need to give any reason why they want to withdraw from study.
3. If a participant chooses to withdraw this does not have to be in writing.
4. The Sponsor cannot stop the study solely for commercial reasons. Please ensure this is reflected in the documentation.
5. Where parentheses are used, please consider just using the simplified/lay language.
6. Regarding the use of photos, please change “your identity will not be revealed” to “any identifying features will be obscured”.
7. It would be useful to include a picture of the Aquabeam instruments.
8. Please include in the Māori cultural statement the potential whakamā of some aspects of participation.
9. Under risks, please add a number to the percentage figure (e.g., less than 1% or fewer than 1 in 1000 people).
10. Please ensure there is clarity regarding what participants can seek reimbursement for including travel and related costs. Please consider revising the wording to remove detail that is applicable in the US but not in New Zealand.” The overall study results will be posted to this registry. Individual participant results will not be posted. Therefore, you may not [seek access to your information and request corrections to mistakes].” After discussion, it was clarified this statement may not be needed. Please review and correct accordingly.
11. Please ensure measurements for fluids are written in millilitres, not teaspoons.
12. Please check for Americanised or incorrect spelling such as “technics”.
13. Bottom is defined as ‘anus’. Please use “anus” directly.
14. Please amend the compensation section to remove reference to the Medicines New Zealand Industry Guidelines as these do not cover device trials. and reword to ensure that it reflects ACC equivalent compensation.
15. Throughout the PIS, there are references to a “patient information sheet”. Please change this to “participant”.
16. Please state that the participant’s General Practitioner (GP) will be informed in event of clinically significant abnormal findings/concerns and delete the optional tick-box in the relevant consent clause, as this should be mandatory.

**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).*
4. Please supply an independent peer review for the current version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
5. 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 Jonathan Darby and Mr Derek Chang.

## General business

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

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| **Meeting date:** | 19 March 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 5.10pm