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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27 August 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12:00 - 12:30pm | 2024 FULL 20847 | A clinical study to determine the safety of study drug EP-104IAR, and how well it works, in adults with eosinophilic esophagitis | Dr Tien Huey Lim | Mrs Helen Walker & Mx Albany Lucas |
| 12:30 - 1:00pm | 2024 FULL 19106 | COG APEC1621SC | Dr Karen Tsui | Ms Jessie Lenagh-Glue & Ms Patricia Mitchell |
| 1:00 - 1:30pm | 2024 FULL 20044 | INTER-EWING-1 | Dr Mark Winstanley | Ms Sandy Gill & Dr Patries Herst |
| 1:30 - 2:00pm | 2024 FULL 19942 | LumAssure Raman Device data collection of skin conditions | Dr Michel Nieuwoudt | Ms Jessie Lenagh-Glue & Ms Patricia Mitchell |
| 2:00 - 2:30pm |  | **BREAK (30 minutes)** |  |  |
| 2:30 - 3:00pm | 2024 FULL 20025 | Glo-BNHL | Dr Timothy Prestidge | Mrs Helen Walker & Ms Patricia Mitchell |
| 3:00 - 3:30pm | 2024 FULL 20752 | A Clinical Study to Assess the Safety and Effectiveness of Tovinontrine in Patients With Chronic Heart Failure. | Dr James Pemberton | Ms Jessie Lenagh-Glue & Mx Albany Lucas |
| 3:30 – 4:00pm | 2024 FULL 20486 | WHISTLE-PF Trial | Dr Andrew Veale | Ms Sandy Gill & Dr Patries Herst |
| 4:00-4:30pm | 2024 AM 8938 | COG AALL1731 | Dr Lochie Teague | Full committee |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mrs Helen Walker  | Lay (Consumer/Community perspectives) (Chair) | 22/05/2018  | 22/05/2020  | Present |
| Mrs Sandy Gill  | Lay (Consumer/Community perspectives)  | 22/05/2020  | 22/05/2023  | Present |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Cordelia Thomas  | Lay (the Law)  | 22/12/2020 | 22/12/2024 | Apologies  |
| Ms Patricia Mitchell  | Non-lay (Health/Disability service provision)  | 08/07/2022 | 08/07/2025 | Present  |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 10am and welcomed Committee members, noting that apologies had been received from Dr Cordelia Thomas.

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 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 FULL 20847** |
|   | Title:  | A clinical study to determine the safety of study drug EP-104IAR, and how well it works, in adults with eosinophilic esophagitis. |
|   | Principal Investigator:  | Dr Tien Huey Lim |
|   | Sponsor:  | Mobius Medical |
|   | Clock Start Date:  | 15 August 2024 |

Dr Tien Huey Lim, Dr Mark Kowalski and Ms Pranali Ravikumar was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the exclusion of participants based on HIV status. The Committee clarified that should a positive test be returned that follow up for this would be provided.
2. The Committee noted that there were concerns with the responses to the cultural issues that largely inappropriate. Please note for future applications that touching of the head is considered Tapu for both Māori and Pasifika people. Please also in future note that there are specific considerations for each of these peoples and that it is not acceptable to simply note “the considerations are the same”.

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 suggested explaining clearly to participants that as many of the participants may have already had an endoscopy and that it will be no more invasive than that procedure with an injection.
2. The Committee queried how the follow-up endoscopies will be arranged as there is currently a shortage of practitioners in this field and that yearly follow up as a recommendation may be unrealistic.
3. The Committee clarified that Auckland is the primary site for the study. Please ensure that the stipend of this is being calculated correctly for the fact that the catchment area for this study may be large and not adequately address the cost of living in New Zealand.
4. The Committee requested that the researchers provide all questionnaires for review by the Committee.

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

1. Please include the main exclusion criteria in the PIS/CF.
2. Please include an image of the procedure where possible for participants to better understand the procedures.
3. Please include that regular follow up is recommended after the study but that this is something that cannot be provided by the study team.
4. Please consider including a chart that explains the dose groups.
5. Please note that requiring participants to organise their own travel after the procedure may be a barrier to access and requested that clinics organise travel for individuals home by the research team. Sections of the PIS relating to this will need to be amended to state this clearly.
6. Please include that doctors will only follow up on a pregnancy should that participant consent to that.
7. Please amend the wording “family doctor” to read General Practitioner
8. Please make it clear that HIV testing will be carried out to determine if the participant should be excluded.
9. Please ensure that it is clear that positive HIV tests will have follow up organised by the study team.
10. Please specify if the physical exam will require the removal of clothing, if the participant may bring a support person and where possible please provide the option for a gender-matched physician for this procedure.
11. Please include risks in a 1-in-100 format rather than percentages.
12. Please clarify how the risk of identification will be managed specifically with the wording on page 13 and amend as required.
13. Please ensure that the wording of HIV tests being reported is mandatory.
14. Please remove mention of the NuvaRing as this is not available in New Zealand.
15. Please note that “reasonable” in terms of reimbursement is not the cheapest, if this is what is meant then please state this.
16. Please note that a stipend is more appropriate for reimbursement as keeping track of receipts is burdensome in New Zealand.
17. Please clarify that no charge will be incurred for the data or tissue samples that may be taken and processed.
18. Please clarify that no questionnaires will include quality of life questions and are only related to the disease.

**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 19106** |
|   | Title:  | COG APEC1621SC |
|   | Principal Investigator:  | Dr Karen Tsui |
|   | Sponsor:  | Child Oncology Group |
|   | Clock Start Date:  | 15 August 2024 |

Dr Karen Tsui was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the testing proposed in this study is not standard of care due to funding.
2. The researcher clarified that the CTSU form is a COG requirement for translation.
3. The Committee clarified that there was no reconsent as when the participants reach 16 they would be reconsented on the main PIS/CF.

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 wording to “avoid pregnancy” should not be in the screening PIS as this would be part of the informed consent of the treatments. Where “avoiding pregnancy” is mentioned in the other forms please include the attachment for pregnancy and contraception with the main PIS and the older child PIS as the onus should not be on the participants to be asking for these.
2. The Committee queried if there is a New Zealand website for clinical details of the CTSU short form. If possible, this should be provided.

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

1. Please reframe the statement noting that there could be a possibility of improving. Such as stating that “we would expect the treatment to last [x] number of years unless [[these things occur]]”

**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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| **3**   | **Ethics ref:**   | **2024 FULL 20044** |
|   | Title:  | INTER-EWING-1 |
|   | Principal Investigator:  | Dr Mark Winstanley |
|   | Sponsor:  | Australia and New Zealand Children's Haematology/Oncology Group (ANZCHOG) |
|   | Clock Start Date:  | 15 August 2024 |

Dr Mark Winstanley and Ms Sonia Alix was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the trial was set up for the radiation arms to be set up as and when the drugs come available and that any arm yet to be determined will be submitted as an amendment. The maintenance trial is currently the only supplied arm for this study.
2. The Committee clarified the use of general anaesthetic for radiation in these participants and how this is done out of necessity and in a manner that is the least burden for the 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 that the researchers clarify the wording around the support provided to participants in terms of the Quality-of-Life (QoL) surveys that are part of participation. The Researchers noted that this would be carried out through the standard of care pathways. Please ensure that this is carried through into the assent forms and acknowledges that some of the questions may be uncomfortable.
2. The Committee requested that older children PISs and Assent forms include the cultural statements.
3. The Committee noted that in PISs where there is mention of a physical exam there should be clarification as to whether clothing will need to be removed for this, if the participant may have a chaperone and the option (if possible) for a gender matched physician.
4. The Committee noted that any and all mentions of “flipping a coin” should be amended to not be so flippant. Please describe this in a manner that is accurate (as randomisation is not the flipping of a coin) and that does not trivialise the condition these participants may have.
5. Particularly in the assent form for older children please include the attachment for pregnancy and contraception as the onus should not be on the participants to be asking for these.

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

1. Please state that tumour material made accessible is excess tissue from the diagnosis etc., please clarify that this tissue is excess from what is required for those diagnostics.
2. Please clarify that the future genetic testing would be related to Ewing sarcoma as well as other genetic pre-dispositions to cancers.
3. Please include the following cultural statement concerning genetic testing “You may hold beliefs about a sacred and shared value of data derived from genetic analysis of you or your whānau. Specific cultural issues associated with genetic testing include the fact that whanau members share a genetic background, and the results of the research may impact your whanau as well as you as the participant. There are a range of views held by Māori around these issues; some iwi disagree with genetic testing, citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”
4. Please clarify that participants *are* able to have the Covid-19 vaccines while participating as currently this is unclear.

**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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| **4**   | **Ethics ref:**   | **2024 FULL 19942** |
|   | Title:  | LumAssure Raman Device data collection of skin conditions |
|   | Principal Investigator:  | Dr Michel Nieuwoudt |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 15 August 2024 |

Dr Michel Nieuwoudt and Ms Julie Jones 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 data is owned and held by the University and that the algorithm would not be going overseas.

Summary of outstanding ethical issues

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

1. The Committee queried whether the researcher was intending on using Artificial Intelligence. The researcher explained that this was not AI but could fall under machine learning. Visible light spectra are uploaded to an algorithm which trains it to be able to diagnose different skin lesions (benign, malignant, infectious, inflammatory). The Committee suggested using the AI form to determine whether the research contains features that may bring it under the banner of ML.

Additionally, the Committee noted that it was unclear what the intent of the research was without more lay-friendly explanation of the use purpose of the data. If data is used in AI training, this must be made explicitly clear. If this is not AI training but machine learning, This must be made clear as most lay people will interpret “algorithm training” as Artificial Intelligence. *National Ethical Standards* para *9.7a, 7.16.*

1. The Committee queried the funding of the research and requested additional information about who is responsible for funding the study. This includes the commercial interest of the Uniservices and the researcher in the study. *National Ethical Standards* para *7.16, 11.23 & HDEC Standard Operating Procedures* para *144.*

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF): *National Ethical Standards* para *7.16.*

1. Please make it very clear that the data will be used to train an algorithm to be able to diagnose different skin lesions, and that this is not AI.
2. The researcher clarified that if people did not want to remove their clothes they could just have their arms assessed in the skin exam, please consider adding this to the PISCF.
3. Please change the image in the PIS with an actual image of the device in use.
4. Please clarify if the skin check is an actual full skin assessment and what it may identify versus what may not be identified. Please make this clearer.
5. Please clarify when mentioning the skin check if the participant is required to remove clothing and if they will be able to have a chaperone/ support person available for this procedure.
6. Please be clear around the cultural significance of touching the head as this is tapu.
7. Please ensure that there is a statement around suitable follow-up should a lesion of concern be identified as part of the study. This should take into account the current scarcity of resource in the public health system. If an alternative, such as the dermatologist doing the exams, be available for referral please include this.
8. Please be clear that the histology slide images will be sent overseas.
9. Please proofread for clarity and ease of reading.
10. Please provide cultural statements acknowledging the use of tissue and data and the significance of this to Māori such as in the [HDEC template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc)

**Decision**

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

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| **5**   | **Ethics ref:**   | **2024 FULL 20025** |
|   | Title:  | Glo-BNHL: A Global Study of Novel Agents in Paediatric and Adolescent Relapsed and Refractory B-cell Non-Hodgkin Lymphoma |
|   | Principal Investigator:  | Dr Timothy Prestidge |
|   | Sponsor:  | Australia and New Zealand Children's Haematology/Oncology Group (ANZCHOG) |
|   | Clock Start Date:  | 15 August 2024 |

Dr Tim Prestidge and Mrs Leani Fourie 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 study may not be terminated for purely commercial reasons.
2. The Committee suggested that should the biobanking be undertaken that this will require an amendment and clarified that the researcher would submit this as an amendment once required. Participants would not have their tissue banked before this.

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 statement around the removal of medication from the study and if some of the information around this be included in the participant information sheet/consent forms (PIS/CFs).
2. The Committee requested a process for the disclosure of discussion around sexual activity especially for minors. Please consider this and how it will be managed for those under 16s and how this may be disclosed where a guardian may not be aware. This may be standard of care but some reference to this should then be made in the protocol. Please consider amending references to “having consensual sex” as just “having sex”.

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

**Older Child Assent Form**

1. Please ensure that overlapping and repeating sections “can anything bad happen” and “will the medicine make me unwell” are combined as they cover the same content.
2. Please attach the contraception appendix to this form.
3. Please mention palliative and comfort care in the options available to participants aside from treatment.

**Younger child PIS**

1. Please remove sterilisation as an contraception method from this PIS as this is quite a dramatic option for this age group.

**All PISs**

1. Please clarify if participants may be required to undress for physical exams and whether they may bring a support person to this procedure. If possible please include the option for people to be examined by someone of the same gender.
2. Please review for gendered language.
3. Please amend the term “sexually active” as this is not necessarily interpreted well by young people and should be clearer.
4. Please note that if following up for pregnancy the statement must state that follow up will only occur if the participant consents to follow up.
5. Please reword the phrase on page 12 stating “if you are happy with this approach” the word “happy” should be replaced with another word or phrase such as “if you agree”.

**All Assent Forms**

1. Please rephrase “they will not be cross with you” or remove this as this cannot be guaranteed.

**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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| **6**   | **Ethics ref:**   | **2024 FULL 20752** |
|   | Title:  | A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Finding Study to Assess the Safety and Effectiveness of Tovinontrine in Patients With Chronic Heart Failure With Reduced Ejection Fraction |
|   | Principal Investigator:  | Dr James Pemberton |
|   | Sponsor:  | Cardurion Pharmaceuticals, Inc. |
|   | Clock Start Date:  | 15 August 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 why patients with HIV, Hepatitis B or Hepatitis C would be excluded from participation.
2. The Committee noted no koha would be offered for participation and queried why. The Committee queried how expenses will be determined. Rather than expecting participants to keep records it is preferable to have a stipend for each visit to cover parking and travel expenses. If a participant has expenses beyond the stipend (e.g., travelling a long distance or other accessibility requirements) this should be discussed with the participant before they sign the consent form.
3. The Committee queried if blood samples are required to determine eligibility.
4. The Committee noted the insurance certificate was valid from 21 June 2024 to 21 June 2025. The Committee requested confirmation this will be extended to the end of the trial. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
5. The Committee noted the study involved the use of quality of life / mental health questionnaires. The Committee noted if a participant indicates distress in these and requires a referral to a service with a waitlist then appropriate psychological support should be arranged and funded by the Sponsor. It is not acceptable to refer a participant indicating distress to contact their GP or find their own services.

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

**Main PIS**

1. Please review for gendered language.
2. Please ensure that there is clarity as to what types of questions may be asked in the questionnaires and please provide a safety plan and be clear about what the follow up procedure is for this.
3. Please be clear that the sponsor will not have access to the identifiable data.
4. Please clarify the inclusion and exclusion criteria.
5. Please specify if undressing is required for the physical examination and if a support person and gender matched physician is available.
6. Please specify if pre/post test counselling is available for a positive HIV / Hepatitis result.
7. Please remove references to teaspoons when discussing blood draws and use millilitres instead.
8. Please specify whether a karakia may be organised by the study team or if a participant must provide their own.
9. Please reframe percentages in terms of how many people experienced symptoms (e.g. “1 in 1000 people”).
10. Please specify if a lay summary be provided to participants who wish to receive one on page 14.
11. Please add “with your consent” to the statement on page 9 “You will need to provide information on your general health, your pregnancy, and its outcome, including any complications or illnesses during the pregnancy.”
12. Please remove the reference to Colpitts Clinical on page 10 if this will not be used in New Zealand.
13. Please include information on a stipend for travel and parking expenses and advise participants to discuss any travel or accessibility requirements with the study team.
14. Please remove the tick box to inform the GP as this should be mandatory.
15. Please add an optional yes / no tick box to allow participants to receive a summary of study results.

**Pre-screening PIS:**

1. Please amend Māori health support to Māori cultural support

**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 confirm ACC-equivalent insurance will be available for the duration of the trial. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mx Albany Lucas and Ms Jessie Lenagh-Glue

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| **7**   | **Ethics ref:**   | **2024 FULL 20486** |
|   | Title:  | A Phase 2, Multi-Center, Randomized, Double-Blind, Controlled Trial Evaluating the Safety and Efficacy of ENV-101 in Patients with Lung Fibrosis |
|   | Principal Investigator:  | Dr Andrew Veale |
|   | Sponsor:  | Endeavor BioMedicines |
|   | Clock Start Date:  | 15 August 2024 |

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

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee requested the Researcher supply a clinical trial protocol that complies with the requirements of [Standard 9.8 of the National Ethical Standards.](https://neac.health.govt.nz/national-ethical-standards/part-two/9-research-development-and-design)
2. The Committee noted the flyer is very similar to the information sheet and queried how it would be used. A flyer alone may not substitute the information sheet.
3. The Committee requested the Researcher upload evidence of professional indemnity for the coordinating investigator (e.g. an MPS certificate). (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6).*
4. The Committee noted F9 of the application form indicated there may be future unspecified uses of tissue but the information sheet only discusses future uses of data. If future testing of tissue is planned then please amend the information sheet and consent form accordingly. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.1; 14.48).*
5. The Committee noted it is preferable to have a stipend for each visit to cover parking and travel expenses instead of requiring them to provide receipts. Please adjust documentation to provide this. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.20a).*
6. The Committee queried who the study sponsor was. The application form stated the trial was commercially-sponsored research and indicated the sponsor was Research Monitoring Services Limited but ENV-101 is manufactured by Endeavor BioMedicines. If Endeavor BioMedicines is the sponsor of the study, please obtain sponsor authorisation in the resubmission.

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 for gender neutral language (e.g. change female participants to participants who are able to become pregnant).
2. Please remove ‘Decisions made in the commercial interests of the sponsor’ for reasons to stop the study as this is not permitted in New Zealand.
3. Please specify if the physical exam involves undressing, if a support person may be present and if it is possible to be gender matched (i.e. the person performing the exam is the same gender as the participant).
4. Please amend the information on page 6 expecting receipts to detail if a stipend is available.
5. Please revise the information on page 7 to specify that GP notification is mandatory and add a non-optional clause on the consent form for this.
6. Please use whole numbers and not percentages (e.g. 1 in 10 patients rather than 10%).
7. Please remove tickbox on the consent form for removing information collected prior to withdrawing from the study if this is not permitted.
8. Please undertake a general revision to make the sheet appropriate for a New Zealand context (e.g., referencing the approval status of drugs in New Zealand and not the United States)
9. The Committee suggested a tabular form may be more easily understood than repeated paragraphs on what the study entails.

**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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| **8**   | **Ethics ref:**   | **2024 AM 8938** |
|   | Title:  | COG AALL1731 |
|   | Principal Investigator:  | Dr Lochie Teague |
|   | Sponsor:  | Child Oncology Group |
|   | Clock Start Date:  | 15 August 2024 |

No one form 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 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 amendment was simply to address the change in side effects.

**Decision**

This application was *approved* by consensus.

## General business

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

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| **Meeting date:** | 24 September 2024 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

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

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

The meeting closed at 4:00pm