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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 21 May 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12.30-1.00pm | 2024 FULL 20088 | DOMENICA: Randomized phase III trial in MMR deficient endometrial cancer patients comparing chemotherapy alone versus Dost | Dr Michelle Wilson | Ms Dianne Glenn & Ms Jade Scott |
| 1.00-1.30pm | 2024 FULL 18331 | SAFE | Dr Shay McGuinness | Mr Jonathan Darby & Mr Derek Chang |
| 1.30-2.00pm | 2024 FULL 20019 | AR882-302: A study to test how AR882 works in people with long-term gout (REDUCE-2) | Dr Claire Thurlow | Ms Dianne Glenn & Dr Kate Parker |
| 2.00-2.30pm | 2024 FULL 19461 | Respiratory sinus arrhythmia pacing post-CABG surgery in patients with HFrEF | A/Prof Martin Stiles | Mr Jonathan Darby & Dr Andrea Forde |
|  | *Break (10)* |  |  |  |
| 2.40-3.10pm | 2024 FULL 19855 | Outcomes in school-aged children after pelvic reconstruction surgery at Starship Children’s Hospital | Dr James Hamill | Ms Catherine Garvey & Dr Sotera Catapang |
| 3.10-3.40pm | 2024 FULL 19845 | GO45006: A clinical trial to compare tiragolumab plus atezolizumab versus placebo plus atezolizumab in people with non-small cell lung cancer | Dr Aileen Ludlow | Mr Jonathan Darby & Ms Jade Scott |
| 3.40-4.10pm | 2024 FULL 19857 | A family centered group intervention for children with neurodevelopmental delay | Dr Parimala Kanagasabai | Ms Catherine Garvey & Mr Derek Chang |
|  | *Break (10)* |  |  |  |
| 4.20-4.50pm | 2024 FULL 20353 | GEO-TBI registry | Professor Giles Critchley | Ms Dianne Glenn & Dr Kate Parker |
| 4.50-5.20pm | 2024 FULL 20359 | MK-720-008: A Phase 3, Program to Evaluate Tulisokibart for Moderately to Severely Active Crohn’s Disease | Dr Sriharan Selvaratnam | Ms Catherine Garvey & Dr Andrea Forde |

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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 Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |

## Welcome

The Chair opened the meeting at 12pm and 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 Dianne Glenn 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 16 April 2024 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 20088** |
|  | Title: | Randomized phase III trial in MMR deficient endometrial cancer patients comparing chemotherapy alone versus Dostarlimab in first line advanced/metastatic setting: DOMENICA STUDY (GINECO-EN105b/ENGOT-en13 study) |
|  | Principal Investigator: | Dr Michelle Wilson |
|  | Sponsor: | Australia New Zealand Gynaecological Oncology Group (ANZGOG) |
|  | Clock Start Date: | 9 May 2024 |

Dr Michelle Wilson and other members of the research team 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 that there may be more sites added to the study in the near future.
2. The Committee queried why women with Hepatitis B, C and HIV were being excluded. The researcher noted that this is due to the potential adverse effects on immunosuppressed individuals. The Committee queried why if this was the case Tuberculosis was not an exclusion.
3. The Committee clarified that vaccination schedules are encouraged to be up to date in the participants prior to those people taking part in the study.
4. The Committee recommended that the participant information sheets be tested in the prospective participant audience for readability.
5. The Committee clarified that the current planned participation was only at the Auckland site.

Summary of outstanding ethical issues

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

1. The Committee requested the insurance certificate owned by ANZGOG as mentioned in the submission.
2. The Committee requested that the person consenting and initially approaching participants be a research nurse or non-treating clinician.
3. The Committee have noted and request that data not be kept indefinitely for future use. This should be limited. Please include a time period for disposal in the protocol and Data and Tissue Management Plan (DTMP).
4. The Committee requested that the mention of formalin fixed paraffin embedded tumour sample at progression is noted in the PIS/CF as it currently is only in the DTMP and Protocol. If this is not occurring in New Zealand, then please clarify this.
5. The Committee requested the central lab be named and the location detailed in all documentation it occurs in.
6. The Committee queried the age stratification in relation to the data analysis and whether the study design will adequately interrogate the efficacy of the study drug.

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

Main PIS/CF:

1. Please expand on MMR the first time it is mentioned.
2. Please clarify the pharmacokinetic tests in relation to the blood testing that will occur.
3. Please clarify the sentence on page 10 “Hyperthyroidism: important secretion of hormones by thyroid” and also the sentence “Diabetic ketoacidosis: increase of blood acidity, related to the accumulation of toxic substances for the "organism" and caused by the lack of insulin”.
4. Please provide an example of immunosuppressants including corticosteroids.
5. Please clarify what a CT and an MRI scan is in case participants are not aware.
6. Please only refer to electrocardiogram in full once. After that it may be abbreviated.
7. Please rephrase the use of “coin tossing” as this is not accurate/appropriate.
8. Please include that karakia is not available at tissue disposal.
9. Please clarify how results from genetic tests will be communicated to participants.
10. Please remove the tick box for the option of General Practitioner notification. This should be mandatory for this type of study.
11. Please clarify on page 5 whether there will be need to repeat testing where it may have already been conducted.

Future Unspecified Research (FUR) PIS/CF:

1. Please amend use of the term ’patients’ to be ‘participants’.
2. Please clarify the statement “This optional study will be in patients in Group 1 as explained in the Master Participant Information and Consent Form (PICF)” by clarifying what Group 1 is in this PIS/CF (Participants randomised to receive Dostarlimab treatment only).

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*
* please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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| **2** | **Ethics ref:** | **2024 FULL 18331** |
|  | Title: | Surgical Ablation of Atrial Fibrillation Efficacy trial |
|  | Principal Investigator: | Dr Shay McGuinness |
|  | Sponsor: | Hamilton Health Sciences Corporation |
|  | Clock Start Date: | 9 May 2024 |

Dr Shay McGuinness and Ms Keri-Anne Crowley 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 that the participants would be recruited as outpatients. Those who are at the clinic would be approached by the study coordinator prior to the day they will be having surgery. The researcher noted that when possible, they do send information to participants prior to that visit to give people as much time as possible to review the study details. The Committee was satisfied that the process in place to manage this was sufficient.
2. The Committee clarified that there was no additional surgical risk for those people randomised to the ablation. The researcher noted that this was described in the participant information sheet/consent form (PIS/CF) is less than 1% but it is in actuality much lower than 1%. The Committee suggested that this wording could be changed if needed but it is reassuring that the researcher provides the actual number to participants when they are being consented.
3. The Committee clarified that the randomisation would be done prior to surgery but should there be issues identified during surgery indicating that ablation was not clinically appropriate then this would not be done, and the participant withdrawn. .
4. The Committee queried what support for participants would be available for mental health care. The researcher clarified that this would be handled by the research and ICU nurses that do care for these participants in this manner as part of Standard of Care (SoC). The researcher noted that study follow up could assist in identifying issues that are not otherwise picked up post operatively and after discharge, and that any findings will be followed up appropriately.
5. The Committee clarified that the researcher was excluding patients of long-term care facilities due to likely inability to see the study through to the end and that the study particularly is focused on episodic heart failure and admission into hospital and that this data would be skewed in these facilities.
6. The Committee clarified that there is an escalation pathway for lack of follow up and that this would be closely monitored by the research team. The researchers noted that there are pathways in place to ensure that responses from the quality-of-life questionnaires were acted on in a timely manner. The Committee was concerned that forwarding to crisis hotlines would not be enough. The research nurse specified that these decisions would be made with participants to make sure they received the best care for them in a timely way.
7. The Committee clarified that all of the surgeons have equipoise for the study and are working together to ensure the safety for the cohort. They are all content with the randomisation and willing to follow this process.
8. The Committee clarified that post-surgery prescription of anti-arrhythmic drugs would occur per SoC after 6 weeks. This would be provided by cardiologists or General Practitioners (GPs).

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 full protocol be provided for review.

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

1. Please ensure that it is clear if there are health concerns for participants identified during surgery that this will be prioritised over participation.
2. Please make it clear what reimbursement will be given to participants for travel and parking.

**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 Mr Derek Chang.

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| **3** | **Ethics ref:** | **2024 FULL 20019** |
|  | Title: | AR882-302: A Phase 3 Randomized, Double-blind, Multi-center, Placebo-controlled Study to Evaluate the Efficacy and Safety of AR882 in Participants with Gout |
|  | Principal Investigator: | Dr Claire Thurlow |
|  | Sponsor: | IQVIA RDS Pty Limited |
|  | Clock Start Date: | 9 May 2024 |

Kim Huljich and Dr Claire Thurlow 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 requested clarification as to what sites in New Zealand, if any, would be doing the sub study testing as noted in the protocol. The Researcher advised that this is currently not planned and an amendment must be uploaded addressing this additional activity if this changes.
2. The Committee clarified that both arms of the study would be given prophylactic colchicine.
3. The Committee queried the consultation process for Māori and Pasifika. The documented approach was considered inappropriate for both groups. The researcher clarified that there was a study-level approach but that this would largely be conducted alongside the locality authorisation by local iwi.
4. The Committee clarified the process around the database and how the participants will be consented for being on the database and if they will then be contactable for future studies.
5. The Committee clarified how referrals from General Practitioners (GPs) may be made and how information will be disseminated to GPs over the life of 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 requested that the number of participants in New Zealand be reflected accurately in the insurance certificate as currently these numbers do not match up.
2. The Committee queried the procedures around avoidance of coercion of participants, requiring submission of protocolisation of the activities that will be undertaken during recruitment to avoid coercion rather than stating it will be determined per site.
3. The Committee queried the exclusion of participants with Hepatitis B and C as well as HIV. The Committee noted that the exclusion of this group for “safety” is not completely appropriate and risks further stigmatisation.
4. The Committee requested that provision of receipts not be the method through which participants may be reimbursed for travel and food etc., during the study. Please note that the preference of the Committee be that this is a flat rate or provided without receipts as this can be burdensome for participants.
5. The Committee requested that there be protocolisation around the review and follow-up for quality-of-life questionnaires and how the researchers intend to respond should there be a disclosure of mental distress.
6. The Committee requested the data and privacy policies of the company that will be holding data and that all relevant information pertaining to this be included in the Data and Tissue Management Plan (DTMP).
7. The Committee requested that the age range of participants likely to be recruited is accurate in the DTMP. Currently there is reference to under 16s which is not relevant to this study.
8. Under the organisational data oversight please include the site policies specifically for Optimal Clinical Trials.
9. The Committee requested that all adverts be made accurate to the New Zealand context and the different adverts note instead of IRB’s that the Northern A HDEC has approved the ethical aspects of this study.

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

1. Please make notification to general practitioners mandatory.
2. Please make clear the process for reimbursement, including the amount possible to be reimbursed and method.
3. Please ensure that the data storage period for pharmacokinetic data is consistent with the protocol and DTMP.
4. Please clarify why participants are tested for HIV / HepC and make it clear that if the results of either of these tests are positive that participants will not be able to continue to participate.
5. Please clarify that there will not be any identifiable features in the images taken of participants.
6. Please include potential side-effects of colchicine.
7. Please condense the two optional cultural paragraphs into one.
8. Please clarify that if participants do not have access to a device for the e-diary that this will be provided for use in the study.
9. Please provide a dollar amount as the reimbursement for time. This must be consistent across the sites.
10. Please be consistent in the use of medicine rather than switching between “medicine” and “drug”.
11. Please refrain from describing colchicine as being an anti-inflammatory, this is not a recognised indication of this medication and should not be described as such for avoidance of incorrect use.
12. Please amend wording of “unborn baby” to foetus.
13. Please clarify the differences between contraceptive requirements (14 days vs 19 days) for males and females.
14. Please clarify why someone who has had a hysterectomy would also be required to use barrier contraception. Please amend as necessary.
15. Please amend the language of “sample destruction” to instead read “sample disposal”.
16. Please ensure that in the disability section that transport organisation and fees are clearly described and that the details of how this will be organised and paid for is made clear.
17. Please review for typos.
18. Please remove the 0800 4 Ethics number and replace instead with the MoH general inquiries number per the [HDEC PIS/CF Template](mailto:https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please update the advertisements, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*
5. Please provide more detail in study documentation to ensure participant safety if there are potential concerns with their well-being raised as part of this study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4-8.6, 8.9)*
6. Please update the data and tissue management plan to ensure the safety and integrity of participant data and tissue *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15, 14.16 & 14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Dianne Glenn and Dr Kate Parker.

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| **4** | **Ethics ref:** | **2024 FULL 19461** |
|  | Title: | Respiratory sinus arrhythmia pacing post-CABG surgery in patients with HFrEF |
|  | Principal Investigator: | A/Prof Martin Stiles |
|  | Sponsor: | Ceryxl Medical |
|  | Clock Start Date: | 9 May 2024 |

Julian Paton, Flora Yuen, Dr Zaheer Yousef, Malcolm Harner, Graham Fisher, Kelly Henderson and Stuart Plant 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 that personnel representing the Sponsor may be present in person when the study device is being used with participants.
2. The Committee clarified that the site budgets would be to the sites directly but any funds for patients would be direct to Waikato Hospital. It was clarified that training costs would be through that process.
3. The Committee clarified that pregnant people were excluded due to the fact that pregnant people do not get offered this type of cardiac surgery.
4. The Committee clarified that the sponsor would pursue licensure in New Zealand should the study prove its efficacy.
5. The Committee clarified the process for participant reimbursement.
6. The Committee clarified the use of anti-arrhythmic medications to prevent atrial fibrillation when required and that there was no risk associated with this even in the control group.
7. The Committee clarified the use of the pacemaker and the role prior to randomisation.

Summary of outstanding ethical issues

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

1. The Committee noted that the peer review was not independent and is required to be undertaken by a person with appropriate qualifications to independently review the study.
2. The Committee requested that an insurance certificate noting New Zealand as a territory under cover and in New Zealand Dollars be provided for review.
3. The Committee requested that the methods that would be used to assess competency to consent be included in the protocol.

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

1. Please reword the exclusion of pregnant people to note that this is because pregnant people are not offered non-emergency cardiac surgery.
2. Please include that provision of receipts is not required by participants in order for reimbursement.
3. Please remove reference to the Medicines NZ Guidelines as these do not apply to devices.
4. Please clearly explain the duration period of pacing as it is affected by the study, and that study participation will not impact the amount of time that participants will stay in hospital. Please make it clear how the pacing may differ depending on the study versus standard of care.
5. Please remove the tick box from the General Practitioner notification in the consent form. This should be mandatory.
6. Please include the possible complications as in the device instructions for use in the PISCF.
7. Please make it clear what the control group will involve should participants be randomised to this group.

**Decision**

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

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

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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| **5** | **Ethics ref:** | **2024 FULL 19855** |
|  | Title: | Paediatric pelvic reconstruction outcomes study |
|  | Principal Investigator: | Dr James Hamill |
|  | Sponsor: |  |
|  | Clock Start Date: | 9 May 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 queried the lack of funding and the scope of the project given the submission referred to resourcing matters; and how to ensure that the proposed timeframe and participant recruitment targets are achievable.
2. The Committee queried if there would be specific Pasifika recruitment.
3. The Committee queried whether there would be questions concerning sexual function of adolescents,
4. The Committee queried what stratification would be present in the study populations in order to ensure that the data set is unbiased.
5. The Committee requested clarification of the consenting process vs the assent process and how participants would be assessed for competency to consent.
6. The Committee raised the following regarding the data management plan:
   1. Please add local sponsor - Te Whatu Ora Te Toka Tumai.
   2. Please include organisational data management oversight policy from Te Whatu Ora | Health NZ.
   3. Amend section 8 (there is no 7.3 or 7.4)
   4. Clarify data retention 10 years after a participant turns 16.
7. The Committee requested to ensure Māori consultation is undertaken as part of locality review.
8. The Committee queried why those 18 and older are not included.
9. The Committee raised concern regarding quality-of-life questionnaires that could indicate distress in a young age group, and queried how this will be handled in more detail in terms of risk management.
10. The criteria for inclusion and exclusion are outlined, but please clarify how "significant learning disabilities" will be assessed. Please identify if this is related to cognitive abilities, diagnosed conditions, etc.
11. The Committee requested clarification around what population/age ranges would be providing consent versus assent, noting that older ages should be able to consent for themselves.
12. The study aims to inform the development of a pelvic reconstruction service. The Committee queried what specific criteria will be used to evaluate the study's success in achieving this goal, and how will these findings be translated into clinical practice.

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

1. Please include the number of New Zealand participants.
2. Please specify how the interviews will be conducted including when, where and how this will be conducted.
3. Please specify if the participants of interviews will be able to amend transcripts of their own data.
4. Please specify if participants can be interviewed in the absence of their parents if they choose to be.
5. Please ensure that there is General Practitioner involvement and notification if this is a development of a national service.
6. Explain how data is de-identified.
7. Please include the correct storage period of 10 years.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Catherine Garvey and Dr Sotera Catapang.

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| **6** | **Ethics ref:** | **2024 FULL 19845** |
|  | Title: | GO45006: A PHASE III, RANDOMIZED, DOUBLE-BLIND STUDY OF TIRAGOLUMAB PLUS ATEZOLIZUMAB COMPARED WITH PLACEBO PLUS ATEZOLIZUMAB IN PARTICIPANTS WITH COMPLETELY RESECTED STAGE IIB, IIIA, OR SELECT IIIB, PD-L1 POSITIVE, NON SMALL CELL LUNG CANCER WHO HAVE RECEIVED ADJUVANT PLATINUM-BASED CHEMOTHERAPY |
|  | Principal Investigator: | Dr Aileen Ludlow |
|  | Sponsor: | Roche Products (New Zealand) Limited |
|  | Clock Start Date: | 9 May 2024 |

Dr Aileen Ludlow, Yvette Mainwaring, Daphne Mason and other members of the research team 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 submission indicates there is no intention for ongoing access for the investigational product. In this case, there is no cross-over for placebo participants either. The Committee queried the rationale behind not providing access if there is shown therapeutic benefit. The Researcher explained why they consider hat there is no clinical justification or therapeutic benefit in having ongoing access in either group.
2. The Committee noted that excluding those with HIV, Hep B and Hep C is a broad and classic exclusion and queried the reasoning for it in this study of people with lung cancer and how the study will therefore address disparities and ethnic differences. The Researcher explained that this is an at-risk population for an experimental product where the benefits are not yet known. The Committee stated that as the safety of the product becomes more known, review of the exclusion could be undertaken.

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 retention of data and tissue by Roche even if the pre-screening participants are not eligible for enrolment in the main study. The Committee requested if it would be at all possible for the participants to request that this not occur and that their data and tissue be withdrawn should they not end up participating in the study. The Researcher said they would seek clarification from the Sponsor. For the pre-screening participants, please also ensure they are provided information around long-term retention of data. Currently it is a very broad reference, but it should be defined and as narrow and relevant as it can be for study purposes.
2. The Committee noted that insurance is provided in Swiss Francs. Please provide letter or equivalent noting what the amount is in New Zealand dollars.
3. The Committee raised the following about the Data and Tissue Management Plan (DTMP):
   1. There is not enough information on governance, such as policies the Sponsor may hold.
   2. Page 9 mentions data servers that are not mentioned elsewhere or clarified. If they are holding data, that should come back through in the PIS and in the DTMP. Please check with Sponsor.
   3. Currently mentions under 16-year-olds. Please remove as its not applicable.

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

Main PIS/CF:

1. Please remove “Veteran status” as this is not applicable in New Zealand.
2. Please refer to the study “drug” as the study ‘medicine’ and use this consistently as this is more New Zealand-specific.
3. On page 5, there is a sentence that says, “You will have 13 visits approximately every 4 weeks”. This could be reworded to state ‘You will have a visit approximately every 4 weeks to a maximum of 13 visits’.
4. Pages 6 and 7 has table of assessments, which could be reduced to one page for readability.
5. Please remove reference to Legally Authorised Representative.
6. Side-effects do not need to be re-stated for emphasis, the table is sufficient.
7. Across all sheets, please rephrase “tissue destruction” to ‘tissue disposal’.
8. Notification to the GP of participation should be mandatory due to the risks of the study, and not an optional item in the Consent Form.
9. Please note that measurement of blood should be in millilitres not teaspoons. Teaspoons can conjure food-related imagery which should not be associated with bodily fluids.
10. Mention of ‘unborn child’ on page 8. Please review and just generally talk about pregnancy/outcome of pregnancy.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data and tissue management plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Jonathan Darby and Ms Jade Scott.

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| **7** | **Ethics ref:** | **2024 FULL 19857** |
|  | Title: | Co-designing a family-centered group intervention for children with neurodevelopmental delay and testing its feasibility |
|  | Principal Investigator: | Dr Parimala Kanagasabai |
|  | Sponsor: |  |
|  | Clock Start Date: | 9 May 2024 |

Dr Parimala Kanagasabai 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 Part 1 is very clear, and some of the final content of Part 2 hinges on Part 1. The Committee clarified with the Researcher that Part 2 may include participants from Part 1, and the Researcher will accommodate as many families who want to participate in Part 2. The Committee stated after discussion that it is very likely that Part 2’s protocol and participant information sheet will need to be reviewed after the feedback of Part 1, and amended accordingly to be clear on what participation will involve. These amended documents should be submitted as an Amendment in Ethics RM to the Committee when it is ready.
2. The Committee noted that this decision is based on Part 1 of the study with the understanding that Part 2 will be submitted as an Amendment when the documents are finalised.

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 there is a risk management or escalation plan when conducting Part 1 of the study. The Researcher responded that the study will take place in a clinical setting with therapists who have their own procedures in place for management or escalation in the event of mental distress. The Committee noted that confidentiality may need to be broken in some circumstances. The participants should be informed in the participant information sheet that if there is acute concern, or a legal obligation, absolute confidentiality cannot be maintained, and the study team will need to act appropriately.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Catherine Garvey and Mr Derek Chang.

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| **8** | **Ethics ref:** | **2024 FULL 20353** |
|  | Title: | GEO-TBI Global Epidemiology and Outcomes following Traumatic Brain Injury - An international registry for supporting care and research excellence in traumatic brain injury. |
|  | Principal Investigator: | Professor Giles Critchley |
|  | Sponsor: |  |
|  | Clock Start Date: | 9 May 2024 |

Prof Giles Critchley was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researcher confirmed disability and ethnicity data will be collected in New Zealand.

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 submission was seeking approval for both the 90-day study and the registry. The Committee noted the protocol for the 90-day study was not included in this submission and requested this was provided.
2. The peer review provided was on the global papers – an independent peer review needs to be sought on the New Zealand-specific protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
3. The Committee noted that the application form identifies non-consenting adults, but sufficient and clear justification has not been outlined for including these participants as required by the National Ethical Standards. These participants can be enrolled into research if [Right 7(4) of the Code of Health and Disability Services Consumers’ Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/) is satisfied. The Committee advised that family members can give their opinion on whether they believe their relative would consent to participation and a sample but they cannot provide proxy consent. This can only be documented as the person saying ‘if they could consent for themselves, I believe they would’ and not by the family member providing that consent. The Committee noted that the previous reviewing Committee were not satisfied that Right 7(4) applied here and gave advice to exclude non-consenting adults which was not folded into this current submission. The Committee recommended reviewing both previous declines and taking on board the Committee’s concerns when submitting again.
4. The Committee noted that no consent form has been provided for an adult consenting for themselves. Please provide this.
5. The Committee raised the following about 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. Very broad future use of data statement in DTMP. Clear justification needs to be provided or this needs to be specified. This also needs to be highlighted in the PIS.
   2. DTMP has statement about commercial use of data, but application states there will be none. Remove from the DTMP.
   3. Incidental findings is mentioned in DTMP but is not relevant to this study. Please remove.
6. The Committee requested update to the planned conclusion date.

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)*:

PIS/CF To Continue:

1. Consent to continue needs to be reworded to be clear the family didn’t assent or consent for the participant, but to state “your family’s opinion was sought, and they believed you would want to participate so you were enrolled by the study PI. We are now seeking your consent for you to continue in the study.”
2. Paragraph 2 should also be reworded that they are consenting to ‘continue’ to participate.
3. Paragraph 3 says ‘you have been contacted about this study’, but this needs to state ‘you have been enrolled in the study’.
4. Please review the whole sheet for consistent language about continuing to participate.
5. Please review for typos.
6. Anonymised data and de-identified data are used interchangeably, please review (these are defined in the NEAC Standards) and use the correct term that is suitable for each use. .
7. It is also important for Māori data sovereignty to confirm whether data sent overseas is anonymised or de-identified. It will also be good to know what safeguards will be put in place once advice has been given following Māori consultation.
8. Please remove reference to a GP being informed of results as this is not relevant.

CF has a statement saying “I agree for my NHI number or equivalent identifier to be used for linking my data to other data” – that is a wide-ranging agreement and there is nothing in the PIS or DTMP about this. Any proposed data linking should be clearly explained in the PIS, and the DTMP, and justified for study purposes.

PIS/Assent Form for Under 16 Year Olds:

1. There is a 9-page document and a 2-page document for this group. The 2-page document is too short. There can be people who can comprehend more information. The Committee suggested making two versions – a simplified version that can be shorter and more comprehensive version This means that both documents need to be reviewed and amended.

Parent/Guardian Assent:

1. Consent for parents to consent with young person’s assent also refers to “I”. If a young person is signing an assent form, they need a place to sign along with their parents.

Assent Form for Adult unable to give consent:

1. This form should be for getting the family member’s opinion about whether they would want to participate, not assenting or consenting for them and needs to be rephrased.
2. It currently also is all about “I” rather than about the other person.

**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 20359** |
|  | Title: | A Phase 3, Randomized, Double-Blind, Placebo-Controlled Program to Evaluate the Efficacy and Safety of Tulisokibart in Participants with Moderately to Severely Active Crohn’s Disease |
|  | Principal Investigator: | Dr Sriharan Selvaratnam |
|  | Sponsor: | Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc. |
|  | Clock Start Date: | 9 May 2024 |

Esther Ji, Natalia Cid, and Cynthia Pendas were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that participants in the first part of the placebo arm will have 52 weeks off standard of care and placebo. The Committee asked for clarity around the safety precautions for this. The Sponsor noted there is an escape criteria and they can enter the open-label part of the study if they are eligible.
2. The Committee queried if there is therapeutic benefit, will ongoing access be provided beyond the extension. The Sponsor confirmed there will be longer-term access provided for those who show benefit.
3. The Committee commended the study for not automatically excluding pregnant people or those with HIV, Hep B and C.

Summary of outstanding ethical issues

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

1. The Committee requested that the insurance coverage amount is clarified in New Zealand dollars.
2. The Committee noted the administering of quality-of-life questionnaires, particularly the timeliness of reviewing if someone is indicating that they have psychological distress. The Committee requested a risk management plan that pulls together the issues of identifying distress and who pays for care if they need to be referred for psychological or psychiatric help.
3. The Committee noted that the autoinjector uses Fahrenheit. Please ensure this is corrected to Celsius for New Zealand.
4. The Committee requested more information in the Data and Tissue Management Plan (DTMP) surrounding Governance, use of Medidata and Patient Cloud. The Committee noted that the privacy statement for the app is concerning, and queried how the application will be ringfenced from other apps on phone and collecting other data.

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

1. GP notification is listed “and/or” but should just be ‘and’.
2. Please note that measurement of blood should be in millilitres not teaspoons or tablespoons. Spoon measurements can conjure food-related imagery which should not be associated with bodily fluids.
3. ‘Injections’ is better to use instead of ‘shots’ as this is Americanised language.
4. There is a statement excluding live vaccines, but later on it says for participants to make sure they have them before joining the study. The Committee recommended joining these statements together and prioritising updating vaccine status if needed. The Committee also requested review for inclusion of smallpox vaccine which isn’t licensed for New Zealand use.
5. The contraception statement needs to be amended to acknowledge there is no exclusion of pregnant women but that it is recommended to not get pregnant during the study. Please also break down when contraception is needed and under what circumstances.
6. The Committee noted TB is also notifiable to Medical Officer of Health so needs to be listed.
7. Please amend page 7 and the reference to the study medication not being available in New Zealand, in light of plans to assess licensure and provide ongoing access if appropriate. Page 7 states medicine won’t be available in New Zealand because it is not registered, but later reference is made to reviewing availability in New Zealand.
8. Please review for spelling mistakes, such as ‘Cron’s’ in the first paragraph.
9. Schedule of assessments table could be combined onto one page for participants ease for both studies.
10. Notifiable conditions are first stated to be notifiable to Ministry of Health but should be corrected to Medical Officer of Health.
11. Please review for consistency in referring to ‘trial drug’, and it is preferred to be referred to as ‘trial medicine’.
12. Please review for font consistency.
13. Cultural statements have inconsistent information about whether karakia will be available at time of tissue disposal. Please ensure this is specified whether it is available in all example statements.
14. Specify that transport that can be arranged will be paid for and how, whether that’s reimbursement or paid on their behalf.
15. Reference that someone of the same gender for a physical examination may not be available, but the Committee emphasised the importance for younger participants to be comfortable. Please firm up that assurance if its available at sites.
16. Future biobanking PIS doesn’t identify tissue bank by name/location.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data and tissue management plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Catherine Garvey and Dr Andrea Forde.

## General business

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

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| **Meeting date:** | 18 June 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 5.30pm