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

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10.30-11.00am | 2024 FULL 20643 | (GOLSEEK-1) A Study to Compare the Efficacy and Safety of Golcadomide Plus R-CHOP vs Placebo Plus RCHOP in Participants with Previously Untreated High-risk Large B-cell Lymphoma | Dr Henry Ngu | Mr Dominic Fitchett and Ms Amy Henry |
| 11.00-11.30am | 2024 FULL 20707 | Asthma Care in Community Pharmacy | Mrs Neera Rajballi-Naidoo | Dr Maree Kirk and Dr Devonie Waaka |
| 11.30am-12.00pm | 2024 FULL 20712 | Prevention of Reperfusion Injury in Myocardial Infarction - PRIME | Dr Adrian Owen | Ms Dianne Glenn and Ms Amy Henry |
| 12.00-12.30pm | 2024 FULL 20423 | A Study to Evaluate the Safety, Pharmacokinetics and Anti-Tumour Activity of Englumufusp when dosed with Obinutuzumab and Glofitamab in Patients with Relapsed/Refractory B-Cell Non-Hodgkin’s Lymphoma | Dr Leanne Berkahn | Mr Dominic Fitchett and Dr Devonie Waaka |

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

## Welcome

The Chair opened the meeting at 10.00am with a karakia, and welcomed Committee members, noting that apologies had been received from Dr Nicola Swain and Ms Neta Tomokino.

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 14 May 2024 were confirmed as the June meeting did not proceed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 20643** |
|  | Title: | A Phase 3, Multicenter, Randomised, Double-blind, Placebo-controlled Study Comparing the Efficacy and Safety of Golcadomide Plus R-CHOP Chemotherapy vs Placebo Plus R-CHOP Chemotherapy in Participants with Previously Untreated High-risk Large B-cell Lymphoma |
|  | Principal Investigator: | Dr Henry Ngu |
|  | Sponsor: | Bristol Myers Squibb |
|  | Clock Start Date: | 27 June 2024 |

Dr Henry Ngu and Vaidehi Chaporkar 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 confirmed with the Researcher that standard treatment is not being withheld.
2. The Committee noted that continued access to study intervention has contrasting statements. Application form says there will, but information to participants states otherwise. The Researcher clarified that there won’t be ongoing access to drugs beyond the study due to the study drugs having a set number of cycles for dosing, so ongoing access is not applicable in this instance.
3. The Committee reminded the Researcher that all tests and assessments needed for the study should be paid for by the Sponsor, as the PIS reads as though some study-mandated tests that could also be required per SOC will be the responsibility of Health NZ or the participant's medical insurance. The Researcher confirmed that the Sponsor would be responsible for those costs.

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 affected participants should be informed of a privacy breach regardless of whether it is considered ‘notifiable’ due to the nature of this study. Please amend the data management plan (DMP).
2. The Committee does not consider anything study related and provided ‘free of charge’ to be a benefit as they are required to be at no cost to participants. Please ensure this is not referred to in any documentation.
3. The Committee requested it be clarified in the DMP and participant information sheet that some assessments done as part of the study will form part of the participant’s medical records for safety reasons.

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

Main PIS/CF:

1. Lay title refers to ‘efficacy’, which is not lay friendly. Please amend.
2. Typo on page 4 which states 50/50 chance of ‘reviving’ either arm, should be ‘receiving’.
3. On page 9, please specify overseas locations where tissue will be sent to and stored (city and country)
4. The Committee noted that having multiple site cultural (tissue and data) site statements can confuse the document. The Committee stated that they can just use the lead site’s statement for all sites, and if local Māori review demands rewording, this can be done without HDEC review.
5. With options for leaving the study, participants should be able to fully withdraw from the study and have the option for data collection to stop. Please amend statement on page 21
6. Please state whether Golcadomide is approved for any indication in New Zealand or overseas (page 3).
7. Please state whether R-CHOP is standard of care for primary treatment of high-risk B-cell lymphoma in NZ (page 3).
8. Please do not use the term 'treatment' to describe dosing or the dosing period (therapeutic misconception).
9. Please replace ‘efficacy’ with ‘effectiveness’ throughout the document.
10. It is suggested unfamiliar acronyms (EOT, IOCBP etc) are avoided.
11. Please fix formatting issues such as inconsistent bullet points and font size (e.g. page 8).
12. Please delete list of optional samples, these are explained in the applicable optional PIS/CFs (page 9).
13. Please state how many people have been exposed to Golcadomide to date (page 10).
14. Please bullet point risks of Golcadomide and provide frequency if available (page 10).
15. Please use the term 'study doctor' consistently, rather than switching between physician and study doctor.
16. Please replace 'subject' with 'participant' throughout the document.
17. Please amend th statement regarding study assessment costs to make it clear that the Sponsor will be responsible for paying for any standard of care tests that are required as part of the study protocol.
18. Please remove paragraph about the risk of stigmatisation; it is not relevant to the current study (page 19).
19. Please provide the international number for the Australian-based privacy officer, or preferably a number that is free to call from New Zealand (page 20).
20. Please amend the statement on page 21 regarding ongoing collection of information post full study withdrawal to specifically address the legal situation in New Zealand. Participants should retain the right to request that no further information, other than that which is publicly available, be collected on study withdrawal.
21. Please include an optional consent clause for provision of a lay summary of study results, once available.

Optional PIS/CF:

1. The Committee noted that having multiple site cultural site statements can confuse the document. The Committee stated that they can just use the lead site’s statement for all sites, and if local Māori review demands rewording, this can be done without HDEC review.

**Decision**

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

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

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| **2** | **Ethics ref:** | **2024 FULL 20707** |
|  | Title: | Assessing the feasibility of a new model of care in pharmacy for the self-management of asthma |
|  | Principal Investigator: | Mrs Neera Rajballi Naidoo |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 27 June 2024 |

Neera Raiballi Naidoo 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 raised the following about the advertisement(s):
   1. Please remove 'parents and caregivers of children with asthma' from the eligibility criteria list.
   2. Please replace 'new' with 'potential' or 'trial'.
   3. Please soften over-promise of benefit (e.g. replace 'will' with 'may').
2. GP notification of significant abnormal results should be a mandatory component of study participation (E4). Please amend study documentation to reflect this, including deletion of '....and permitted by participant' in Section 5 of the Data Management Plan.
3. The Committee raised the following about the Data Management Plan (DMP):
   1. Please amend Section 7.1 of the DMP to state what identifiable data will be accessed and held by the study team.
   2. Please correct the typographical error in Section 9.2 of the DMP, which currently states that data will be retained for 0 years.
4. Sponsor authorisation from the University of Otago using the Ethics RM (ERM) application form, and locality authorisations using the ERM sub forms, are required prior to commencing the study. The University’s research office will be familiar and can help the Researcher with this, and the prompt for Sponsor signoff will be available in the application form created. Locality authorisation is signed off via a subform in the project. The [Ethics RM user manual](https://ethics.health.govt.nz/ethicsrm/ethics-rm-manual) also details how to perform these functions and the [HDEC secretariat](mailto:hdecs@health.govt.nz) can be contacted for further assistance.
5. B.3 of the application form notes the study will takes place in three pharmacies and participant interaction with a nurse is mentioned. The Committee queried if this is a GP practice nurse or an Asthma nurse (as mentioned in C.11) or an on-location pharmacy nurse. After discussion, the Committee requested to link this with the information from the Protocol (page 5 Local Primary Care Teams) and describe in more detail what is the level of participant interaction with the Nurse, and the Primary Care team.
6. Please clarify in documentation that there are 5 visits, the 5th visit is with a pharmacist, and that it is 20 weeks instead of 16. Ensure protocol and participant information sheet line up with this.
7. Participant group numbers referred to as 4-6, but then elsewhere it is mentioned it is 4-5 or 3-5. Please review and amend for consistency across documentation.
8. Please change reference to ‘patient’ to ‘participant’ in all documentation.

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

1. Please amend 'asthma medicine consultation' to 'asthma control consultation' on page 2, and make it clear in that section that the pharmacist will not prescribe or change asthma medications as part of the study.
2. Please state that there may be no benefits to taking part.
3. Please include the ACC cover statement from the [HDEC PIS/CF template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
4. State who may have access to identifiable data.
5. State whether data may be used for future research or shared with other researchers.
6. Address the risk of privacy breach.
7. If the survey is anonymous, please state this - and that survey responses cannot be withdrawn post-submission due to their anonymous nature. However, given the small sample size, the demographic data collected in the patient survey may well be sufficient for the research team to re-identify the individual. Please also make this clear.
8. Please include YES/NO tick boxes only for those consent clauses that are truly optional, noting that GP notification of significant abnormal findings should be mandatory.

**Decision**

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

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

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| **3** | **Ethics ref:** | **2024 FULL 20712** |
|  | Title: | Does Paracetamol decrease reperfusion injury to patients presenting with acute ST-elevation myocardial infarction when given prior to primary percutaneous intervention. |
|  | Principal Investigator: | Dr Adrian Owen |
|  | Sponsor: | Te Whatu Ora Waikato |
|  | Clock Start Date: | 27 June 2024 |

Dr Adrian Owen 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 an advertisement was referred to but not uploaded for review. After discussion, it was clarified that this is not used for recruitment of participants but to let clinicians know about the study.

Summary of outstanding ethical issues

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

All:

1. On both the short Concise Information and consent sheet and the full PIS /CF, at the beginning of first page, please write the statement "An interpreter is available to help you with understanding this document if you require it"
2. Please review for grammar and typos.

Concise PIS/CF:

1. There is no need for the first paragraph of the black box statement given the approval status of paracetamol - please delete.

Main PIS/CF:

1. Please delete black box warning.
2. Please state that there may be no benefits to study participation.
3. "..you were not asked to give consent at that time" is incorrect as they were asked to complete the short Concise PIS/CF.
4. Please add that the approving HDEC may have access to identifiable information in the event the study is audited.
5. Please make it clear that paracetamol dosing and the echocardiogram (if study-specific) will form part of the participant's clinical record and will be retained indefinitely.
6. Please append the paracetamol CMI medsafe data sheet to the PISCF.
7. Please include optional tickboxes only for those consent clauses that are truly optional (i.e. the participant can check NO and still be enrolled in the study).
8. Page 4 there is a statement about "passive follow up". Please clarify to the participant what this means.

**Decision**

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

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

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| **4** | **Ethics ref:** | **REFERENCE** |
|  | Title: | AN OPEN-LABEL, PHASE I/II STUDY TO EVALUATE THE SAFETY, PHARMACOKINETICS AND PRELIMINARY ANTI-TUMOR ACTIVITY OF ENGLUMAFUSP ALFA (RO7227166, A CD19 TARGETED 4-1BB LIGAND) IN COMBINATION WITH OBINUTUZUMAB AND IN COMBINATION WITH GLOFITAMAB FOLLOWING A PRE-TREATMENT DOSE OF OBINUTUZUMAB ADMINISTERED IN PARTICIPANTS WITH RELAPSED/REFRACTORY B-CELL NON-HODGKIN’S LYMPHOMA |
|  | Principal Investigator: | Dr Leanne Berkahn |
|  | Sponsor: | Roche Products (New Zealand) Limited |
|  | Clock Start Date: | 27 June 2024 |

Dr Leanne Berkahn and Azmeena Sajid were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researcher clarified that the dosing regimen for Glofitamab, including number of cycles, is the usual therapeutic treatment course. The Committee requested this is noted in the participant information sheet (PIS).
2. Prostate cancer was discussed in C4 of the application form in error. The Researcher provided a summary of the relative incidence of NHL in Māori in New Zealand.
3. The Committee asked for a summary of the most common adverse events, and serious adverse events, seen on dosing with Englumufusp in the study to date (E1). The Researcher responded that the impact of the medication observed will be minimal on the participant and not too dissimilar in them enrolling in a previous similar trial. It is well tolerated so long as they follow the protocol.

Summary of outstanding ethical issues

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

1. Please ensure good quality ethnicity data relevant to the New Zealand population is collected at a site level, if necessary in addition to CRF-specified race/ethnicity fields (C16).
2. The Committee noted that a short summary sheet of the study would be a great asset with the length of the PIS.

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

All:

1. The Committee noted that having multiple site cultural site statements can confuse the document. The Committee stated that they can just use the lead site’s statement for all sites, and if local Māori review demands rewording, this can be done without HDEC review. If Option 2 is used, it will need to be separately specified that a karakia will not be available on sample destruction. The Committee queried if this also means that cultural support is not available outside of Auckland.

Main PIS/CF:

1. Please simplify the lay title.
2. Per recent combined Chair decision re potential for therapeutic misconception, please delete references to 'treatment' from descriptions of study drug dosing (e.g. use 'dosing' phase rather than 'treatment' phase).
3. Please delete references to acetaminophen; use paracetamol only.
4. Please state whether participation in this clinical trial may affect the participant's ability to take part in other therapeutic trials.
5. Please delete repeated information (e.g. reasons for blood tests, access to identifiable data for audit purposes etc, sharing of coded data etc)
6. Please state that affected participants will be informed of any privacy breaches.

Research Biosample Repository (RBR) PIS/CF:

1. Please delete local laboratory staff access to identifiable data; this is not applicable for the RBR.

**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).*

## General business

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

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| **Meeting date:** | 13 August 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 12.10pm