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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 23 July 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00 - 12:30pm | 2024 FULL 20434 | COG ANBL2131 | Dr Andrew Wood | Dr Cordelia Thomas & Dr Patries Herst |
| 12:30 - 1:00pm | 2024 FULL 20733 | CIC-E-303: Phase 3 Lot Consistency Study of COVID-19 and Influenza Combination Vaccine | Dr Sarah (Polly) Bradford | Ms Sandy Gill & Mx Albany Lucas |
| 1:00 - 1:30pm | 2024 FULL 20653 | Evaluation of a Simple-PrepControlled Embolic | Dr Andrew Holden | Ms Jessie Lenagh- Glue & Dr Patries Herst |
| 1:30 - 2:00pm |  | General Discussion |  | Dr Patries Herst |

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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  | Apologies |
| 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 | Present  |
| Ms Patricia Mitchell  | Non-lay (Health/Disability service provision)  | 08/07/2022 | 08/07/2025 | Apologies  |
| 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 11:30am and welcomed Committee members, noting that apologies had been received from Helen Walker

The Chair noted that it would be necessary to delegate chair responsibility to Cordelia Thomas of Central HDECs in accordance with the Standard Operating Procedures.

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 20434** |
|   | Title:  | A Phase 3 Study of Dinutuximab Added to Intensive Multimodal Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma  |
|   | Principal Investigator:  | Dr Andrew Wood |
|   | Sponsor:  | Child Oncology Group |
|   | Clock Start Date:  | 12 July 2024 |

Olga Ksoinda and Dr Mark Winstanley 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 optional studies were templated into the main participant information sheet (PIS) by COG and could not be removed from the PIS/CFs.
2. The Committee clarified that the risks of standard treatments were all listed in the main PIS/CF as a catch all and for future reference.
3. The Committee clarified that there are no extra visits to the site per this study.

Summary of outstanding ethical issues

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

1. The Committee queried the inclusion of the AI proponent of the study and if this was part of the protocol or if it was being included as a separate exploratory measure for this study. The researcher noted that interpretation of the scans (intended to be utilised in the AI portion of this study) is exceedingly difficult and that better interpretation was being sought through the AI component. The Committee suggested that this should be included in the participant information sheet. The Secretariat noted that there is a form being rolled out that should be included in the response from the researchers for inclusion in resubmission.
2. The Committee queried the use of the questionnaires and where and how they would be assessed and provided to the participants. The researcher noted that screening would be done immediately and that any readings above neutral would be notified to the nurses and specialists treating participants to ensure that the participants were followed up. The Committee queried the use of emergency phone numbers and the researcher noted that emergency numbers were provided as required in standard of care.
3. The Committee suggested a koha for participation for the children in the study as acknowledgement that information is taonga and should just be shown as appreciation or recognition for participation.
4. The researcher noted that there was another study that the genetic testing was happening under. If the study is relevant to this study or the consent form will be used alongside this study for the sake of genetic testing then that form should be provided in this submission for the Committee’s reference.
5. The Committee noted that the assent forms for younger children are overly complicated and could be simplified and contain images for a clearer and easier read.
6. The Committee requested consent for the sending of samples being sent overseas to be clear and included in every consent form.
7. All documents where it is relevant should include information about the cultural sensitivities around genetic testing and biobanking where those procedures are mentioned or required and the Committee suggested consultation with relevant parties regarding appropriate wording.

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

1. Please include information as to what the provision of additional care if the questionnaires suggest participants are distressed will include.
2. Please refrain from using the term “flipping of a coin” and replace with wording stating that random assignment will be done by a computer.
3. Please state that this is unblinded.
4. Please include information as to Medsafe and the approval of the drug to make this more applicable to New Zealand.
5. Please clarify that this drug is not yet approved in New Zealand but that it is not first in human for this use.
6. Please be consistent in use of acronyms concerning US or USA and write out the term in full the first time it is used.
7. Please ensure that the use of acronyms is clear and the first time they are used they are written in full such as the reference to overseas labs.
8. Please include a cultural paragraph for use of tissue and data and consideration of these as taonga.
9. Please be clear where the COG laboratory is located, especially if it is overseas.
10. Please amend the wording “there are no plans to pay you” to state “you will not be paid”.

The Committee requested the following changes to the younger children Assent Form:

1. Please simplify and include pictures for ease of reading and use.
2. Please clarify that there will be no additional needle pricks or painful procedures as part of this study.
3. Please amend the word “want” to “agree” when noting willingness to participate.
4. Please refrain from using the name of the drug.
5. Please simplify months into years where possible.
6. Please remove the reference to not being able to have children in the future.

The Committee requested the following changes to the reconsent for 16 years and older PIS/CF:

1. Please remove the phrase “adult enough to sign” and reword as this has nothing to do with adulthood which can have cultural significance and is only about the age of consent in New Zealand per the law.

The Committee requested the following changes to the older children Assent Form:

1. Please provide the contraception details as an appendix to this form instead of placing the responsibility to ask about contraception and pregnancy on the child.

**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 Dr Patries Herst and Dr Cordelia Thomas.

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| **2**   | **Ethics ref:**   | **2024 FULL 20733** |  |
|   | Title:  | A Phase 3, Randomized, Observer-Blinded, Study to Compare the Safety and Immunogenicity of 3 Lots of SARS‑CoV‑2 rS Nanoparticle and Trivalent Hemagglutinin Nanoparticle Influenza Combination Vaccine with Matrix M™ Adjuvant in Participants ≥ 60 Years of Age |  |
|   | Principal Investigator:  | Dr Polly Bradford |  |
|   | Sponsor:  | Novavax, Inc |  |
|   | Clock Start Date:  | 12 July 2024 |  |

Dr Polly Bradford and Dr Dean Quinn 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 insurance expires prior to the end of the study and noted that this should be renewed prior to that expiry.
2. The Committee clarified that any access of electronic records would be in the capacity as clinic staff and not as researchers. This would be to verify if the participants would be eligible.
3. The Committee clarified the uptake and provision of study documents.

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 what was being collected in the pre-screening in terms of health data and suggested that if any questions were being asked with intent to use the data prior to consent that the researchers could collect verbal consent prior to this and document it before then continuing with the pre-screening questions.
2. The Committee requested clarification of reimbursement and requested that the amounts be clear in all the study documentation. If there is anything additional to this this must also be reviewed by the Committee before the application can be approved. Please note that the phrasing relating to this will matter for tax purposes and there should be a clarifier if tax will apply.
3. The Committee noted that the advertising does not meet the [standards set by HDECs](https://ethics.health.govt.nz/guides-templates-and-forms/advertising-guidelines-for-clinical-research) and NEAC under the National Ethical Standards. The wording is misleading and potentially inducing. Please review all of the adverts to ensure they are appropriate. Ensure it is made clear on all ads that this is an investigation/research study and a positive outcome is not guaranteed.

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

1. Please note on page 3 that “rolling a dice” is not appropriate language for randomisation.
2. Please clarify what EOS is the first time you use it on page 4.
3. Please let the participants know if they will be required to undress for the physical exam and if they are able to bring a support person.
4. Please include a cultural paragraph concerning and addressing the touching of the head. This should be explicitly mentioned in the PISCF.
5. Please clarify the phrase “This may not include…” in the physical examination description.
6. Please clarify the term “post authorisation use”.
7. Please include a statement about the use of any photos taken as part of the study in the consent form.
8. Please note that pregnancy risk may not be appropriate to mention in this context and amending or removing this may be a good idea.
9. Please note how many New Zealand specific participants there may be.
10. Please refer to having had covid in the exclusion criteria on page 5.
11. Please amend the statements on page 0 to note that blood tests on this day are as a baseline not to see how the participant is reacting to the vaccine as they will not have received it at that stage.
12. Please remove the risk of partner pregnancy from the consent form.
13. Please include the samples being sent overseas to the consent form.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).
4. Please update the advertisements, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mx Albany Lucas and Ms Sandy Gill.

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| **3**   | **Ethics ref:**   | **2024 FULL 20653** |  |
|   | Title:  | Evaluation of a Simple-Prep Controlled Embolic |  |
|   | Principal Investigator:  | Dr Andrew Holden |  |
|   | Sponsor:  | Fluidx Medical Technology, Inc |  |
|   | Clock Start Date:  | 12 July 2024 |  |

Dr Andrew Holden, Ms Helen Knight and other members of the research team were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the pregnancy exclusion. The researcher noted that pregnancy would not require withdrawal from the study. Should pregnancy occur in follow-up there should be no ongoing issues that could not be managed by standard of care.

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 is the second in human study of this device. The Committee requested that this appear in a black box at the start of the participant information sheet/consent form (PIS/CF).
2. The Committee requested that requirement of receipts for reimbursement be removed from the PIS/CFs or be amended to not require the receipts. Please be clear about this.
3. The Committee noted that the study cannot be terminated for purely commercial reasons and that the study protocol should reflect this. If this is not what was meant, then please amend this.

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

1. Please remove reference to the legally authorized representative as this is not applicable in New Zealand.
2. Please remove apostrophes from “pros” and “cons”.
3. Please amend the location of the sentence stating “we encourage to bring your whānau and family” from where it currently is to ensure the sentence does not read as bringing that support to the procedures.
4. Please check the formatting of images to ensure that the words are not obscured when printed.

**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).*

## General business

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

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| **Meeting date:** | 27 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 4:00pm.