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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 14 February 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10.30-11.00am | 2023 FULL 14014 | A Study to Evaluate the Efficacy, Safety, Tolerability, and Immunogenicity of a Modified RNA Vaccine Against Influenza in Adults 18 Years of Age or Older | Dr Claire Thurlow | Mr Dominic Fitchett and Associate Professor Mira Harrison-Woolrych |
| 11.00-11.30am | 2023 FULL 15140 | Advancing Palliative Care among Pacific Children - PPC Study | Associate Professor Sunia Foliaki | Ms Dianne Glenn and Ms Amy Henry |
| 11.30am-12.00pm | 2023 FULL 15203 | Flourishing with care in older age | Joyce Cook Chair in Ageing Well Ngaire Kerse | Ms Neta Tomokino and Associate Professor Nicola Swain |

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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  |
| Assc Prof Mira Harrison-Woolrych  | Non-lay Intervention/Observational studies) | 28/06/2019  | 28/06/2020  | Present |
| Mr Dominic Fitchett  | Lay (the Law)  | 05/07/2019  | 05/07/2022  | Present  |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Ascc. Prof Nicola Swain | Non-lay Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| 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 | Present |

## Welcome

The Chair opened the meeting at 10.00am and welcomed Committee members, noting that no apologies had been received.

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 13 December 2022 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 14014** |
|   | Title:  | C4781004 - A PHASE 3, RANDOMIZED, OBSERVER-BLINDED STUDY TO EVALUATE THE EFFICACY, SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF A MODIFIED RNA VACCINE AGAINST INFLUENZA COMPARED TO LICENSED INACTIVATED INFLUENZA VACCINE IN HEALTHY ADULTS 18 YEARS OF AGE OR OLDER. |
|   | Principal Investigator:  | Dr Claire Thurlow |
|   | Sponsor:  | Pfizer New Zealand Limited |
|   | Clock Start Date:  | 02 February 2023 |

Dr Claire Thurlow, Tristan Riley, Jen Coetzee and Dr Mike Williams 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 more lay language should be used in the application form and asked the Researcher to bear this in mind for future applications.
2. The Committee asked for more detail about the recruitment process. After discussion, the Committee were satisfied with the use of site databases including potential participants already consented to being contacted about future studies, and that the initial approach through GP surgeries would be done by the GP and with referral to the research team for more information if interested.

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 advertisement material states the vaccine is ‘investigational’ in places, but ‘new’ in others. Please ensure all material states ‘investigational’ or ‘potential new’. They also requested that the vaccine and study procedures being provided for free is not phrased as a potential benefit of participation in the study.
2. The Committee noted that participants are advised not to become pregnant/father children while in this study. They also commented that cervical caps are not commonly used in New Zealand and spermicide is not widely available. Please clarify the acceptable contraceptive methods for this study, including whether barrier methods alone (rather than in addition to other methods) would be recommended by the sponsor.
3. The Data and Tissue Management Plan states that HDEC will only be informed of notifiable breaches. The Committee stated that any privacy breach is a significant protocol deviation and would therefore require notification to the HDEC. The Committee clarified that the phrasing should be changed as this currently implies the HDEC and participants will only be made aware of what is considered notifiable to the privacy commissioner, but participants and the Committee should be notified of any breach.
4. Please ensure e-diaries are localized for the New Zealand context e.g., using Celsius rather than Fahrenheit.

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

1. A new lay title is required as the short title is too technical.
2. Too much technical language is used throughout. Medical terms are explained much later in the document rather than when they are first referenced. Please review and amend.
3. The current layout is not great for readability, the Committee recommended mirroring the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc) for flow of information.
4. Please use the [HDEC template for reproductive risks](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-v.3.0-july2022.docx) and appropriate contraceptive methods available in New Zealand. This template states barrier methods are not a highly effective method of contraception.
5. On page 9, the statement around payment for travel expenses is duplicated. Please remove one of these statements.
6. The response to F8 of application form states collected samples will continue to be analysed, however page 14 of PIS says participants can withdraw tissue from analysis at any time. Please correct whichever statement is incorrect.
7. Please include some reference to the use of the Nano-Cool system to return self-collected swabs.

**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:**   | **2023 FULL 15140** |
|   | Title:  | Advancing Palliative Care among Pacific Children |
|   | Principal Investigator:  | Dr Sunia Foliaki |
|   | Sponsor:  | Massey University |
|   | Clock Start Date:  | 02 February 2023 |

Dr Sunia Foliaki 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 confirmed with the Researcher that the age of participants is 0-19, noting it was inconsistent across information supplied. Please update documentation to ensure the age of participants is consistent throughout.
2. The Committee requested more information about the very young group (under 7s) and how they will be participating if they cannot be interviewed. The Committee noted the under 7s need assent sheets. The committee requested the protocol be amended to specifically address how under 7s will be interviewed or the nature of their participation in this study, considering their age and any relevant health or disability needs, and whether parents will be providing answers on behalf of this age group.
3. The Committee noted that Māori consultation had been provided by one of the co-investigators and requested this be done by someone independent of the study.
4. The Committee queried how many children would be involved in the study. The application states there would be 130 participants total, but it wasn’t entirely clear whether the 75 health care providers were included in this number. Please outline how many children are expected to be involved, and how many in each age bracket.
5. The Committee queried the recruitment process and asked for the Researcher to clearly state and detail the recruitment steps, as the current documentation was not clear on this process. The Researcher clarified that the initial approach for the children/young persons and their family will be via a clinician at Starship, and there would be a panel involved in determining suitability. The Researcher further confirmed that the panel would include community leaders. The Committee raised concerns about the panel being involved in the identification stage of recruitment and the disclosure of private health information to persons outside of the health care team without authorisation from the potential participants. The researcher stated that the panel would not be provided with any identifiable information but the Committee remained unclear about the nature of their involvement. The Committee requested that the exact role of the panel in determining recruitment, and what information the panel would have access to, etc., is clearly outlined in the protocol. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* 7.7, 9.1-9.3, 9.7, 9.8).
6. The Committee requested further clarity around the role of the community leaders in the study in terms of the panel and the wider study. Please outline whether they would be providing study data and would count as participants, or whether their role would be advisory only. Please also clarify whether community panel members may be asked to identify potential participants. If this is planned, please clarify how this will be done without the consent of the potential participants.
7. The Committee sought reassurance that the privacy of these palliative children and families would be respected, and that this could not currently be guaranteed in the way the study is documented. Please ensure the protocol more adequately describes how safety and privacy will be consistently assured (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* 8.4-8.6).
8. The Committee queried if the focus groups will be a mix of ages or split into age-groups. The Researcher responded that they would be a mixture of ages. The Committee stated that this is a very broad range of ages to put together and this has significant potential to cause distress, for example a 17-year-old expressing their views freely in front of an 8-year-old.
9. The previous reviewing HDEC Committee requested a distress protocol which has been uploaded, but the focus appears to be on the researchers rather than the children and parents. Please amend to state clearly how the potential for distress, especially for younger and vulnerable participants, will be mitigated. This should be tailored to suit the respective age and needs of participants.
10. The Committee noted it is important to seek views but suggested the study could be simplified to be interviews with healthcare providers, community leaders and families to identify common themes outside of focus groups (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* 6.25, 6.29, 6.30).
11. The Committee outlined the processes required of researchers for consenting children and young adults in research studies, based on ascertaining their competency [*National Ethical Standards for Health and Disability Research and Quality Improvement, para* 6.20, 6.22-6.27]. In future applications researchers should demonstrate knowledge of these ethical standards and how they would undertake these processes in their study (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* 6.20, 6.22-6.27).
12. The Committee further noted that the 16+ PIS should be used for all young people able to consent for themselves, rather than the 12-15 Assent Form.
13. The Committee acknowledged that they could not continue the review of the application until fundamental foundations were addressed and elaborated on. It was suggested the study protocol should be completely reviewed, giving ethical consideration to each point in the study design including identifying study participants, recruitment and consent and the methods used to obtain information for analysis. Given the safety considerations around focus groups involving children of different ages, the committee suggested the methodology of this study should be reviewed, perhaps offering private structured interviews to all participants.
14. Due to time restraints (the discussion of this application continued more than 15 minutes past the next application’s timeslot) several significant issues that needed addressing were not discussed at the meeting. These are included below (points 17 onwards and the Participant Information Sheet section).
15. The Committee noted that the online survey requires more statements at the beginning so that it reads like a participation information sheet. The Committee suggested that the following is outlined (*7.15 – 7.17)*:
	1. Make it clear that responses are anonymous (i.e., that the researchers are unable to link the survey responses to individuals).
	2. Include a statement that data cannot be withdrawn as the survey is anonymous.
	3. Clarify whether responses are uploaded in real time (i.e., if a participant completes part of the survey, then stops, whether already completed responses will be included in the data set).
16. The Committee noted the response to B17.1 of the application form, and stated that participants should have the right to access transcripts from structured interviews they have participated in. Please ensure documentation is amended to reflect this.
17. The Committee stated that participants should not have to request reimbursement for travel expenses; this should be offered to all participants. Please amend the participant information accordingly.
18. The Committee requested clarification in the Data Management Plan (DMP) around what 'audio-visual' formats are being collected (Section 7.2); if participants will be videoed this should also be clearly stated in the participant information sheet (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*.
19. Consent is sought to inform the participant’s GP, but application states the opposite (E2) - please clarify which is correct and amend as necessary. Clarify why GPs will be notified of study participation, as the study is purely observational.
20. The Committee concluded that the previous reasons for decline of this application (2022 FULL 13802) had not been addressed in this resubmission. The Researcher disagreed, stating he considered he had addressed these issues.
21. The Committee noted there were several additional ethical issues which also needed addressing. It was agreed after 45 minutes of discussion that these items (see points 16 to 19 above and participant information sheet issues below) would be included in the decline letter, which is directly drafted from the HDEC Committee minutes.
22. The Committee encouraged the researcher to resubmit their application to Southern HDEC, noting it would aid the Committee’s review of the resubmission if each issue were responded to point by point in a cover letter.

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 6.27, 7.15 – 7.17)*:

Children 16 Years Above PIS/CF:

1. Review the first two pages and simplify language where possible.
2. Replace 'digital' recordings with audio or video for clarity. State what happens to the recordings (voice is a biometric identifier), whether the recordings are transcribed, and whether any potentially identifiable information is redacted from the transcripts. State whether participants can review and request corrections to the transcripts.
3. State how long the individual interviews will take.
4. State whether the interviews may be conducted in the participant's first language on request.
5. State that data from the current study will not be used for future research or shared with other researchers.
6. Some data may require retention for 10 years after the youngest study participant turns 16. Please check whether this applies to any data collected in the current study, and amend documentation accordingly if applicable (applies to PIS/CF and DMP)
7. Please correct the typo of the title (“particiapnt”)
8. The Committee queried if every participant is required to participate in a focus group and semi-structured interviews, if not please correct the applicable statement on page 3.
9. Please update the section on who can take part in the study, as the current definitions do not match the proposed participants.
10. On page 2, capitalise Pacific in following sentence: “You identify as of pacific descent”.
11. On page 3, please remove text “It is free to participate in this study”, which suggests there is some individual benefit from participation.
12. On page 4, heading includes the words “or if I change my mind”, but there is no information in this regard, i.e., what happens if the participant wishes to withdraw during the study, and what happens to their information if they withdraw. State whether participants can withdraw their data (presumably they will be able to withdraw interview data until it is analysed). Explain why participants are unable to withdraw their information from the focus groups.
13. Remove reference to accessing medical records for key informants, health care providers and parents – this information is not being collected for these groups
14. The Committee noted that the ACC statements are not required given no injury could occur as a result of participation.
15. There is a yes/no option in the consent form in respect of withdrawal from the study. This may need to be amended depending on how withdrawal from study is dealt with (as above).

Assent form 7-11

1. It is suggested that this is retitled as ‘Assent Form Younger Children’ as choice of assent form should be based on level of comprehension rather than age alone.
2. Please review the document and simplify significantly, removing jargon and acronyms such as FG PPC Please use age-appropriate language and consider use of pictures of diagrams to help younger children understand what is being asked of them.
3. Please explain what a focus group is in simple language or use another term

Assent form 12-15

1. It is suggested that this is retitled as ‘Assent Form Older Children’ as choice of assent form should be based on level of comprehension rather than age alone.
2. The PIS for adolescents is identical to the assent form for the younger age group (7-11). Please review and pitch between the full consent form and Younger Child Assent Form.

Parent/Caregiver PIS/CF:

1. This PIS invites the parent to take part but does not cover consenting for a younger child (paired with their assent). Please amend accordingly, including all the information needed for a parent to consider giving their agreement for a younger child to participate in this research.
2. On page 2, please remove text “It is free to participate in this study”, which suggests there is some individual benefit from participation.
3. On page 2 under heading “WHO CAN TAKE PART IN THE STUDY?”, the text from the health care provider PIS has been used, please amend accordingly for this participant group.
4. On page 3, heading includes the words “or if I change my mind”, but there is no information in this regard, i.e., what happens if the participant wishes to withdraw during the study, and what happens to their information if they withdraw. State whether participants can withdraw their data (presumably they will be able to withdraw interview data until it is analysed).
5. There is a yes/no option in respect of withdrawal from the study. This may need to be amended depending on how withdrawal from study is dealt with (as above).

Key Informant PIS/CF

1. Please ensure this PIS is specifically directed at the group of participants for who it is intended, addressing all issues these participants need to consider before agreeing to take part in this study.
2. On page 1, explain in lay language the difference between this cohort and the health care provider cohort.
3. On page 1, the following text isn’t required: “and it won’t affect the care you receive” as these participants aren’t receiving any care.
4. On page 2, it states this cohort is participating in the focus groups, however this is contrary to the application and study protocol. Please remove if not.
5. On page 2, please remove text “It is free to participate in this study”, which suggests there is some individual benefit from participation.
6. On page 3, heading includes the words “or if I change my mind”, but there is no information in this regard, i.e., what happens if the participant wishes to withdraw during the study, and what happens to their information if they withdraw. State whether participants can withdraw their data (presumably they will be able to withdraw interview data until it is analysed).
7. There is a yes/no option in respect of withdrawal from the study. This may need to be amended depending on how withdrawal from study is dealt with (as above).

Health Provider PIS/CF

1. Please ensure this PIS is specifically directed at the group of participants for who it is intended, addressing all issues these participants need to consider before agreeing to take part in this study
2. On page 2, it states this cohort is participating in the focus groups, however this is contrary to the application and study protocol. Please correct.
3. On page 2, please remove text “It is free to participate in this study”, which suggests there is some individual benefit from participation.
4. On page 3, heading includes the words “or if I change my mind”, but there is no information in this regard, i.e., what happens if the participant wishes to withdraw during the study, and what happens to their information if they withdraw. State whether participants can withdraw their data (presumably they will be able to withdraw interview data until it is analysed).
5. There is a yes/no option in respect of withdrawal from the study. This may need to be amended depending on how withdrawal from study is dealt with (as above).

**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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| **3**   | **Ethics ref:**   | **2023 FULL 15203** |
|   | Title:  | Aged Care in a Changing World; Flourishing with care |
|   | Principal Investigator:  | Professor Ngaire Kerse |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 02 February 2023 |

Professor Ngaire Kerse and Dr Tamika Simpson 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. After discussion, it was confirmed that there are adequate measures in place for determining capacity to consent.
2. The Committee noted the 3-hour session duration for participants. After discussion with the Researcher, they were assured that the time and strain will be adapted to the needs of the group.
3. The Researchers confirmed there will be a Te Reo Māori translation version of the participant information sheet available.
4. The Committee confirmed with the Researchers that advertisements are in development and will be submitted as an amendment for review when completed before use.

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 a few questions in the application form were answered in error, such as collecting health data.
2. The Committee queried the video recording, noting that if someone doesn’t consent to be recorded, they are asked to sit outside of the video. The Researcher clarified that these recordings will be short snippets if someone wishes to deliver it to a camera. The Committee was assured no participant would feel excluded but requested further information around the videos are included in the participant information sheet (PIS), as well as stating they are not anonymous.
3. The Data Management Plan does not describe how data will be destroyed. Please amend.
4. The Committee requested clarification on the definition and role of ‘stakeholders’ in this research, as this was not specified in the study protocol or PIS. The Researchers explained that stakeholders may include aged-care facility owners who might be included in the Research Development Group but will not be present in the study discussion sessions with older people. The Researchers acknowledged that stakeholders on the research development group might be able to identify study participants living in their facility. It was agreed that the PIS should explain the nature and role of stakeholders on the research development group and inform participants that these might include owners or operators of the facilities in which they live. The PIS should also explain that the stakeholders will have access to the information and views the participants provide in this study.
5. The Committee noted that data should be stored for 10 years, not 6. Please amend across documentation.
6. The Committee requested consideration is made around the potential disruption to the schedules of carers for the timeslot planning, and to be mindful for the sessions and times. Being whānau-centric when planning the interactions will ensure this is not a one-size fits all approach.

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

1. Please explain in lay terms on what is meant by ‘flourish’.
2. Remove reference to the Sponsor, risks to getting health insurance and employment, and other things that are kept in the template for clinical trials.
3. Please state how the videos might be used in future and specify who might view them.
4. Please add a point explaining the role of stakeholders on the Research Development Group, including stating that they might be the owners/operators of aged care facilities in which the participants live. Please also explain the access they may have to participants’ personal information and views expressed during the sessions.
5. Please review the PIS for typographical errors.
6. Please reword the PIS where necessary to include whānau as participants.

**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:** | 14 March 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 12.30pm with a karakia.