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| **Committee:** | South Health and Disability Ethics Committee |
| **Meeting date:** | 11 July 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10:30am-11:00am | 2023 FULL 13574 | Biomarkers and risk of future diabetic kidney disease | Associate Professor John Baker | Dr Devonie Waaka & Mr Dominic Fitchett |
| 11:00am – 11:30am | 2023 FULL 14037 | RATIONALISE | Dr Robert Weinkove | Assc Prof Mira Harrison-Woolrych & Ms Neta Tomokino |
| 11:30am – 12:00pm | 2023 EXP 18255 | Feel Good Study - Studying the relationship between fruits, vegetables, and mental well-being in children. | Dr Nicola Gillies | Ms Amy Henry & Ms Dianne Glenn |
|  |  | **BREAK 10 MINUTES** |  |  |
| 12:10pm – 12:40pm | 2023 FULL 13944 | App-based swallowing skill rehabilitation after stroke. | PhD student Ruth FLYNN | Ascc. Prof Nicola Swain & Mr Dominic Fitchett |
| 12:40pm – 1:10pm | 2023 FULL 17890 | A clinical trial to determine if antibiotics prevent chest infections in patients with brain injuries requiring life support in the intensive care unit | Prof Paul Young | Dr Devonie Waaka & Ms Neta Tomokino |
| 1:10pm – 1:40pm | 2023 FULL 18186 | INBRX101-01-201: Phase 2 multicentre, trial to assess safety and efficacy of INBRX-101 compared to Plasma Derived therapy in adults with AATD Emphysema | Dr Michelle Baker | Ms Amy Henry & Ms Dianne Glenn |
|  |  | **BREAK 20 MINUTES** |  |  |
| 2:00pm – 2:30pm | 2023 FULL 13960 | ALLIANCE | Dr James Blake | Dr Devonie Waaka & Ms Neta Tomokino |
| 2:30pm – 3:00pm | 2023 EXP 18047 | Advancing Palliative Care among Pacific Children | Associate Professor Sunia Foliaki | Ms Amy Henry & Ms Dianne Glenn |

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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 | Apologies |

## Welcome

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

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 13 June 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 13574** |
|   | Title:  | New Techniques to Understand the Development of Diabetic Kidney Disease Amongst Māori and Pasifika. |
|   | Principal Investigator:  | Associate Professor John Baker |
|   | Sponsor:  | 2022 Fisher & Paykel Healthcare Foundation Research Fund. |
|   | Clock Start Date:  | 29 June 2023 |

Associate Professor John Baker 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 aims of the current study appear to be aligned with the original application, with the researchers making use of significant advances in technology. The Committee further noted that the current study involves genomic research, and the sending of tissue overseas. Committee asked the researchers to provide a justification for waiver of consent for re-use of the original samples. The researchers explained that all documentation relating to the original study has been lost since the original study was conducted in the 1990s, due to office changes and water damage. The samples are labelled with participant ID only, and with no signed consent forms or contact lists there is no way to re-identify the participants and seek consent.
2. The Committee asked how the Researchers plan to feed study results back to the communities they have consulted with. The Researchers explained that the plan is to report back to the communities with a hui and they will take further advice when that stage is ready and whatever is found during the study will be published.
3. The Researchers noted that this study is part of a PhD study that will also be published.

Summary of outstanding ethical issues

1. The Committee asked what the previous participants had consented to in the original participant information sheet and consent forms and asked the researchers about the parameters of future research as described in the participant information sheet/consent form (PIS/CF). The Researchers explained that as they have lost the PIS/CFs, they could not comment further on the parameters of future research consented to by the initial participants. The Committee noted that without this information it is difficult to approve the current application. The Committee suggested the researchers contact the HDEC Secretariat and request copies of the original documents, as the Researchers submitted the original project through the previous Ethics system.
2. The Committee queried how artificial intelligence would be used in the study. The researcher confirmed that this was limited to the use of machine-learning to analyse data. The Committee requested this be described clearly in the data management plan.

**Decision**

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

1. Please submit the previous PIS/CF and any other relevant documentation from the original application.
2. Please supply a more detailed data management plan to ensure the safety and integrity of participant data. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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

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| **2**   | **Ethics ref:**   | **2023 FULL 14037** |
|   | Title:  | A randomised multi-arm trial evaluating the role of antibiotic therapy or immunoglobulin to prevent infection in patients with acquired hypogammaglobulinemia secondary to haematological malignancies. |
|   | Principal Investigator:  | Dr Robert Weinkove |
|   | Sponsor:  | Monash University |
|   | Clock Start Date:  | 29 June 2023 |

Dr Robert Weinkove 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 asked about the recruitment process and if there will be separation between the research team and the clinicians. The Researcher explained that they know who all the patients are due to the regularly scheduled day units. A note is left on the patient’s file for the clinician to discuss the study with the patient and see if the patient is interested in taking part in the study. The other approach is a phone call to the patient. The Committee noted that it is important the initial approach comes from the clinician to introduce the idea of the study and then if interested it can be discussed further with a member of the research team.
2. The Committee asked about the registry referenced in the application and asked for more clarification around it. The Researcher explained the Lymphoma and Related Disease Registry has HDEC approval in New Zealand, however the researcher’s site is currently not enrolled into that registry. The Researcher confirmed that patients would have to be separately consented for participation in the registry.
3. The Committee asked about the sub-study and the plan for future research. The Researcher explained that most patients at the site are enrolled in the Lymphoma and Related Disease Registry, and these registries have provided key information that has helped the research team recognize the issues with infections. As this study is fixed-duration, the researchers are interested in what happens later. The Researchers explained that they will do this by adding data from this study to the patient’s existing registry data.
4. The Committee noted that very little information was provided about the interview sub-study in the application form, no interview schedule had been submitted, and the optional PISCF for the interviews noted in the main PISCF had not been made available for review. The Researcher asked the Committee if it would be better to leave out the mention of the interview sub-study from the PISCF, as that component of the study was not yet finalised. The Committee agreed and recommended submission of the interview sub-study as an amendment.

**Summary of outstanding ethical issues**

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

1. Please ensure the patients have an opportunity to discuss participation with a member of the research team not involved directly in their clinical care. This helps prevent patients feeling pressure to participate due to the existing doctor-patient relationship.
2. Should ethnicity fields in the eCRF not reflect the New Zealand population, please ensure relevant ethnicity data is collected at a site level. This will be required to be submitted to HDEC with the final study report.
3. Please clarify how study data will be linked to registry data when Monash University will not be provided with identifiers.
4. In section 2 of the data management plan please reference the New Zealand Coordinating Investigator (CI) rather than the international CI’s.
5. In section 12 of the data management plan, please clarify why participants will not be able to access their individual results; this should be possible given that data is de-identified, not anonymised as stated.

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

1. On page 1 please include a lay title/simplify.
2. Please review all the participant information sheets and revise for New Zealand participants, it is currently Australian-participant focused.
3. On page 3 and onwards please delete references to tablespoons of blood.
4. On page 4, please make it clear how long the study timeframe is.
5. On page 6 participants should not be required to pay for any costs associated with medication or additional travel expenses required for the study. Please ensure any such costs are reimbursed in a timely manner and amend the relevant text to reflect this.
6. On page 8 please use the HDEC reproductive risks template for this section.
7. On page 9 please amend Section 10 to make it clearer what is mandatory and what is optional research, by moving all text that applies to the optional related research under a separate subheading.
8. On page 9 please state whether the optional future research may involve genomic/genetic testing. If genomic/genetic research is a possibility, please explain in lay language what this is and the extent of the testing that may be undertaken.
9. On page 9 please state how long samples retained for optional future research may be retained.
10. On page 9 please state whether participants may withdraw consent for ongoing use of samples for future research.
11. On page 11 please provide information about who has access to identifiable versus de-identified data, and state how data is de-identified.
12. On page 11 please address the risk associated with sending data and tissue overseas.
13. On page 19 please replace” other research that is closely related to this research project” with “optional related research as described on page 9”.
14. Please reduce the size of the footer.
15. Please explain in lay language the plans for the data-linking sub-study and the linkage between this study, the sub-study, and the registries. This will help the participants understand the future use of the participant’s data. Please include the HDEC statements about data privacy and confidentiality.

**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).*

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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| **3**   | **Ethics ref:**   | **2023 EXP 18255** |
|   | Title:  | Feel Good Study - Effects of increased fruit and vegetable intake on mental well-being and cognitive function in children: A pilot/feasibility Study. |
|   | Principal Investigator:  | Dr Nicola Gillies |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 03 July 2023 |

Dr Nicola Gillies 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 the previously declined study (2023 EXP 17861), and that the Researchers appear to have addressed all issues raised by the decline letter.
2. The Committee noted that the study is investigator initiated (per section E10), not commercially sponsored, and hence should be eligible for ACC cover.

**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 stated that the Researchers will need to register the study in a WHO-approved clinical trials registry before commencement, which is a standard requirement for all Intervention studies.

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

1. Please include more information in the section headed “What will happen with our data?” regarding access to identifiable and de-identified data, etc. Please refer to the [HDEC template PIS/CF](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for additional content.
2. The Committee noted that the cultural issues are covered, but please provide interpreters for parents/caregivers who may struggle to read/understand the English participant information sheet and consent forms.

**Decision**

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

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

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| **4**   | **Ethics ref:**   | **2023 FULL 13944** |
|   | Title:  | Effectiveness of intensive, app-based swallowing skill rehabilitation vs. usual dysphagia management for post-stroke dysphagia inhospital and community settings: A Randomized Controlled Trial. |
|   | Principal Investigator:  | Miss Ruth Flynn |
|   | Sponsor:  | Swallowing Technologies Ltd. |
|   | Clock Start Date:  | 03 July 2023 |

Jia Hao Foong, Dr Maggie-Lee Huckabee, Shnece Duncan, Madeline Mills, and Ruth Flynn 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 asked if the study is commercially sponsored. The Researchers explained that they are doing the research under a university scholarship and that is how the research is being funded. Swallowing Technologies will provide the device and software for use in the study but have had no input into study design and will have no access to data until it is peer reviewed and published. The Committee agreed that this study is not commercially sponsored, and participants should be eligible to apply to ACC for compensation in event of study-related injury.
2. The Committee asked about the treatment sessions and if any of them will require clinic visits more than standard of care. The Researchers explained that there will be no reimbursement for transport, as all treatment visits above standard of care will involve the researchers going to the participant’s home or will be conducted remotely via telehealth.

**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 intervention group have up to 10 hours additional swallowing practice when compared to the control group. The Researchers explained that they did speak about having a placebo treatment for the control group but there is no skill-based training equivalent. The Researchers want to see if usual management with skill training firstly improves functional swallowing outcomes, with the next step being understanding how skill training works and would not feel comfortable restricting usual management from either group. The Committee noted this conversation is something to talk about between the researchers and the supervisors, however noted that using an app-based mindfulness condition or similar could account for the same amount of time spent in a skill-based learning situation and make the results more valid. The Researchers explained that they will have a discussion as a team about the placebo condition. The Committee explained adding in a placebo would not change the documentation that much as the study and the collection of data is still the same, and it should mainly change the protocol.
2. The Committee asked the researchers to clarify how the study could be described as double-blind when the two study arms are clearly described in the participant information sheet/consent form (PIS/CF). The protocol statement that participants will not be able to overtly determine which study arm they have been assigned to if the meaning of the randomisation code is not explained is incorrect, as it will be very clear once treatment commences which arm, they have been assigned to. Please amend the protocol to reflect that the study will be single blind or explain in the response to Provisional Approval how the double-blind will be maintained.
3. The Committee asked about the questionnaires, and the processes in place when a participant’s responses indicate significant distress. The Researchers explained that it is out of scope of their practice, but they have plans in place to contact the medical team if this occurs. The Committee requested the plans be formalised in the study protocol or associated documents.
4. The Committee asked what data Swallowing Technologies LTD will have access to. The Researchers explained the company will have information on the treatment sessions, success rates, and number of trials prescribed in each session. This information will be uploaded to the cloud, but all data will be de-identified. The researchers further explained that the company has no intention to do anything with the data however they own the cloud where the data will be stored. The researchers confirmed that video recordings will not be uploaded to the cloud. The Committee requested that access to identifiable data by Swallowing Therapies Ltd personnel be specifically addressed in the Data Management Plan (DMP).
5. The Committee requested that the researcher ensure the trial is registered with a WHO-approved Clinical Trial Registry before commencement.
6. Please upload the researcher safety plan for home visits.
7. The Committee requested the following additional changes to the protocol:
	1. The Committee requested the protocol be amended to describe clearly how data will be handled for participants who have been withdrawn from the study due to a further medical event, as they noted that the current approach may result in participants experiencing significant study-related adverse events being excluded from data analysis.
	2. Please insert version and page numbers.
	3. Please amend to address reasons for early study termination, for example safety concerns, failure to recruit, or futility.
8. The Committee requested the following additional changes are made to the DMP:
	1. Please amend section 7.3 as it refers to section 7.2.1, which does not exist.
	2. Please amend section 8 as it refers to sections 7.4 and 7.5, which do not exist.
	3. Please amend sections 7.1 and 8.1 to address audio recordings of interviews.
	4. Please amend section 7.3 1 of the data management plan, as no study data will be collected anonymously.

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

1. On page 1 please use 'invited' rather than 'selected' to participate.
2. Please check for typographical errors, including in subheadings (aphasia PIS/CF).
3. On page 3 please amend the statement “You have internet access at study location”, which does not make sense, as presumably the researchers mean the participant’s home or care facility.
4. On page 8 and 9 the section headed “What will happen to my information?” needs to be expanded, please refer to [the HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for additional content.
5. On page 9 please include more detail as to what will happen to the original audio recordings of interviews following transcription and if these are to be kept.
6. Please delete yes/no tick boxes unless truly optional (i.e., consenting to anonymised data being used in future studies which is optional).
7. On page 9, please explain in further detail what data Swallowing Technologies will have access to, whether this is identifiable, and whether it will include video, transcripts, etc.
8. On page 10 please review and amend the compensation statement.
9. On page 20 please make it clear that seeing a copy of the results is optional, as opposed to the other tick boxes.
10. Please include more information for participants on how data will be handled for participants who are withdrawn from the study due to being “deemed no longer to meet the inclusion and exclusion criteria due to additional medical event”.
11. Please amend wording around “Treatment Groups”, as the term is used as a title to describe both study arms and the active treatment group. Please use different terminology to clarify exactly which group is being described, for example, the intervention group.

**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 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).*
3. Please update the data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
4. 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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Associate Professor Nicola Swain.

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| **5**   | **Ethics ref:**   | **2023 FULL 17890** |
|   | Title:  | Prophylaxis Against Early Ventilator Associated Lower Respiratory Tract Infection |
|   | Principal Investigator:  | Dr Paul Young |
|   | Sponsor:  | Australian Medical Research Future Fund and bythe Medical Research Institute of New Zealand |
|   | Clock Start Date:  | 03 July 2023 |

Dr Paul Young 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 study would enrol unconscious adults under Right 7(4) of the Code of Health and Disability Services Consumer’s Rights, and that the Researchers had justified the request for waiver of consent well. The Committee further noted that the researchers had sound processes in place for enrolment, re-consenting of participants where capacity to consent was regained, and the ongoing use of data under different consent scenarios.
2. The Committee asked what phase this study is in. The Researcher explained this study is the first stage of a study that the researchers want to evolve into a phase 3 trial.

**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 reasons for study termination are not set out in the protocol or application. It would be expected that these reasons would usually include unacceptable risk to participants (safety issues) or study futility. Please explain and include the conditions under which site participation and/or the entire study may be concluded prematurely and amend the protocol accordingly.
2. The Committee requested amendment of section 3.10 of the protocol appendix; it is inconsistent with the protocol Scenarios Table, PISCF and application form (G6), which state that participants can withdraw consent for the use of their previously collected data should they wish.
3. The Committee noted that this study will need to be registered by a WHO approved clinical trial registry before commencement.

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

1. On page 1 please add a lay title for the Relative/Whanau/Friend (RWF) information sheet.
2. Please replace ‘you’ with ‘your relative/whānau/friend’ where this has been missed, i.e. page 5 of the RWF information sheet.
3. On page 5 please rephrase paragraphs under ‘Rights to Withdraw Information’, as the RWF is not providing their consent so cannot withdraw their consent.
4. On page 1 of the main participant information sheet and consent form please add a lay title.
5. Please clarify whether participants can find out at the end of the study whether they were randomised to antibiotics or placebo.
6. Please ensure the information directed at the family member makes it clear that the participant may have already been enrolled into the study prior to the whānau being approached.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*
* please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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| **6**   | **Ethics ref:**   | **2023 FULL 18186** |
|   | Title:  | A Phase 2, Double-Blind, Randomized, Active-Control, Parallel Group Study to Assess the Pharmacokinetics, Pharmacodynamics,Immunogenicity, and Safety of INBRX-101 Compared to Plasma Derived Alpha1-Proteinase Inhibitor (A1PI) Augmentation Therapy in Adults with Alpha-1 Antitrypsin Deficiency (AATD) Emphysema |
|   | Principal Investigator:  | Dr. Michelle Baker |
|   | Sponsor:  | Inhibrx, Inc. |
|   | Clock Start Date:  | 03 July 2023 |

Dr Andrew Veale, Melissa Gane, Erin Babcock, Stephanie Pollard, and Fay Sommerville 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 asked about the compound the study is examining. The Researcher explained that they have done studies with this compound in the past, which was a safety study, it’s a synthetic product which allowed three weekly infusions rather than one, further explaining this study compound seems both better and comes with a more convenient dosing frequency for the patients.
2. The Committee asked for clarification of the washout period, which is 5 weeks, and how this would be monitored. The Researcher explained that the washout period statement is largely related to people overseas, as they do not have funded treatment for this compound in New Zealand because it is too expensive, any mention of washout periods is largely directed at North America and Europe sites.
3. The Committee asked about the CI’s experience and clinical expertise in the disorder under study as the provided CV indicated no specialist training or experience in respiratory medicine. The Researcher explained that Dr Veale, a sub-investigator, will be providing the bulk of the clinical expertise and will be undertaking the bronchoscopy, and that he would provide clinical oversight of participants.

**Summary of outstanding ethical issues**

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

1. The Committee asked whether the bronchoscopy and PK sub-studies were mandatory or optional for participants. The Researcher explained that no New Zealand sites were participating in the PK sub study, but at least the lead site would be involved in the bronchoscopy sub study. The researcher also confirmed, that at sites involved in the bronchoscopy sub study, participation will be mandatory. The Committee requested that the bronchoscopy information be included in the main participant information sheet/consent form (PIS/CF) as it was a mandatory component of study participation. The information could be deleted when the PIS/CF is localised, for sites not taking part in the sub study. The Committee further requested that, as no New Zealand sites are undertaking the PK sub study, all information related to it is removed from the main PIS/CF.
2. The Committee asked about the paragraph in the data and tissue management plan (DTMP) regarding future unspecified research. Section 8.5 of the DTMP states no future unspecified tissue research is planned but then states that “tissue will be used by the Sponsor for future …. medical or scientific purposes which are not related to the study questions”. The Researcher explained that there are no plans for future unspecified research and the text was included in error. Please remove the incorrect statements from the DTMP.
3. The Committee noted that the submission must be authorised by the commercial sponsor. Please ensure the correct button is selected ('Yes, my study requires authorisation from the sponsor now') and obtain authorisation prior to submitting the response to provisional approval.
4. The Committee asked what the reimbursement rate was for participants per visit, as the PIS/CF has been left blank in this respect. The researcher stated the amount was being finalised with the Sponsor. Please provide the reimbursement amount for the lead site. Any subsequent differences in rate for other sites should be submitted to HDEC for approval. Please note that the per-visit rate should be consistent across New Zealand sites unless a satisfactory rationale is provided for different rates of reimbursement.
5. On page 3 of the data management plan please remove the note to researchers.
6. Please ensure that all New Zealand sites collect ethnicity data relevant to the New Zealand population, if necessary, in addition to that specified in the protocol or eCRF.

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

1. Please further simplify the short title (remove Phase 2 multicentre and replace efficacy with effectiveness).
2. Please remove the black box warning on page 1, it is required only for first-in-human trials.
3. Please include the statement "If you need an interpreter, please tell us” at the beginning of the participant information sheet also.
4. On page 6 please state what HbA1c measures in lay language.
5. Please delete all references to teaspoons/tablespoons of blood, millilitres will suffice.
6. Please advise participants that a karakia will not be available at the time of tissue destruction.
7. Please correct the typographical error regarding notification of the study doctor on page 11.
8. Please amend the reimbursement section to reflect the New Zealand public health system.
9. On page 16 please tidy up formatting in the compensation section.
10. On page 17 please clarify why 'contractors and consultants working for Inhibrx, Inc. and for health authorities and other representatives of Inhibrx, Inc.' other than monitors or auditors should require access to participants' identifiable information.
11. On page 18 please delete the statement 'Your personal data will be shared with Inhibrx, Inc. if you agree to take part in the study', as the statement in isolation is too broad.
12. Please review and delete repetitive statements regarding access to personal information.
13. Please include the amount of reimbursable travel cost expenses.
14. Please include all information relevant to the bronchoscopy sub study. When the bronchoscopy information is added to the main PIS/CF, please tidy up the formatting (i.e., different fonts are used throughout the sub study PIS/CF).
15. Please delete references to the intensive PK sub study.
16. In the consent form please add an optional consent clause for participants wishing to receive a lay summary of study findings.
17. Please simplify the table of assessments.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please update the data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Amy Henry and Ms Dianne Glenn.

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| **7**   | **Ethics ref:**   | **2023 FULL 13960** |
|   | Title:  | ALLIANCE: Safety and Effectiveness of Balloon-Expandable Bioprosthetic SAPIEN X4 Transcatheter Heart Valve. |
|   | Principal Investigator:  | James Blake |
|   | Sponsor:  | Edwards Lifesciences LLC |
|   | Clock Start Date:  | 03 July 2023 |

James Blake 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 asked about the device and how closely it is related to previous versions of the device. The Researcher explained that the study device should be a slight improvement over the device that is used now, and that over 200 cases have been done in Christchurch with the current approved device. The researcher further explained that the main changes are the device sizing and a change to the valves to make the valves last longer.
2. The Committee asked if any participants have been enrolled into the study overseas. The Researcher explained that the study has not started the recruitment process yet.
3. The Committee asked if the new device has any clinical experience yet. The Researcher explained that no clinical experience has occurred yet, but a significant amount of bench testing has been undertaken. The Committee asked for clarification of whether this study was therefore the first in human use of the study device. The Researcher confirmed that, however noted that the device is very similar to previous iterations and that 95% of the device is the same.
4. The Committee asked about the recruitment process. The Researcher explained that they have 15 cardiologists who will all recruit patients, and that the study co-ordinators will introduce the study to the participant.

**Summary of outstanding ethical issues**

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

1. Please note for section C10 of the application, when identifying main cultural issues for Māori and Pasifika, there may be similar reservations around blood transfusions, cultural issues may not necessarily just be financial for Pasifika, please consider other impacts if participants from these ethnic groups are referred.
2. Please note that the response to B1 is incorrect; this is a therapeutic trial.
3. Please ensure ethnicity data relevant to the New Zealand population is collected at New Zealand sites. This may need to be collected in addition to eCRF-mandated fields.
4. The application form states no tissue will be collected other standard of care safety samples analysed locally. The data management plan (DMP) references valves 'with surrounding tissue' being sent to an overseas laboratory. The researcher confirmed that the DMP was correct, but he did not think any surrounding tissue would be analysed.

The Committee stated that, if any human tissue is to be sent overseas, this should be more fully addressed in the participant information sheet and consent form.

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

1. On page 3, please state approximately how many New Zealand participants will be enrolled.
2. Please explain how the investigational device differs from previous versions on the market and make it clear that this is the first time the study device has been used in humans. A sentence regarding local experience with previous versions of the device would also be useful.
3. On page 5, please further clarify what roll-in subjects are. Please also ensure the term ‘participants’ is used rather than ‘subjects’ throughout the PIS/CF.
4. On page 8 please advise participants that a karakia will not be available at the time of tissue destruction.
5. On page 11 please use the [HDEC reproductive risks template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
6. Please use millilitres rather than tablespoon for blood volume measurements.
7. Please insert an appropriate subheading regarding the sending of explanted valves and surrounding tissue overseas; this is currently included under Māori sovereignty, which is inappropriate. The discussion should sit under 'what will happen to my samples' and should include a clear description of where the valve and tissue will be sent, whether the participant's tissue will be analysed (and the purpose of the analysis), and how long the tissue will be retained. A cultural tissue statement should also be included.
8. Please insert an optional yes/no tick box next to the consent clause regarding being informed of study results.

**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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| **8**   | **Ethics ref:**   | **2023 EXP 18047** |
|   | Title:  | Advancing Palliative Care among Pacific Children. |
|   | Principal Investigator:  | Dr Sunia Foliak |
|   | Sponsor:  | Massey University |
|   | Clock Start Date:  | 03 July 2023 |

Dr Sunia Foliak 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 application was a re-submission of a previously declined application and commended the Researcher on the thorough response to all issues raised in the previous decline.
2. The Committee asked about the peer review process and whether a rebuttal had been made to issues raised in the Health Research Council’s review. The Researcher confirmed that this was done.
3. The Committee asked about the reasoning of the participants needing to consent to auditors and regulatory bodies reviewing the participant medical records. The Researcher explained that this was included in case the research team need to verify participants who have been discharged from Starship, and to ensure only eligible participants are being recruited for the study.

**Summary of outstanding ethical issues**

1. The Committee asked for clarification about how survey data will be collected, as the Data Management Plan (DMP) states 'Online survey stored as PDF files will be deidentified after transcribing', while the cover letter and participant information sheet/consent form (PIS/CF) states surveys are collected anonymously. The Researcher explained that the survey will be anonymous and will be completed online. Please amend the incorrect statement in the DMP and ensure information regarding the method of survey administration is provided in the protocol or DMP.
2. The Committee asked for clarification about what questionnaires were being referred to in Section 7.1 and onward, as no written questionnaires are being completed other than the anonymous online survey, and the participant subgroups referenced in Section 7.1 are not completing the survey. The Researcher confirmed that the DMP should have referred to interviews rather than questionnaires. Please amend this in the DMP.

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

1. In all PIS/CFs, please address the risk of distress for young people, parents/caregivers or clinicians discussing issues related to palliative care. Please also consider this for the key informant participant information sheet. The Committee suggests connecting parents to grief counselling if/when appropriate.
2. In all PIS/CFs, please add the statement ‘There will be an interpreter available on request’ to the top of page 1.
3. In all PIS/CFs, please state whether a support person can attend the interview with the participant.
4. In the young person and parent/caregiver PIS/CFs, please include the risk of confidentiality breach.
5. In the young person and parent/caregiver PIS/CFs, please give a brief outline of what will be asked / discussed in the interview.
6. In the young person and parent/caregiver PIS/CFs, please state how long data will be retained.
7. In the parent/caregiver PIS/CF the two eligibility bullet points appear very similar – please delete one if both are not required.
8. Please note that data cannot usually be withdrawn from focus groups as one participant's comments may alter the context of other contributions. In the PIS/CFs that include focus groups, please state that focus group data cannot be withdrawn, although the participant is free to stop taking part in the group at any time.

**Decision**

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

* 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:** | 08 August 2023 |
| **Zoom details:** | To be determined |

 The following members tendered apologies for this meeting.

* Ms Dianne Glenn
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 3:00pm.