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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 19 September 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:30pm - 1:00pm | 2023 FULL 18512 | V940-002: A Phase 3 study to investigate the effectiveness of V940 plus Pembrolizumab compared to Pembrolizumab plus placebo after surgery in participants with resected non-small cell Lung Cancer | Miss Holly Thirlwall | Catherine Garvey & Derek Chang |
| 1:00pm – 1:30pm | 2023 FULL 16735 | Mi-labour Trial  | Doctor Meghan Hill | Jonathan Darby & Sotera Catapang |
| 1:30pm – 2:00pm | 2023 EXP 17876 | Offering Hepatitis C testing at the laboratory | Ms Jenny Richards | Catherine Garvey & Kate Parker |
|  |  | **BREAK 30 MINUTES** |  |  |
| 2:30pm - 3:00pm | 2023 FULL 18075 | He Kōwhiringa Hōu – A new primary care treatment pathway for whānau impacted by treatment-resistant depression | Ms Kimberley Arrowsmith | Jonathan Darby & Andrea Forde |
| 3:00pm – 3:30pm | 2023 FULL 18508 | Phase 1/2 trial of GEN3014 in relapsed or refractory hematologic malignancies | Dr Sophie Leitch | Catherine Garvey & Kate Parker |
| 3:30pm – 4:00pm | 2023 FULL 18573 | R13335-HV-2289: A Study to Evaluate REGN13335 in Healthy Participants for the Potential Treatment of Pulmonary Arterial Hypertension (PAH) | Dr Cory Sellwood | Jonathan Darby & Derek Chang |
|  |  | **BREAK 10 MINUTES** |  |  |
| 4:10pm – 4:40pm | 2023 EXP 18493 | Exploring the assisted dying service | Dr Jessica Young | Catherine Garvey & Andrea Forde |
| 4:40pm - 5:10pm | (PLEASE note that these applications are all like each other, please refer to the email explanation) 2023 FULL 15270 & 2023 FULL 15261 & 2023 FULL 15258 | A Phase 3, randomised, double-blind, parallel-group, 76-week, efficacy and safety study of BI 456906 administeredsubcutaneously compared with placebo in participants with overweight or obesity without type 2 diabetes  & 1404-0041: A study to test whether BI 456906 helps people living with overweight or obesity who have diabetes to lose weight & 1404-0040: A study to test the effect of BI 456906 on cardiovascular safety in people with overweight or obesity | Ms Jemimah Esguerra | Catherine Garvey & Sotera Catapang |

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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 | Apologies |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Ms Jade Scott

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 15 August 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 18512** |
|   | Title:  | A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants with Resected Stage II, IIIA, IIIB (N2) Non-small Cell Lung Cancer |
|   | Principal Investigator:  | Dr Anthony Rahman |
|   | Sponsor:  | Merck Sharp & Dohme (New Zealand) Limited |
|   | Clock Start Date:  | 07 September 2023 |

Holly Thirwall, Kayla Malate and Dr Anthony Rahman were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee noted that the study had been submitted to GTAC and requested that this review be provided to HDEC once review is complete.
2. The Committee clarified that Moderna is manufacturing the mRNA study drug and that the researchers and Sponsor had discussed insurance at length and were satisfied the insurance provided by Merck Sharp & Dohme would cover all aspects of the study such that separate insurance from Moderna was not required.
3. The Committee clarified that recruitment would include the ability for participants to discuss the study with someone other than the study doctor.
4. The Committee clarified that there was funding for and access to psychiatric care if required.

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 mandatory genetic analysis be limited to the study drug and study procedures. The researcher noted that the current wording was too broad, and this would be clarified with the sponsor.
2. The Committee queried if the study drug would be licensed in New Zealand on conclusion of the trial.

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

1. Please revise and narrow the scope of mandatory genetic testing.
2. Please note on page 9 that the reporting must be to the Medical Officer of Health not the Ministry of Health.
3. Please clarify and amend reference to Hepatitis as a notifiable disease so as to only include Hep B and C in this category.
4. Please add SCOTT as a reviewing body in “Who has approved the study”.
5. Please review for typos and grammar.
6. On page 18 please amend “New Zealand Health and Disability Ethics Committee” to state “Northern A Health and Disability Ethics Committee”.

**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 provide evidence of review from the Gene Technology Advisory Committee (GTAC) once review is complete.

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| **2**   | **Ethics ref:**   | **2023 FULL 16735** |
|   | Title:  | Mifepristone versus placebo to increase the rate of spontaneous labour in women with a prior caesarean: A double blind randomised controlled trial (Mi-labour Trial) |
|   | Principal Investigator:  | Dr Meghan Hill |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 07 September 2023 |

Dr Meghan Hill was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee noted that the advertising would be uploaded as an amendment in the event that this was to be used.
2. The Committee clarified the end points of the study.
3. The Researcher clarified that there was minimal safety risk to the foetuses and neonates as the foetal lung tissue would be mature at the time of the intervention.
4. The researcher clarified the process for examination for cervical dilatation and that this may be optional on day one and two but that this would be necessary upon drug ingestion and on the day following ingestion.
5. The Researcher clarified the use of baseline demographics for those not participating and the consent process for access to clinical information.
6. The Committee noted that in this case it may not be appropriate for General Practitioners to be informed and were satisfied by the Researcher’s response.
7. The Committee raised the notion that certain confounders may have some impact on the study’s end points. The Researcher noted that there was no research to support the effect of any of the potential confounding factors and as such they would not be altering standard advice to pregnant people participating in the study.
8. It was clarified with the Researcher that the research midwife noted as carrying out study procedures would also include consenting 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 requested clarification as to the involvement of the Lead Maternity Carers (LMCs). The Researcher noted that there was opportunity to contact LMCs via various means and avenues and that this would be undertaken to reduce potential burden as much as possible for both the LMCs and the pregnant people.
2. The Committee queried if it would be possible for the cervical examinations done as part of the research to be available in the pregnant person’s medical record for the LMCs reference. The Researcher noted that there would be the option for results as part of a cervical examination to be forwarded to the LMCs.

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

1. Please remove the Ethics 0800 number and replace with the general inquiry number for the Ministry of Health as per the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).
2. Please clarify that the study drug is indicated for the induction of labour overseas, with examples, or is used for the induction of labour overseas without this as a licensed indication, with examples, but that this is not a licensed indication in New Zealand.
3. Please include breech presentation in the malpresentation section.
4. Please include a statement noting that there will likely not be any impact of the study drug on the health of the fetus or baby as pregnancy is a progesterone dominant state and the investigational medicine is also a progesterone.

**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 Sotera Catapang and Mr Jonathan Darby.

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| **3**   | **Ethics ref:**   | **2023 EXP 17876** |
|   | Title:  | Protocol for a pilot to assess the effectiveness, acceptability and feasibility of two models of verbal consent for Hepatitis C atcommunity laboratory collection sites in the Northern Region |
|   | Principal Investigator:  | Dr Karen Bartholomew |
|   | Sponsor:  | Te Whatu Ora Northern Region |
|   | Clock Start Date:  | 07 September 2023 |

Dr Karen Bartholomew and Professor Edward Gane 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.

Dr Kate Parker declared a potential conflict of interest and the Committee agreed to recuse her from the discussion and decision.

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 on the process for consenting people in public spaces with minimal privacy. The Researcher explained they would use temporary partitions to provide a private space for discussion.
2. The Committee noted that the broad inclusion criteria did not appear to provide for discretion approaching potential participants, in particular those who appeared distressed or unwell. The researcher clarified that distressed people or those who did not welcome an approach by the study team would be treated with respect and their participation not sought.
3. The Committee noted that the study is looking at acceptability of two possible consent processes, and queried if they need people to go through with their blood being tested for hepatitis C. The Researcher responded that it would produce a different result to theoretically test consent in that situation. They noted that testing is relevant to the need to determine prevalence, and once testing has been done there is a need to follow up with results and to offer treatment to anyone RNA positive. They expect that number to be very small. The researcher clarified that there had not been a seroprevalence study done in Aotearoa NZ., and that they think there is a potential to inform the national approach to such testing through this research.
4. It was noted in the application that there was discussion around the decision not to routinely notify a participant’s GP of a positive result. The researcher explained that experience shows that some members of groups at higher risk of infection will not want their GP to be notified due to potential stigma, and as such rather than mandatory notification to the GP clarified that participants would be asked to provide consent for this. Although GPs will not be copied into the results, they will be able to access test results via standard electronic reporting of these. The Committee were satisfied with the response clarifying that participants would be asked to consent to notify their GP; and that if the answer was negative appropriate treatment pathways remained available.
5. The Committee clarified the scope of the waiver sought by the researchers to access data using NHI numbers. The researchers confirmed that NHI numbers could not be used as the denominator and that names and contact details would not be obtained for any people other than the small number for whom a waiver was sought to follow up by telephone. The researchers referred to a Privacy Impact Assessment obtained in relation to the data being sought under a waiver of consent and agreed to provide this to the Committee.

Summary of outstanding ethical issues

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

1. The Committee discussed the exclusion of people who are not eligible for funded healthcare in New Zealand from the research Please ensure the option is available for those people to be able to participate, as having presented for laboratory testing, they will be aware that this is a health service that they will have to pay for. Although this is a notifiable disease the duty of care for arranging unfunded treatment and follow up will be with their GP.
2. The Committee noted that the posters referred to in the application were not provided. Please provide for review before use (either in response, or as an amendment).

**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 provide the privacy impact assessment.

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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| **4**   | **Ethics ref:**   | **2023 FULL 18075** |
|   | Title:  | He Kōwhiringa Hōu – A new primary care treatment pathway for whānau impacted by treatment-resistant depression |
|   | Principal Investigator:  | Suaree Borell |
|   | Sponsor:  | National Hauora Coalition |
|   | Clock Start Date:  | 07 September 2023 |

Suaree Borell was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee confirmed that the general practices involved have an existing partnership and relationship with the National Hauora Coalition.

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 practices involved have a Hauora Coach (HC)/ Health Improvement Practitioner (HIP) who are expected to have capacity for this study. The Committee noted that two grounds on which it was anticipated the study might be terminated were inappropriate, namely insufficient resources to support the study and unforeseen impact on workflow. The Committee needs to be satisfied that when this is offered and started that the resources are there to be able to see it through. Please provide evidence of assurance that these resources are available. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.23-9.24).*

The Committee noted that GP clinics were to be used for identifying eligible participants and assisting with recruitment into the study and queried the planned process for this. The Committee requested clarification of how eligible participants would be identified and recruited. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.7)*

1. The Committee noted if there is a funding agreement in place with the GP practices (such as being reimbursed for identifying eligible participants, and their role in the interventions) the requirements of the Medical Council for health professionals involved with commercial organisations must be adhered to including transparency with participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.8)*
2. The study drug Esketamine is to be provided by Janssen under an Early Access Provision. The Committee queried the size of the grant that Janssen are also providing which the researcher agreed to clarify. The Researcher was also requested to clarify any other involvement of Janssen such as reviewing results or input into publication.is the researcher is requested to identify whether this study is commercially sponsored (and if so, needs insurance), or if not, explain ACC cover. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.3)*
3. The Committee requested clarification of all study interventions, in particular, those which are mandatory and those which are optional. The Researcher clarified that all participants are expected to receive the same parallel interventions of Esketamine and a programme of cultural therapy. The Committee noted that this is unclear from the Protocol and PIS and requested revision of these documents. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17, 9.7-9.8)*
4. The Committee queried the plan for psychiatric assistance and funding for and availability of this if required by participants. The Committee was assured considerable thought had been put into this and requested that the plan was clearly documented.
5. The Researcher clarified that if a participant withdraws, they are not required to discuss this but will be invited to do so. The Committee noted that the voluntary nature of a discussion following withdrawal be made clear. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15)*
6. The Committee noted the use of three questionnaires on psychosocial distress and queried the use of one of these that is not validated. The Researcher responded that this is currently in the process of being validated.
7. The Committee suggested a Data Monitoring Committee for the Researcher to consider for this study to ensure the safety of participants.
8. The Committee acknowledged the peer review done by a public health physician but stated that it would be appropriate for a psychiatrist or psychologist with experience in esketamine to peer review the study. The Researcher acknowledged this suggestion, noting that they consulted with Māori public health but will seek further peer review. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.32)*
9. The Data Management Plan provided was unrelated to this study. The Committee requested a Data Management Plan and referred the researcher to the [template on the HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*
10. The Committee noted that a HIP is qualified health professional, but a Hauora Coach is not and sought reassurance that the scope of practice of those involved in the study was suitable for the interventions provided. To ensure clarity for both participants and the study team, it is essential to clarify the differences in roles and scope of practice for these two positions within the study protocol. This information should also be available in PIS.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please review the PIS for lay language and ensure it is simplified for a lay reader.
2. Please acknowledge that the head is tapu in regard to the administration of the intra-nasal medicine.
3. Pregnancy inclusion/exclusion is not stated in the PIS but is in protocol. Please amend to reflect the correct criteria.
4. The Committee noted that health information collected in the study should be kept for 10 years, not 6.
5. Under the heading ‘who has approved the study’, please use the following wording: The ethical aspects of this study have been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northern A HDEC has approved this study.
6. Please use the contact information for the HDEC secretariat in the [main PIS template on the website.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) The Committee further recommended looking at the template in aiding the Researcher in their response to changes requested for the PIS/CF.
7. Please note in the PIS that the interventions will not be available following the conclusion of the trial.
8. Please explain that treatment/therapy (both interventions) will be undertaken at the usual clinic of whānau, overseen by their GP and usual practice nurse.
9. Disclosure of any commercial benefit to the Sponsor and/or GP practices should be noted.
10. Please refer to the fact that part of the intervention is esketamine – what it is, that it is a novel treatment, what the known risks and side effects are, how it is administered and so on.
11. Please explain the fact it is mandatory to commence a new anti-depressant medication to take esketamine.
12. Please outline what is required of participants within the first 9 weeks of the study, and then beyond. You may wish to adapt the table on page 21 of the protocol and use this in the PIS.
13. Please explain who the Hauora Coach is and that they will be present at study visits, and whether this is optional.
14. Please include the contraception requirements (see protocol requirements p11)
15. Please include a section on compensation for participants if they are injured in this study.
16. Describe the focus group and interview component of the study and if these are mandatory or optional.
17. State if the PTPT sessions are audio recorded or just the interviews and focus groups.
18. If there is any koha or reimbursement, please consider including this (or alternately advising participants they will not incur costs for appointments or the interventions but will not be compensated). Participants should be reimbursed for any out-of-pocket expenses.
19. Please clarify what data is collected in identifiable form and how identifiable and de-identifiable data is collected stored and managed.
20. Details regarding the focus group and interviews should be included. You may consider a separate PIS for these purposes.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above. The Committee recommended resubmitting to the Northern A HDEC.

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| **5**   | **Ethics ref:**   | **2023 FULL 18508** |
|   | Title:  | An Open-Label, Multicenter, Phase 1/2 Trial of GEN3014 (HexaBody® -CD38) in Relapsed or Refractory Multiple Myeloma and Other Hematologic Malignancies |
|   | Principal Investigator:  | Dr Sophie Leitch |
|   | Sponsor:  | Syneos Health New Zealand Limited |
|   | Clock Start Date:  | 07 September 2023 |

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 resolved ethical issues.

The main ethical issues considered by the Committee

1. The Committee commended the Researcher on the content of the cover letter and encouraged use of that for future studies.

Summary of outstanding ethical issues

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

1. The Committee clarified that this submission is for Part 2 only.
2. The Committee queried the commitment to provide the drug following the trial provided the participant(s) is receiving therapeutic benefit and provide confirmation that this will be fully funded and provided. If not, provide justification.
3. The Committee requested further clarity around how pregnancy is managed.
4. The Committee noted the wide-reaching additional studies and requested justification for why all of them are needed for participation. Please consider making these optional.
5. The Committee requested more information about the recruitment process.
6. The Committee noted that a pregnant participant/partner participant information sheet/consent form should only be submitted as an amendment in the event that a pregnancy occurs so it can be fit-for-purpose. As such, these have not approved for use with the current submission. Please also refrain from referring to unborn child and suggested use of ‘complicate your pregnancy or affect the outcome’.
7. The Committee noted provision of a practising certificate and requested that proof of indemnity for the coordinating investigator provided.
8. Section 4 of the Data and Tissue Management Plan refers to opt-out consent for tissue and data which is inconsistent with other documentation. Please clarify what is meant by this.

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

1. Please ensure there is a more lay-friendly title in the PIS.
2. Please amend the ‘black box’ first-in human warnings for consistency and to reflect who the study drug has been trialled with to date. Participants should not be required to provide receipts for reimbursement. Please amend.
3. Please ensure measurements for fluids are written in millilitres, not teaspoons.
4. The Committee requested the researcher include [the HDEC reproductive risks template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
5. The Committee noted that given the nature of the study, the notification to the GP should not be optional in the CF.
6. The Committee noted that reactivation of viral infections was included in the PIS, but reactivation of tuberculosis was not and requested that this be reviewed.
7. The PIS references both US and EU law in respect of data privacy. Please clarify and preferably include NZ-specific references.
8. SCOTT is not part of Medsafe, and the error in the HDEC template has been recognised. Please amend to state “which conveys its recommendation to Medsafe.”

**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 Dr Kate Parker.

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| **6**   | **Ethics ref:**   | **2023 FULL 18573** |
|   | Title:  | A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, SINGLE ASCENDING DOSE STUDY TO ASSESS THE SAFETY,TOLERABILITY, AND PHARMACOKINETICS OF INTRAVENOUSLY OR SUBCUTANEOUSLY ADMINSTERED REGN13335, A PLATELET-DERIVED GROWTH FACTOR-B ANTAGONIST, IN HEALTHY ADULT PARTICIPANTS |
|   | Principal Investigator:  | Dr Cory Sellwood |
|   | Sponsor:  | ICON Clinical Research (New Zealand) Ltd |
|   | Clock Start Date:  | 07 September 2023 |

Dr Cory Sellwood, Julia O’Sullivan and Kayla Malate 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 considering that the study involves tissue and data collected overseas, it might be beneficial to arrange formal consultation for Māori endorsement. The Researcher responded that this is currently underway.
2. The Committee queried the exclusion criteria for this study, specifically related to those who "have a history of significant medical problems or mental health issues" and what would meet this criterion. The Researcher responded that a history of mental health will not necessarily be exclusionary, and the investigator will make a clinical judgement.in consultation with a GP where appropriate.
3. The Committee queried if reproductive and developmental toxicology is ongoing as the protocol states it has not been conducted. The researcher confirmed that this will be completed before Phase 2 trials start.

Summary of outstanding ethical issues

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

1. Under risks, reference is made to ‘swelling’. Please elaborate further on the potential extent and duration of swelling using lay language.

**Decision**

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

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

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| **7**   | **Ethics ref:**   | **2023 EXP 18493** |
|   | Title:  | Exploring the early experiences of the assisted dying service in Aotearoa |
|   | Principal Investigator:  | Dr Jessica Young |
|   | Sponsor:  | Victoria University of Wellington |
|   | Clock Start Date:  | 07 September 2023 |

Dr Jessica Young, Dr Kate Diesfeld and Dr Jeanne Snelling 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 requested clarification on what will be done with the data for those who undertake pre-screening but do not enrol in the study. The Researcher responded that they would retain that until they finish data collection, and participants will be asked to consent for this.
2. The Researcher clarified that the proposed media release is separate- to the advertisements provided to the Committee and will provide this as an amendment.
3. The Committee acknowledged ongoing engagement with Taranaki Iwi and noted the intention to submit an amendment when the relevant participant information sheet (PIS) and interview questions were finalised as a result of this engagement.
4. The Committee commended the plan for managing participant distress, which may arise during the study, including coverage of costs relating to this.
5. The Researcher clarified the rationale for deidentifying all participants.
6. The Researcher noted that they have not set up a privacy process for those who bring a support person to the interviews, and queried the Committee on whether they need a confidentiality agreement. The Committee noted these can be used, but it is more important to set out the guidance for the support person in terms of their role (such as just there for support and not to comment).
7. The Researcher stated they want to add to the interview guide that the interview does not have any impact on the assisted dying eligibility assessment, and queried whether this needs to be reviewed by the Committee. The Committee considered this an appropriate inclusion. It can be submitted with any other amendments by the Researcher along with any other changes the Researcher wishes to make.

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 tax-liability or implication with the amount of koha given for participant’s time. The Committee recommended looking into this and clarifying this in participant information sheets.
2. The Committee noted that recordings will be transcribed from Zoom. The Committee requested that the researchers ensured this was checked for accuracy and the researcher confirmed this would be done by a research assistant. Any conversations in Te Reo Māori will be transcribed by someone fluent. The Committee requested that this is included in the PIS.
3. The Committee noted that public servants cannot typically receive gifts in their role as public servants and the researcher should determine whether they should offer to donate in their stead. The Committee recommended seeking clarification from any agency involved what is appropriate as a koha for participation, if any.
4. The Committee requested the following changes to the advertisement:
	1. For the Disabled or Deaf Assisted Dying Services Users, please change ‘Are you disabled or Deaf?’ to ‘Do you live with an impairment or are you Deaf?’
	2. For the Disabled or Deaf Assisted Dying Services Users, please change ‘Do you have experience contacting the assisted dying service?’ to ‘Do you have experience with the assisted dying service?’ to encapsulate the whole process.

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

1. The PIS currently states “This study has been approved by an independent group of people called the Health and Disability Ethics Committee (HDEC). It checks that studies meet ethical standards. The Health and Disability Ethics Committees has approved this study.” It would be better to say “The ethical aspects of this study have been approved by an independent group of people called the Health and Disability Ethics Committee (HDEC). It checks that studies meet ethical standards. The Northern a Health and Disability Ethics Committee has approved this study.”

**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 advertisements, taking into account the feedback provided by the Committee. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12*).

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| **8**   | **Ethics ref:**   | **2023 FULL 15270** |
|   | Title:  | A Phase 3, randomised, double-blind, parallel-group, event-driven, cardiovascular safety study with BI 456906 administered.subcutaneously compared with placebo in participants with overweight or obesity with established cardiovascular disease (CVD) or chronic kidney disease, and/or at least two weight-related complications or risk factors for CVD. |
|   | Principal Investigator:  | Dr Andrew Edwards |
|   | Sponsor:  | Boehringer Ingelheim Pty Ltd |
|   | Clock Start Date:  | 07 September 2023 |

Dr Dean Quinn and Dr Andrew Edwards 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 the researchers had submitted a summary document covering three submitted studies. FULL 15270, FULL 15261 and FULL 15258.
2. The Committee noted that this, and as studies 2023 FULL 15261 and 2023 FULL 15258 were substantially similar the three studies were reviewed at the same time as ethical concerns raised largely pertained to all three with both CIs for the three studies present.
3. The Committee confirmed with the Researchers that ethnicity data collected will be in line with New Zealand categories.
4. The Committee queried what dietary and exercise requirements would be required of participants and whether they would incur any expenses. The Researchers responded that participants are assigned a dietician who provides advice and assigns a diet with a reduction of-500 calories and encourages them to meet exercise targets (duration, not intensity).
5. The Committee clarified that participants should not incur costs from this.
6. The Committee noted that the Investigator Brochures state Phase 1 was in healthy Japanese males however the IB does not provide information on sex breakdown or numbers in Phase 2. The Researchers confirmed for the Committee that females had been included in Phase 2.

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 Researchers confirmed that participants have ample time to decide their participation and investigators who are treating clinicians will not directly recruit participants. Researchers will contact people signed up on a database who want to be approached for this type of study and may also advertise. The Committee noted that any advertising is required to be uploaded for review before being used.
2. The Committee noted the substantial volume of documents for each of the related studies and requested that for future applications t that only NZ relevant material be uploaded; final versions of documents rather than drafts, and clearly marking what documents are non-review.
3. The Committee requested New Zealand-specific insurance certificate to ensure the New Zealand participants are adequately covered. The current insurance covers Australia and NZ, with an undefined number of participants.
4. The submission states that participants will not have ongoing access to the study drug despite this being a Phase 3 trial with anticipated benefit, and participants randomised to placebo may be on this for a significant length of time, up to 76 weeks. The Committee queried the justification for this. The Researcher responded that placebo participants still receive potential benefit from their involvement such as regular health reviews and dietary input. The Researcher also noted that they do not have any evidence that continued access will show benefit. The Committee requested that if there is benefit demonstrated in the study that ongoing access be provided, or a justification from the Sponsor for why this will not be provided.
5. The Committee noted for future applications that the response section C in the submission required further consideration such as prevalence, cultural considerations, whether there is targeted recruitment as a result, and other relevant issues The researcher acknowledged relevance of this study to Māori and Pacific peoples and the intention to target recruitment accordingly.
6. The Committee noted the Sponsor’s preference for e-consent and sought assurance that participants would have the opportunity for 1:1 discussion of the study and access to a hard copy of the Participant Information Sheet and Consent Form. The Researchers responded that they expect to be able to email out participants the PIS ahead of their visit, or post a hard copy, but the consenting process will be in person at the unit on a tablet. The Committee requested further detail about what happens if someone clicks the help options in the electronic PIS, and a copy of the hard copy version of the PISCF.
7. The Committee queried what Te Whatu Ora sites the study will be conducted in. Please clarify this.
8. The Committee noted the search terms provided for advertising, and one was ‘paid weight loss study’, which is misleading. Please review and update these.
9. Regarding the biobanking, please ensure there is proper governance in place for the biobanks the tissue is being sent to and the researchers are satisfied the requirements of Chapter 15 of the Standards are met.
10. The Committee requested clarification of mental health resources for participants should these be required. The Researchers respond that they have a mental health management plan which includes escalation to GP then a psychiatrist if required. The Committee requested the researchers ensure they have a robust plan for this and confirmation whether the escalation pathways, including referral to a psychiatrist, will be paid for by the Sponsor.

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

1. Some PIS/CFs are still in draft with sections missing such as the black sections under the heading compensation/costs. Please amend.
2. Please clarify what the reimbursement level is.
3. Please provide detail around the diet and lifestyle changes that will be required as part of the study and related support.
4. A food diary is mentioned but the three other diaries included in the submission are not mentioned. Please include these with detail of how often they need to be done and what they involve.
5. Please include in the Main PIS/CF that there will be a separate PIS for a support person who agrees to assist with injections.
6. Please ensure measurements for fluids are written in millilitres, not teaspoons.
7. SCOTT is not part of Medsafe, and the error in the HDEC template has been recognised. Please amend to state “which conveys its recommendation to Medsafe.
8. The reference to 'these people check' is about organisations, not people. Please amend.

Optional biobanking PIS:

1. The risks should include reference to risks relating to whole genome sequencing, information and privacy, whether this will be shared, etc. Please refer to the NEAC Standards.
2. There are also two versions of cultural impact statement, please use the second longer one and remove the other.
3. Please include information of where samples are sent and confirm it is a registered biobank.

**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 Kate Parker.

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| **9**   | **Ethics ref:**   | **2023 FULL 15261** |
|   | Title:  | A Phase 3, randomised, double-blind, parallel-group, 76-week, efficacy and safety study of BI 456906 administered subcutaneously compared with placebo in participants with overweight or obesity and type 2 diabetes mellitus |
|   | Principal Investigator:  | Dr Dean Quinn |
|   | Sponsor:  | Boehringer Ingelheim Pty Ltd |
|   | Clock Start Date:  | 07 September 2023 |

Dr Dean Quinn and Dr Andrew Edwards 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 the researchers had submitted a summary document covering three submitted studies. FULL 15270, FULL 15261 and FULL 15258.
2. The Committee noted that this, and studies and 2023 FULL 15270 and 2023 FULL 15258 were substantially similar and reviewed at the same time. The Committee discussed all three at the same time as ethical concerns raised pertained to all three with both CIs for the three studies present.
3. The Committee confirmed with the Researchers that ethnicity data collected will be in line with New Zealand categories.
4. The Committee queried what dietary and exercise requirements would be required of participants and whether they would incur any expenses. The Researchers responded that participants are assigned a dietician who provides advice and \ assigns a diet with a reduction of -500 calories and encourages them to meet exercise targets (duration, not intensity).
5. The Committee clarified that participants should not incur costs from this.
6. The Committee noted that the Investigator Brochures state Phase 1 was in healthy Japanese males however the IB does not provide information on sex breakdown or numbers in Phase 2. The Researchers confirmed for the Committee that females had been included in Phase 2.

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 Researchers confirmed that participants have ample time to decide their participation and investigators who are treating clinicians will not directly recruit participants. Researchers will contact people signed up on a database who want to be approached for this type of study and may also advertise. The Committee noted that any advertising is required to be uploaded for review before being used.
2. The Committee noted the substantial volume of documents for each of the related studies and requested that for future applications that only New Zealand relevant material be uploaded; final versions of documents rather than drafts, and clearly marking what documents are non-review.
3. The Committee requested New Zealand-specific insurance certificate to ensure the New Zealand participants are adequately covered. The current insurance covers Australia and NZ, with an undefined number of participants.
4. The submission states that participants will not have ongoing access to the study drug despite this being a Phase 3 trial with anticipated benefit, and participants randomised to placebo may be on this for a significant length of time, up to 76 weeks. The Committee queried the justification for this. The Researcher responded that placebo participants still receive potential benefit from their involvement such as regular health reviews and dietary input. The Researcher also noted that they do not have any evidence that continued access will show benefit. The Committee requested that if there is benefit demonstrated in the study that ongoing access be provided, or a justification from the Sponsor for why this will not be provided.
5. The Committee noted for future applications that the response section C in the submission required further consideration such as prevalence, cultural considerations, whether there is targeted recruitment as a result, and other relevant issues The researcher acknowledged relevance of this study to Māori and Pacific peoples and the intention to target recruitment accordingly.
6. The Committee noted the Sponsor’s preference for e-consent and sought assurance that participants would have the opportunity for 1:1 discussion of the study and access to a hard copy of the Participant Information Sheet and Consent Form. The Researchers responded that they expect to be able to email out participants the PIS ahead of their visit, or post a hard copy, but the consenting process will be in person at the unit on a tablet. The Committee requested further detail about what happens if someone clicks the help options in the electronic PIS, and a copy of the hard copy version of the PISCF.
7. The Committee queried what Te Whatu Ora sites the study will be conducted in. Please clarify this.
8. The Committee noted the search terms provided for advertising, and one was ‘paid weight loss study’, which is misleading. Please review and update these.
9. Regarding the biobanking, please ensure there is proper governance in place for the biobanks the tissue is being sent to and the researchers are satisfied the requirements of Chapter 15 of the Standards are met.
10. The Committee requested clarification of mental health resources for participants should these be required. The Researchers respond that they have a mental health management plan which includes escalation to GP then a psychiatrist if required. The Committee requested the researchers ensure they have a robust plan for this and confirmation whether the escalation pathways, including referral to a psychiatrist, will be paid for by the Sponsor.

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

1. Some PIS/CFs are still in draft with sections missing such as the black sections under the heading compensation/costs. Please amend.
2. Please clarify what the reimbursement level is.
3. Please provide detail around the diet and lifestyle changes that will be required as part of the study and related support.
4. A food diary is mentioned but the three other diaries included in the submission are not mentioned. Please include these with detail of how often they need to be done and what they involve.
5. Please include in the Main PIS/CF that there will be a separate PIS for a support person who agrees to assist with injections.
6. Please ensure measurements for fluids are written in millilitres, not teaspoons.
7. SCOTT is not part of Medsafe, and the error in the HDEC template has been recognised. Please amend to state “which conveys its recommendation to Medsafe.
8. The reference to 'these people check' is about organisations, not people. Please amend.

Optional biobanking PIS:

1. The risks should include reference to risks relating to whole genome sequencing, information and privacy, whether this will be shared, etc. Please refer to the NEAC Standards.
2. There are also two versions of cultural impact statement, please use the second longer one and remove the other.
3. Please include information of where samples are sent and confirm it is a registered biobank.

**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 Kate Parker.

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| **10**   | **Ethics ref:**   | **2023 FULL 15258**  |
|   | Title:  | A Phase 3, randomised, double-blind, parallel-group, 76-week, efficacy and safety study of BI 456906 administered.subcutaneously compared with placebo in participants with overweight or obesity without type 2 diabetes |
|   | Principal Investigator:  | Dr Dean Quinn |
|   | Sponsor:  | Boehringer Ingelheim Pty Ltd |
|   | Clock Start Date:  | 07 September 2023 |

Dr Dean Quinn and Dr Andrew Edwards 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 the researchers had submitted a summary document covering three submitted studies. FULL 15270, FULL 15261 and FULL 15258.
2. The Committee noted that this, and studies and 2023 FULL 15270 and 2023 FULL 15261 were substantially similar and reviewed at the same time. The Committee discussed all three at the same time as ethical concerns raised pertained to all three with both CIs for the three studies present.
3. The Committee confirmed with the Researchers that ethnicity data collected will be in line with New Zealand categories.
4. The Committee queried what dietary and exercise requirements would be required of participants and whether they would incur any expenses. The Researchers responded that participants are assigned a dietician who provides advice and assigns a diet with a reduction of-500 calories and encourages them to meet exercise targets (duration, not intensity).
5. The Committee clarified that participants should not incur costs from this.
6. The Committee noted that the Investigator Brochures state Phase 1 was in healthy Japanese males however the IB does not provide information on sex breakdown or numbers in Phase 2. The Researchers confirmed for the Committee that females had been included in Phase 2.

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 Researchers confirmed that participants have ample time to decide their participation and investigators who are treating clinicians will not directly recruit participants. Researchers will contact people signed up on a database who want to be approached for this type of study and may also advertise. The Committee noted that any advertising is required to be uploaded for review before being used.
2. The Committee noted the substantial volume of documents for each of the related studies and requested that for future applications t that only NZ relevant material be uploaded; final versions of documents rather than drafts, and clearly marking what documents are non-review.
3. The Committee requested New Zealand-specific insurance certificate to ensure the New Zealand participants are adequately covered. The current insurance covers Australia and NZ, with an undefined number of participants.
4. The submission states that participants will not have ongoing access to the study drug despite this being a Phase 3 trial with anticipated benefit, and participants randomised to placebo may be on this for a significant length of time, up to 76 weeks. The Committee queried the justification for this. The Researcher responded that placebo participants still receive potential benefit from their involvement such as regular health reviews and dietary input. The Researcher also noted that they do not have any evidence that continued access will show benefit. The Committee requested that if there is benefit demonstrated in the study that ongoing access be provided, or a justification from the Sponsor for why this will not be provided.
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6. The Committee noted the Sponsor’s preference for e-consent and sought assurance that participants would have the opportunity for 1:1 discussion of the study and access to a hard copy of the Participant Information Sheet and Consent Form. The Researchers responded that they expect to be able to email out participants the PIS ahead of their visit, or post a hard copy, but the consenting process will be in person at the unit on a tablet. The Committee requested further detail about what happens if someone clicks the help options in the electronic PIS, and a copy of the hard copy version of the PISCF.
7. The Committee queried what Te Whatu Ora sites the study will be conducted in. Please clarify this.
8. The Committee noted the search terms provided for advertising, and one was ‘paid weight loss study’, which is misleading. Please review and update these.
9. Regarding the biobanking, please ensure there is proper governance in place for the biobanks the tissue is being sent to and the researchers are satisfied the requirements of Chapter 15 of the Standards are met.
10. The Committee requested clarification of mental health resources for participants should these be required. The Researchers respond that they have a mental health management plan which includes escalation to GP then a psychiatrist if required. The Committee requested the researchers ensure they have a robust plan for this and confirmation whether the escalation pathways, including referral to a psychiatrist, will be paid for by the Sponsor.

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

1. Some PIS/CFs are still in draft with sections missing such as the black sections under the heading compensation/costs. Please amend.
2. Please clarify what the reimbursement level is.
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4. A food diary is mentioned but the three other diaries included in the submission are not mentioned. Please include these with detail of how often they need to be done and what they involve.
5. Please include in the Main PIS/CF that there will be a separate PIS for a support person who agrees to assist with injections.
6. Please ensure measurements for fluids are written in millilitres, not teaspoons.
7. SCOTT is not part of Medsafe, and the error in the HDEC template has been recognised. Please amend to state “which conveys its recommendation to Medsafe.
8. The reference to 'these people check' is about organisations, not people. Please amend.

Optional biobanking PIS:

1. The risks should include reference to risks relating to whole genome sequencing, information and privacy, whether this will be shared, etc. Please refer to the NEAC Standards.
2. There are also two versions of cultural impact statement, please use the second longer one and remove the other.
3. Please include information of where samples are sent and confirm it is a registered biobank.

**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 Kate Parker.

## General business

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

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| --- | --- |
| **Meeting date:** | 17 October 2023 |
| **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