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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 13 February 2024 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 10.30am-11.00am | 2023 FULL 18728 | CardioVascular Disease Risk Assessment by Pharmacy in secondary care for high-risk ethnicities (CVD RAP) | Mr Ev Tolerton | Mr Dominic Fitchett & Dr Devonie Waaka |
| 11.00am-11:30am | 2024 FULL 18811 | Medication Safety in Resuscitations | Dr Andrew Brainard | Mr Jonathan Darby & Ms Amy Henry |
| 11.30am- 12.00pm | 2024 FULL 18893 | Warfarin self testing in individuals living with rheumatic heart disease and mechanical valve replacement | Dr Miriam Wheeler | Mr Dominic Fitchett & Dr Patries Herst |
| 12.00pm-12.30pm | 2024 FULL 19513 | Evaluation of the Bimatoprost Implant System Used inCombination With the SpyGlass Intraocular LensCompared to Timolol Ophthalmic Solution (Tigris) | Dr Dean Corbett | Mrs Dianne Glenn & Mr Barry Taylor |
| **12.30pm-1.00pm** |  | **Break 30 minutes** |  |  |
| 1.00pm-1.30pm | 2024 FULL 17928 | BerriQi-kids study | Dr Starin McKeen | Dr Maree Kirk & Ms Amy Henry |
| 1.30pm-2.00pm | 2024 FULL 18545 | Bacterial killing by white bloodcells from individuals with cystic fibrosis | Dr Nina Dickerhoff | Mr Jonathan Darby & Dr Patries Herst |
| 2.00pm-2.30pm | 2024 FULL 19228 | Efficacy and safety study ofTAK 101 in participants with Celiac Disease on a gluten-free diet | Dr Nah Yeon Baik | Mrs Dianne Glenn & Dr Devonie Waaka |
| 2.30pm-3.00pm | 2024 FULL 19556 | Dementia prevalence survey | Dr Ngaire Kerse | Mr Jonathan Darby & Mr Barry Taylor |
| **3.00pm-3.20pm** |  | **Break 20 minutes** |  |  |
| 3.20pm-3.50pm | 2024 FULL 18552 | Safety and efficacy ofINCB000928 in people withFibrodysplasia ossificans progressiva (FOP) | Dr Patrick Yap | Mr Dominic Fitchett & Dr Devonie Waaka |
| 3.50pm-4.20pm | 2024 FULL 19519 | Safety, efficacy andpharmacokinetics of TAVO101 in adults with severe eczema | Dr Penelope Montgomery | Dr Maree Kirk & Ms Amy Henry |

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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 |
| Ascc. Prof Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Apologies |
| 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 | Apologies |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Mrs Carla Strubbia | Non-lay (Intervention Studies) | 03/07/2023 | 02/07/2026 | Apologies |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Present  |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Mr Jonathan Darby | Lay (Law and Ethical Reasoning) | 13/08/2021 | 13/08/2024 | Present |

Welcome

The Chair opened the meeting at 10am and welcomed Committee members, noting that apologies had been received from Mrs Carla Strubbia, Dr Nicola Swain and Ms Neta Tomokino.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mr Barry Taylor, Mr Jonathan Darby and Dr Patries Herst confirmed their eligibility and were co-opted by the Chair as members of the Committee for the duration of the meeting.

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:**   | **2023 FULL 18728** |
|   | Title:  | CardioVascular Disease Risk Assessment by Pharmacy in secondary care for high-risk ethnicities (CVD RAP) |
|   | Principal Investigator:  | Mr Ev Tolerton |
|   | Sponsor:  | Te Whatu Ora |
|   | Clock Start Date:  | 1 February 2024 |

Mr Ev Tolerton and another member 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 why Southern HDEC was requested for review.
2. The Committee noted the researcher’s query about whether formal consent is required for this study and confirmed that written consent is required.

Summary of outstanding ethical issues

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

1. The Committee requested that participants be provided with the Participant Information Sheet and given enough time to consider participation, and that this be clearly protocolised.
2. The Committee queried how participants will access care after the study. The Committee requests detail on who will monitor medication effects, organise repeat blood tests or provide repeat prescriptions as the study is predicated on the fact that these people do not have access to primary care. Please note that this could result in added stress for the participant who cannot afford the care they are told they require.
3. The Committee queried how the vouchers mentioned in the response to D22.1 in the submission will be provided and who will fund them. The Committee requested more information regarding this and if primary care providers had been approached regarding this model.
4. The Committee queried how Māori-specific care may be provided and if any consideration had been taken into how this may be made available to participants.
5. The Committee requested a finalised protocol.
6. The Committee noted that the sample size was very broad and asked how the sample size was selected. The researchers confirmed it was based on how many participants were expected to be recruited during a set period of time. The Committee requested this be explained in the protocol.
7. The Committee queried how Kaupapa Māori methodology was being utilised in this study, as was stated in the application form. Please review what Kaupapa Māori methodology is and consider answering the submission question differently.
8. The Committee noted that there had been no formal Māori or Pacific consultation. This is required as there is a focus on specific ethnicities in this study.
9. The Committee noted that focusing on one ethnicity can increase or create potential for stigmatisation. This will need to be mitigated and considered in the Protocol.
10. The Committee noted that there was no Data Management Plan as is required to meet the NEAC Standards, *para* 12.15a. Please refer to the HDEC [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) for guidance.
11. The Committee noted that withdrawal of data from a research study is not the same as withdrawal of data from the clinical record. In a study of this nature participants should have the right to request withdrawal of their data from the study database, up until the point it is analysed. Please ensure this is reflected in the DMP.
12. The Committee noted that there was mention of a satisfaction survey. This needs to be provided for review.
13. The Committee queried whether the comments from the peer reviewers have been answered. Please provide evidence of this to the Committee for review.
14. The committee noted that the trial may not be stopped for purely commercial reasons.
15. The Committee noted the trial must be registered with a WHO approved clinical trials registry prior to commencement.

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

1. Please review for lay language. This document should be easy to read and short enough to not be burdensome.
2. Please include a short lay-friendly title.
3. Please mention the different medication classes participants may be given.
4. Please specify that a potential benefit of this study is that those who would not normally have access to risk assessment will have access.
5. Please clarify who the Sponsor, referred to throughout, is.
6. Much of the highlighted information section appears to be taken from a commercially sponsored study. Please amend to ensure the information is applicable to the current study. Please remove all information that is not study-specific or that is highlighted and not relevant.
7. Please ensure that participants are provided with the option to withdraw study data on request.
8. Please ensure a clear distinction is made between information included in the clinical record, and information held in the study data set.
9. Please amend the reference for details of ‘Māori health’ support to Māori cultural support.
10. Please include Pacific cultural support where possible.
11. Please ensure that there is a footer with protocol number.
12. Please amend the name of the relevant HDEC to ‘Southern’, not ‘Southern A’.
13. Please remove the 0800 4 Ethic number as this is no longer active. This can be amended to the general enquiries number in the [PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).
14. Please amend the wording in the study to directly address the participants.
15. Please remove mention of data going overseas if this is not going to happen in this study.

**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 supply a more detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*
5. Please supply evidence of Māori consultation to ensure the study is appropriate for a New Zealand context *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Devonie Waaka and Mr Dominic Fitchett.

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| **2**   | **Ethics ref:**   | **2024 FULL 18811** |
|   | Title:  | Medication Safety in Resuscitations |
|   | Principal Investigator:  | Dr Andrew Brainard |
|   | Sponsor:  | Te Whatu Ora Counties Manukau |
|   | Clock Start Date:  | 1 February 2024 |

Dr Eunicia Tan, Mrs Catherine Wong and Dr Andrew Brainard 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 participation would include about 87 resuscitations.
2. The Committee queried the thought given to the timing of resuscitations subject to data collection. The researcher clarified that whilst data from evening resuscitations would be valuable this would not be possible due to funding constraints.
3. The Committee clarified the level of detail recorded about the patient being resuscitated. This would be bundled and not identified by NHI numbers and would be detailed as “Resus. 1, Resus. 2…” etc. The Committee agreed that a waiver of consent was appropriate for patient participants, given the nature of the data collected and the difficulties associated with obtaining patient consent in a resuscitation setting.

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 participating staff members were not being consented.
2. The staff need to be made aware that this research is being undertaken. The researcher will be able to intervene in the resuscitation and as such the people in the room should be able to know that is happening and why the observer is present. An information sheet should be distributed to personnel that may attend emergency department resuscitations. It should be made clear that observation is opt-out and if anyone attending the resuscitation states they do not want to be observed, the research will not be conducted on that resuscitation. Please provide this communication to the Committee for review. This can be in language appropriate for clinicians. *National Ethical Standards* para *7.15*
3. The Committee requested clarification regarding the process for managing medication errors detected by the observer, specifically whether the error could result in incident form completion or other censure of staff involved.
4. The Committee requested that the staff who participate in the optional survey are provided with information on the study as a cover sheet to the survey, as they *are* participants in the study. The Committee requested that the survey’s cover page detail the nature of the research and why it is being conducted and the details of participation. If direct quotes may be used this should be detailed here. Please also note in the information provided that people cannot withdraw their responses as the survey is anonymous. *National Ethical Standards* para *7.15*. Please provide this documentation to the Committee for review.
5. The Committee requested an adequately detailed Data Management Plan. Please refer to the [HDEC DMP template for guidance](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx). *National Ethical Standards* para *12.15*
6. The Committee noted that whilst the survey may appear to be anonymous there was potential for data to identify individual participants. Please aggregate any data that may lead to potential identification. *National Ethical Standards* para *12.15*
7. The Committee requested it is made clear in the protocol that not all senior medical officers would be excluded, only those conducting or responsible for the trial.

**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:**   | **2024 FULL 18893** |
|   | Title:  | Warfarin self testing in individuals living with rheumatic heart disease and mechanical valve replacement |
|   | Principal Investigator:  | Dr Miriam Wheeler |
|   | Sponsor:  | NAME OR BLANK |
|   | Clock Start Date:  | 1 February 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 noted that the protocol states that 'Enrolled patients will be used as historical controls as the comparator group'. Please clarify whether consent will be sought for use of data, or whether a waiver of consent is requested. If the latter, please provide a justification for waiver of consent. This should include the practical, scientific, and/or ethical reasons why consent cannot be obtained. See NEAC Standards 7.47 and 7.48 for guidance.
2. The Committee requested provision of further detail about the interview component proposed in the protocol (number of participants, method of recording, venue etc). An outline of the interview must be submitted for approval prior to use. *National Ethical Standards* para *7.16*
3. The Committee requested the following changes to the Data management Plan:
	1. Please ensure that this document complies with para 12.15a of the NEAC Standards. It is recommended that the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) is referred to for guidance.
	2. Please ensure the amended DMP clearly distinguishes between data retained in the clinical / Community Pharmacy Anticoagulation Management Service (CPAMS) record (which is assumed to be identifiable) and data collected purely for the purposes of the study. Participants may not be able to request deletion of information from the clinical record, for example, but should retain the right to request their data be deleted from the study analysis dataset. *National Ethical Standards* para *12.15a*

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

1. Please rewrite this PISCF as it is too brief in its current form. Please refer to the HDEC [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) for guidance. *National Ethical Standards* para *7.15 & 7.16*
2. Please specify who pays for the study and note that there is a Koha available to participants as a thank you for participation.
3. Please include an ACC clause.
4. Please describe the risks of the study, in particular, what can happen in the INR falls outside of the recommended parameters.
5. Please provide more information as to what happens in cases where participants do not communicate with researchers and how and what follow up will occur in these circumstances. *National Ethical Standards* para *7.15 & 7.16*
6. Please state if participants will need to have internet access.
7. Please specify how data will be treated and how it may be different to what is normally placed in the participants medical record. *National Ethical Standards* para *12.15a, 7.15 & 7.16*
8. Please specify what parts of the information provided is CPAMS standard of care.
9. Please specify if people who have visual impairments will be excluded or how this study may be made accessible to these participants.
10. Please consider including a table of what tests will occur when.
11. Please detail the acceptability and safety of an online patient portal to communicate with and support participants.
12. Please specify how acceptability will be assessed.
13. Please specify when and if deidentified or anonymous or identifiable data will be collected.

**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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| **4**   | **Ethics ref:**   | **2024 FULL 19513** |
|   | Title:  | Evaluation of the Bimatoprost Implant System Used in Combination With the SpyGlass Intraocular Lens Compared to Timolol Ophthalmic Solution (Tigris) |
|   | Principal Investigator:  | Dr Dean Corbett |
|   | Sponsor:  | SpyGlass Pharma, Inc |
|   | Clock Start Date:  | 1 February 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 resolved ethical issues

1. The Committee noted that the request for the application to be considered in a closed meeting has been declined. There was no adequate justification of why a closed meeting was necessary given the HDECs would not be considering or speaking on matters of commercial sensitivity which was the only cited reason provided to the Committee.

Summary of outstanding ethical issues

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

1. The Committee requested assurance that given the complicated nature of the PISCF that participants would be given sufficient time to be able to consider participation.
2. The Committee requested a detailed plan for participant care during the washout period and stated that this should be detailed in the PISCF.
3. The Committee noted that the inclusion of the statement “SpyGlass Pharma, Inc. has not agreed to pay you or anyone else for any other medical costs related to your participation in the study. This includes, but is not limited to, any prescriptions you may take (excluding study medications), medical equipment, etc' on page 18 of the PISCF. The Committee noted that this is not acceptable, and that the sponsor is responsible for payment of all trial-related costs. Please confirm that participants will not be required to pay for medications or medical equipment related to study participation and amend the PISCF accordingly.
4. The Committee requested that there be an explanation provided as to what will occur with the second eye after the study is concluded.
5. The committee noted that page 22 of the PISCF infers that employees may be permitted to enrol in the study: 'Regarding employees who participate in the study, there will be no privilege given for participating in this research study....' The enrolment of Sponsor or site employees in a clinical trial raises significant potential ethical issues as outlined on pages 63 and 64 of the NEAC Standards. Please clarify whether NZ sites are considering allowing employees to participate, and the measures in place to mitigate the associated ethical challenges this would present.
6. The Committee requested confirmation that SCOTT has reviewed the device. Should this not be done, the Committee requires independent peer review.
7. The Committee DMP provided fails to address many of the requirements of NEAC Standard 12.15a, including the life cycle of identifiable and de-identified data, future uses of data, privacy breach processes, named accountability for data security, return of results, and withdrawal of data. Please refer to the HDEC [DMP template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) for guidance.
8. The Committee requested that all recruitment material states up front the study system is investigational. This is currently noted in very small font at the end of the documents and references US rather than NZ regulators.

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

1. Please replace “Northern B” with “Southern” on page 22.
2. Please consider creating a table describing study tests where they will be detailed once rather than the repetitious nature of the current PISCF.
3. Please provide the approximate timeframe for each study visit.
4. Please clarify if someone else will need to be able to drive participants home after the study and which visits may require this.
5. Please clarify if there will be an opportunity for the participants to be provided surgery on the second eye after the study is concluded. This is an expensive procedure.
6. Please clarify if this group of participants would already be enrolled for cataract surgery.
7. Please only reference New Zealand regulators.
8. Please clarify what happens to the implant after the 3-year study period, specifically whether it remains in the eye, has dissolved, requires removal, etc.
9. Please provide an image of the actual device.
10. Please do not describe participation being like the flip of a coin as participants are randomised to more than two groups.
11. Please include frequency of occurrence out of 100 or 1000 etc, for risks associated with the study grouping common, uncommon, and rare events together.
12. Please move the sentence: “Māori participants will be treated in a culturally appropriate way” from under the title “What will happen to my urine sample”.
13. Please avoid the use of acronyms.
14. Please state how many NZ participants are expected to take part.

**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 supply a more detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*
5. 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 Ms Dianne Glenn and Mr Barry Taylor.

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| **5**   | **Ethics ref:**   | **2024 FULL 17928** |
|   | Title:  | BerriQi-kids study |
|   | Principal Investigator:  | Dr Starin McKeen |
|   | Sponsor:  | Anagenix Ltd |
|   | Clock Start Date:  | 1 February 2024 |

Dr Starin McKeen and Dr Aahana Shrestha 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 age of participants.
2. The Committee clarified that locality authorisation has not yet been sought.
3. The Committee clarified that the whole school may be enrolled but participation will only begin once the participant logs absence from school associated with the symptoms under study.
4. The Committee clarified that parents would not be participating but would be answering questions about the child.
5. The Committee clarified why there was a quality-of-life questionnaire included in the study.
6. The Committee clarified that 52 participants is the minimum number for recruitment. 62 participants is the number the researchers would ideally like to recruit.
7. The Committee clarified that recruitment material would be submitted for review once this has been approved by the school.
8. The Committee queried how family members would be participating. The researcher noted that the family would not have data collected but would be offered study treatment.

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 a range of child information sheets and assent forms. These should be separate from the parent information sheet and consent form. These should be appropriate for the full range of age groups and there will need to be several forms provided to this effect. *National Ethical Standards* para *6.25- 6.27.*
2. The Committee requested that there be provision of a data management plan that meets the requirements set out in NEAC Standards, *para* 12.15a.
3. The Committee requested a valid insurance certificate and indemnity be provided.
4. The Committee noted that whilst there is a large Māori population at the school in the study that there was no intent to collect ethnicity data in the study. This is a requirement per the NEAC guidelines para 9.20. Please include the collection of this in the protocol and Data Management Plan (DMP). *National Ethical Standards* para *3.1*
5. The Committee requested that the product be sent to the Standing Committee on Therapeutic Trial (SCOTT) for review if therapeutic claims may be made based on the results of this study. *National Ethical Standards* para *9.25-9.32.*
6. The Committee requested that there be a defined age range for whānau receiving the treatment. There is potentially some risk of choking or other health-related issues in very young children that needs to be considered.
7. The Committee queried who was responsible for adverse events. This should be protocolised and there needs to be a plan should the contact person for the study be contacted in the event that something does occur. ‘Access and referral to GP’ is not sufficient. This should be healthcare provided by the study staff or local links that can provide care for those who may not have access to primary care.
8. The Committee noted that the school should not provide researchers with absence lists that include children who have not been consented to participate in this trial. Please ensure a list of all consented children is provided to the school, and only absence and contact information for people who have consented be provided back to the study researchers. *National Ethical Standards* para *9.7 & 9.8*
9. The Committee noted that all study documents need to have consistent information on the withdrawal of data.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *National Ethical Standards* para *7.15 & 7.16*:

1. Please refer to the [HDEC PISCF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) to include all information as required.
2. Please detail a clear plan for follow up and forwarding of people to care in the event of an adverse reaction.
3. Please remove any leading language.
4. Please inform the participants their general practitioner (GP) may be contacted if during the trial the researchers note any concerning or serious results.
5. Please include the sponsor’s details.
6. Please clarify that the whānau will receive the same blinded treatment as the participating child.
7. Please include the full commercial compensation statement per 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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| **6**   | **Ethics ref:**   | **2024 FULL 18545** |
|   | Title:  | Bacterial killing by white blood cells from individuals with cystic fibrosis |
|   | Principal Investigator:  | Dr Nina Dickerhoff |
|   | Sponsor:  | Research and Enterprise, University of Otago |
|   | Clock Start Date:  | 1 February 2024 |

Dr Nina Dickerhoff and Dr Anthony Kettle 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 age groups of children involved in the study. The children in the study will be between 5 and 7.
2. The Committee questioned if the inclusion of an adult control group actually provides a suitable control. The committee suggested an amendment to collect blood from healthy children in the future to create better comparators for data collection.
3. The Committee clarified that the study not involve supported decision making, as assent is a different concept to 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 requested that there be a provision of assent forms. Please refer to the [HDEC template for guidance](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/hdec-assent-form-instructions-and-checklist-may18.doc).
2. The Committee requested that there be someone else who approaches the participants to take part in the study. The clinician could invite bias in the process. If possible, a research nurse should be the person approaching potential participants.
3. The Committee requested an amendment to the Data Management Plan (DMP). Please do not use the full date of birth to the data set as this is a direct identifier. This document is also missing several sections. Please refer to the [HDEC DMP template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx)

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

1. Please amend the information sheets so that the sheets address the parents as giving consent for their child to participate and not as the people participating in the study.
2. Please make it clearer that there will be two (before and after therapy) blood tests. Please include information about the timing of this second blood test.
3. Please include more information about “What will happen to my information”. Please refer to the [HDEC PISCF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) for reference of what level of detail is expected to be included in this document.
4. Please amend mention of collection of identifiable data as this is happening but the data is being coded. Please expand on how the data will be coded and how the coded data will be managed. The DMP template will be able to help with this.
5. Please remove mention of benefits to this study as there are no benefits directly derived from participating in this study.
6. Please include the option to be provided a lay summary of the study in the consent form.
7. Please amend mention of what HDEC reviews to only state that HDEC reviews the ethical aspects of studies.
8. Please specify for parents that individual study results are unlikely to inform the participant’s future care.

**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 Mr Jonathan Darby.

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| **7**   | **Ethics ref:**   | **2024 FULL 19228** |
|   | Title:  | Efficacy and safety study of TAK 101 in participants with Celiac Disease on a gluten-free diet |
|   | Principal Investigator:  | Dr Tina Baik |
|   | Sponsor:  | Takeda Development Center Americas, Inc. |
|   | Clock Start Date:  | 1 February 2024 |

Dr Tina Baik, Miss Samyuktha Anand, Ms Stefania Simeone, Mr Adwait Bhadbhade 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 informed the researchers that the request for the application to be considered in a closed meeting has been declined. There was no adequate justification of why a closed meeting was necessary. The HDECs do not consider or review matters of commercial sensitivity or intellectual property (which was the only cited reason provided to the Committee).
2. The Committee clarified that only the Optimal clinical trials advertising material will be used in New Zealand. After the meeting this was discussed further and all advertising was to be used. The Committee have included their comments to ensure that all advertising materials meet the ethical standards.

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 the CI indemnity that had been provided was at registrar level and queried whether this was sufficient for the coordinating investigator, who has overall responsibility for the study nationally and is would usually be considered to be at consultant level. The Committee requests provision of written confirmation from MPS that registrar capacity indemnity is sufficient. Otherwise, please amend cover.
2. The Committee queried what processes are in place to respond to severe reactions to gluten challenge.
3. The Committee requested that the researchers outline the processes in place during the recruitment process to ensure individuals are provided with an opportunity to speak with research team members not involved in their clinical care.
4. Please ensure good quality ethnicity data relevant to the New Zealand population is collected at a site level, if necessary, in addition to eCRF-specified race / ethnicity fields
5. The Committee requested the following changes to the Recruitment Material and Advertisements:
	1. The Committee noted that recruitment material states compensation for time and travel is 'possible' or 'may be provided'. Clarify what is intended for NZ participants and address this definitively in all participant-facing material. Please provide details of reimbursement amounts to the Committee.
	2. Please delete 'paid clinical trials' from the Headline options in the Optimal Clinical Trials advertising document.
	3. Please delete 'Possible' from 'Possible compensation for time + travel' and remove this from the 'benefits' section of all material.
	4. Please delete 'Study-related care at no cost' from the benefits section of all material; this infers participants could reasonably be expected to pay for care required to conduct the study.
	5. Please delete 'Participation is limited.', 'click as soon as you can' etc., from messaging; this places inappropriate sense of urgency and or time pressure to agree to take part.
	6. Please delete 'Retargeting' messages from Digital Ad Packet and Search Ads documents, for example:
	* Limited Spots Remain in Coeliac Disease Research Study
	* Enrol in Coeliac Disease Research Study Before It Fills Up
	* Coeliac Disease Study Close to Reaching Maximum Enrolment'
	* Don't miss out!
	* Where individuals decline interest, please ensure they are asked whether they wish to be removed from the database prior to ending messaging.
	1. Please delete 'If NO/ not interested: OK as a reminder, the generosity of your time and effort would be helping others with similar symptoms, both now and in the future. If you change your mind...'; as this adds pressure to the individual to participate.
	2. Please clarify to the committee how patients sent the 'Dear Patient' emails will be identified, and who they will be sent from.
	3. Please amend the Doctor to Doctor email to clarify that agreement should be sought from the patient prior to referral to the study team.
	4. Please review and correct misspellings and lack of tohūto (macron) for 'tena kotou'(tēnā koutou) and 'nga' (ngā) in the Participant Visit Guide and Brochure.
6. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
	1. Please address inconsistencies within the DTMP (Sections 8.5, 8.8 and 12), and between the DTMP and PISCF, regarding future use of data.
	2. Please explain what is meant by the statement regarding tissue withdrawal in Section 13; the text states requests to withdraw tissue will be 'documented', but also that tissue will continue to be analysed.

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

1. Please clarify the risks in lay terms and clarify what the acronyms used mean, and what potential safety issues may be associated with raised complement.
2. Please amend “efficacy” to “effectiveness” in the lay title.
3. Please remove all repeated information regarding randomisation, blinding, time on study, the requirement to have maintained a gluten free diet, disclosures and use of con meds, contraception requirements, study procedures, HIV testing, etc.
4. Please simplify the exclusion criteria as this is currently too technical.
5. Please delete the information about chances of receiving each treatment; it is too complicated.
6. Please correct the page numbers, in particular around the assessment table.
7. Please carry the headings of the assessment table across each new page.
8. Please clarify what is meant by 'or genetic samples' and under ‘Genetic tests’. The protocol states the only analysis that will be performed is HLA typing and RNA biomarker analysis. If this is the case then state that these will be the only targets as currently the wording is far too broad.
9. Please amend all amounts of blood measured in teaspoons etc., to be in millilitres.
10. Please amend mention of number of NZ participants to be consistent.
11. Please note that it is not acceptable for participants to be expected to pay for treatment to address side effects or symptoms deemed potentially study-related. Please amend the text under the heading “Can I have other Treatments” accordingly and ensure participants are fully reimbursed for any such treatment.
12. Please include the option for an interpreter at the beginning of the PIS and not just at the beginning of 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).
5. Please supply a more detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Devonie Waaka and Mrs Dianne Glenn.

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| **8**   | **Ethics ref:**   | **2024 FULL 19556** |
|   | Title:  | Dementia prevalence survey |
|   | Principal Investigator:  | Sharon (Xiaojing) Wu |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 1 February 2024 |

Ms Ngaire Kerse, Mr Gary Cheung and Dr Sharon Wu 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 University of Auckland is the sponsor despite no indication of sponsorship in the application submission.
2. The Committee clarified how the process of including participants in aged residential care would occur and the safeguards in place to protect those who may not cope with being approached.

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 the questionnaire scores would not be provided back to the people in the study with dementia, but the General Practitioners (GPs) would be informed. Support, however, would still be made available regardless of this to the participants. Care/support people would be included in this conversation as well. The Committee raised the point that there should be provision or results in some form back to the participants once the result is calculated. The researchers requested if it would be possible to give a response that was not as specific as the score but a good indication of where they are at and the Committee noted that there was the ability to support this. Please amend this in the protocol.
2. The Committee noted that the feeding back of results to a GP only works so long as there is a GP to refer to. They requested that some specific protocolisation be added to account for cases where the participant does not or may not have a GP.
3. The Committee requested that the word “informants” be amended to something that sounds less sinister.
4. The Committee suggested amending the use of the “head of the household” and instead just including the primary support person.

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

Facility PIS/CF:

1. Please insert "for themselves" in sentence "provide informed consent for themselves with the support of their whānau and/or friends.
2. Please amend wording to be consistent as to who the target audience of the form is.

Retirement Village PIS/CF:

1. Please replace “rooms” with “apartment”.

Decision Maker PIS/CF:

1. Please include a description of who is a family decision maker why they are asking these questions.
2. Please amend the wording around consenting to collection for “their health”. This should be for the person participating.
3. Please remove the option to inform the GP of participation.

**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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| **9**  | **Ethics ref:**   | **2024 FULL 18552** |
|   | Title:  | Safety and efficacy of INCB000928 in people with Fibrodysplasia ossificans progressiva (FOP) |
|   | Principal Investigator:  | Dr Patrick Yap |
|   | Sponsor:  | Syneos Health New Zealand Ltd |
|   | Clock Start Date:  | 1 February 2024 |

Dr Patrick Yap and Ms Margaret Joppa were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted the transfer of participants from the Australian sites, and clarified whether there were more new participants in the pipeline.
2. The Committee clarified that a capacity assessment would be necessary for those participants between 16 and 18 as this group should be, by default, giving consent. The researcher noted that while the study concerns a condition that does not cause mental deterioration or impairment it could still be possible if the participants have other conditions as yet undisclosed to the researchers.
3. The Committee clarified the process of assessing capacity to consent.

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 there was no allowance in the protocol for independent consent by participants 16 to 18 years of age. The Committee requested that a protocol note to file be provided to allow this for New Zealand participants.
2. The Committee requested confirmation from the sponsor as to whether there would be ongoing compassionate provision of study drug should there be therapeutic benefit during the study. Per NEAC standards para *10.15*
3. The Committee queried the ability for bank transfers for reimbursement to be done locally. Please clarify this in all relevant documentation.
4. The Committee requested that information be included in the GP letter of medications that should be avoided during participation.
5. The Committee requested clarification in the safety plan for the quality-of-life questionnaire as to how soon after the questionnaire had been filled out that the responses would be reviewed and responded to.
6. The Committee requested that the updated insurance documents be uploaded for review once received from the sponsor.
7. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
	1. Please clarify what reasoning there is to not notify participants of a privacy breach unless where it is classified as “notifiable”. This needs to be justified by a robust argument for not informing participants of any privacy breach. The Committee also notes that informing participants of a breach should be the default.
	2. Please clarify the future use of tissue in Section 8.5 in the DTMP.

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

Parent PIS/CF:

1. Please remove the repetitive information about randomisation and blinding.
2. Please simplify the assessment table to list “blood tests” rather than going into as much technical detail.
3. Please delete “also called the AIDS virus” as this is stigmatizing language.
4. Please explain what alkaline phosphatase and CRP are in the risks section.
5. Please amend “cardiac failure” to “heart failure”.
6. The risk of heterotypic ossification at stick needle sites is stated in the application form but not included in the PIS/CF. Please either include in the risks section or clarify to the Committee why it is not required.
7. Please delete the stigmatisation risk paragraph.
8. Please amend the term “Menarche” as this is not lay-friendly.
9. Please clarify that karakia will not be made available at time of tissue destruction.

Mature Participant Assent:

1. Please simplify if this is to be used. It currently is too technical and inappropriate for the comprehension of younger people (if more future enrolment occurs).
2. Please include a simpler table of assessments.
3. Please provide basic statements about the use of information and privacy per the HDEC template.
4. Please amend the term “Menarche” as it is not lay-friendly.
5. Please clarify that karakia will not be made available at time of tissue destruction.

Elligo Assent:

1. Please confirm whether 24-hour support is available to NZ participants given the travel and home health services are based in the US. Please include this in all other PISCFs.
2. Please clarify whether “anywhere travel” will book travel within NZ as stated in the PISCF.

**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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| **10**   | **Ethics ref:**   | **2024 FULL 19519** |
|   | Title:  | Safety, efficacy and pharmacokinetics of TAVO101 in adults with severe eczema |
|   | Principal Investigator:  | Dr. Penny Montgomery |
|   | Sponsor:  | Pharmaceutical Solutions Ltd |
|   | Clock Start Date:  | 1 February 2024 |

Ms Amelia Bohle, Dr Penny Montgomery, Ms Kheshmina Mhaskar and Ms Rabiya Atif 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 noted that there had been no data provided as to the incidence of eczema in Māori. This is not acceptable given there is a plethora of data on this incidence. In future it is expected that these questions be responded to adequately.
2. The Committee noted that there had been no sponsor authorisation to the submission. This is required for an application to approved.
3. The Committee requested that study-specific email addresses for participants be created for use with the application. This should be done to bring the identifiable information use in line with what is included in the DTMP. Email addresses are considered identifiable, and a work around should be provided to prevent the third part app developers from receiving that data. The Committee noted many clinical trial e-diary apps did not require personal email addresses.
4. The Committee noted that the researchers must ensure good quality ethnicity data reflective of the New Zealand population is collected at a site level, should eCRF ethnicity / race fields not be informative (C16).
5. The Committee requested the following changes to the advertising material:
	1. Please delete 'All study related tests and procedures at no cost' from the benefits section of the advertising document. This statement does not comply with HDEC Guidelines.
	2. Please delete 'Paid Clinical Trials' from the Headlines section of the advertising document. Compensation should not be emphasised, per HDEC Guidelines.
	3. D6.1 states a 3rd party recruitment service may be used to pre-screen potential participants. Please provide details of the service if it is to be used, the script or text that will be used, and the recruitment service's privacy policy.
6. The Committee requested the following changes to the Data and Tissue Management Plan

(DTMP):

* 1. Section 8.4 of the DTMP states data sent overseas will be sent to two Australian laboratories only. As the study Sponsor is based in the USA, please confirm that the information provided is correct.
	2. Section 8.5 of the DTMP has 'N/A' under Future Use of Data. Please confirm that the information provided is correct, as trial data is usually combined with other studies of the IMP, for example, to provide cumulative efficacy and safety data. Note also that Section 12.2.1 implies that future use of data is likely.
	3. As all participants are receiving study drug unblinded, please clarify why they will be unable to access on-study safety results (lab tests, ECGs etc) as stated in Section 12 of the DTMP. The site will hold identifiable data and should be able to provide results on request.
	4. Section 13 of the DTMP states tissue will continue to be analysed post study withdrawal; F8 of the application form states any collected tissue will be destroyed. Please clarify what is intended.

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

1. Please replace 'efficacy' and 'pharmacokinetics' with lay-friendly terms in the study lay title.
2. Please delete 'You may ask for it (data) to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken'; this statement is inconsistent with the application form and DTMP.
3. Please delete the optional tick boxes from the consent form; both relate to mandatory components of study participation.
4. Please remove reference to cups when referring to the measurement of blood.
5. Please ensure the listed laboratories used are consistent across DTMP and PISCF.

**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 supply a more detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*
5. 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 Ms Amy Henry and Dr Maree Kirk.

## General business

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

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| **Meeting date:** | 12 March 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 4:45pm.