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| **Committee:** | South Health and Disability Ethics Committee |
| **Meeting date:** | 09 May 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 10:30am-11:00am | 2023 FULL 13901 | Investigating chemoprevention for breast cancer | Dr George Wiggins | Mr Dominic Fitchett & A/Professor Mira Harrison-Woolrych |
| 11:00am-11:30am | 2023 FULL 13996 | Validation of Age and Stages: Aotearoa adaptation | Dr Alison Leversha | Ms Catherine Garvey & Ms Amy Henry |
| 11:30am-12:00pm | 2023 FULL 13945 | Effect of smartphone screen surround colour on childhood myopia progression | Dr John Phillips | Mr Jonathan Darby & A/Prof Nicola Swain |
| 12:00pm-12:30pm | 2023 FULL 13454 | Māori communication support for mate wareware (dementia) | Miss Megan Eustace | Ms Dianne Glenn & Ms Amy Henry |
| 12.30pm-1.00pm | 2023 FULL 13824 | Home Blood Pressure Monitor for Optimising Cardiac Medications Study | Dr Tze Vun Liew | Mr Dominic Fitchett & Dr Devonie Waaka |
|  |  | **BREAK 30 MINUTES** |  |  |
| 1:30pm-2:00pm | 2023 EXP 15582 | Intergenerational conflict in Chinese mental health service users | Dr Richard Yu | Ms Catherine Garvey & A/Prof Mira Harrison-Woolrych |
| 2:00pm-2:30pm | 2023 FULL 13521 | A study of PTC518 in patients with Huntington's Disease (PIVOT HD) | Prof Tim Anderson | Mr Jonathan Darby & Dr Devonie Waaka |
| 2:30pm-3:00pm | 2023 FULL 16764 | A soft pressure-sensitive skin to measure lymphoedema treatment efficiency. | Dr Anna Rolleston | Ms Dianne Glenn & A/Prof Nicola Swain |
| 3:00pm-3:30pm | 2023 EXP 17847 | Testing a Wellbeing App on New Zealand High School Students | Dr Hiran Thabrew | Mr Dominic Fitchett & Ms Amy Henry |
| 3:30pm-4:00pm | 2023 FULL 15347 | A clinical trial to see how well different doses of astegolimab plus standard treatment work compared with a placebo plus standard treatment to reduce certain symptoms of chronic obstructive pulmonary | Mr Andrew Edwards | Ms Catherine Garvey & Dr Devonie Waaka |

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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 | 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 |
| Ms Catherine Garvey | Lay (the Law) | 19/03/2019 | 19/03/2022 | Present |

## Welcome

The Chair opened the meeting at 10:00am and welcomed Committee members, noting that apologies had been received from Ms Neta Tomokino and Associate Professor Nicola Swain.  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Catherine Garvey confirmed their eligibility and were co-opted by the Chair as a member 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 14 March 2023 were confirmed. The Committee noted that the meeting of 11 April 2023 did not go ahead, so no minutes for that meeting needed to be confirmed.

## New applications

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| **1** | **Ethics ref:** | **2023 FULL 13901** |
|  | Title: | Novel approaches for the chemoprevention of high-risk breast cancer |
|  | Principal Investigator: | Dr George Wiggins |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 April 2023 |

Dr George Wiggins was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the testing of study treatments would be in donated tissue formed into organoid models.
2. The Committee asked if the researchers are testing for more genes not being identified as being associated with breast cancer. The Researcher explained that some participants will have genetic modifiers of risks that have been identified through previous genetic studies. The researcher further explained that every participant that agrees to be in this study and has the blood test taken will have genetic testing performed.
3. The Committee asked about how the researcher plans to feedback to the participants. The Researcher explained that incidental findings and high-risk genes will be reported back to the governance board of the cancer society tissue bank. On the small chance the researchers pick up a mutation from a participant who is unaware, there are systems in place to inform the participant and arrange further follow-up as indicated.
4. The Committee asked if all participants are from the local area of the Researchers. The Researcher explained that all participants will be coming through Christchurch hospitals.
5. The Committee asked what the role of the governance board of the Cancer Society Tissue Bank is in this study. The Researcher explained that the board assess the results that come back and then determines who is best to follow up with those participants that may experience abnormal study results. The Researchers confirmed the board does organize follow up alongside the researchers.
6. The Committee asked about other genetic testing and if those results would be fed back to participants. The Researcher explained that the results will not be clinically relevant as they are still experimental and would make no difference to clinical care, so participants would not be informed of results.
7. The Committee asked about the scientific peer-review and if the Researchers have considered the points raised in the peer-review. The Researchers confirmed they have considered the points raised and will be implementing them into the study documentation.

Summary of outstanding ethical issues

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

1. The Committee requested the following changes to the Protocol:
   1. Please provide a more detailed written plan to explain the return of results for genetic testing and explain what is meant by return of results 'at the discretion of' the clinicians. This should include a distinction between clinically significant and exploratory genetic findings.
   2. Please elaborate on the formation of the organoid and the use of all tissue that is collected.
2. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
   1. Please update table of contents to reflect the removal of section 3.
   2. Please note and amend documentation to reflect that health data that relates to an identifiable individual is required to be held for a minimum of ten years after the end of the study.
   3. Please remove non-study-specific information such as that concerning notifiable diseases.
   4. Please amend that tissue may be sent overseas.
   5. Please include that the University of Otago is the local sponsor of the study.

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

1. Please proofread for typos.
2. On page 1, please remove template instructions.
3. For the introduction of the study, please change the first sentence to make it clear to participants what the study is doing.
4. Please include more detail about what tissue samples are being sent overseas in lay language.
5. On page 3, please provide more lay-friendly information on organoids. For example, do they look like a small clump of tissue or a recognisable organ, what size are they once developed, do the researchers manipulate the participant's genes to grow the organoid or to run tests, etc. A diagram may be useful here.
6. Please clarify that the named drug being tested on the organoids is approved for use, and that in the current study it will not be administered to participants.
7. Please include information explaining that this study will not be manipulating the participant’s genes during development or testing of the organoid.
8. Please amend the genetic testing section, by splitting the planned genetic testing into two sections and providing more details and explanations to participants. This should include the following:
   1. that the participant will be contacted after the blood tests if they are identified as high risk due to mutation of genes BRCA1 and/or 2 and appropriate follow-up will be arranged.
   2. that the second part of the genetic testing is early lab-based model work and as results will not affect participants clinically, participants will not be informed of results.
9. Please remove “and should you consent to this” from the sentence “if a clinically significant mutation is identified and should you consent to this”, as the participant will be followed up and it will not be an optional choice.
10. Please state where blood will be analysed, including overseas if this is a possibility.
11. On page 4, please correct 'risk-alternating therapies'.
12. On page 5, please include Māori cultural support contact details.
13. On page 5, please include whether an interpreter will be available, if needed.
14. On page 5, karakia misspelled, please correct.
15. On page 6, please remove the text “about my participation in the study and” from following paragraph in the consent form (as you are not informing the participants’ health care provider of their participation in the study): "I consent to my current provider being informed about my participation in the study and of any significant abnormal results obtained during the study."
16. Please include a more specific consent clause in the PISCF regarding return of clinically significant abnormal results.

**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 and tissue 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, 14.16&14.17).*
5. Please provide more detail in study documentation to ensure participant safety if there are potential concerns with their well-being raised as part of this study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4-8.6, 8.9)*

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 Mira Harrison-Woolrych

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| **2** | **Ethics ref:** | **2023 FULL 13996** |
|  | Title: | Validation of Age and Stages ASQ:Ao: Aotearoa cultural and linguistic adaptation |
|  | Principal Investigator: | Dr Alison Leversha |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 April 2023 |

Dr Alison Leversha 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 if all children would come in and do the assessment. The Researcher explained that all children will be doing the assessments because the researchers need gold standard development and language assessments to be able to validate the assessment.
2. The Committee asked about the professionals and the roles they will be playing in this study. The Researcher explained that there will be different groups of professionals, with key people doing most of the assessments in the clinic, and some well-child professionals and early childhood teachers doing a few assessments only. The Researcher explained that they will travel to other services such as Plunket to carry out these assessments if needed.
3. The Committee asked if the Researchers are accessing any information without consent, as a waiver of consent was requested. The Researcher explained they have no plans to do so and understands they do not need the waiver.
4. The Committee clarified the plans for recruitment of professionals. The Researcher explained that it is mostly through existing relationships and the researchers will be training the professionals on how to conduct the assessment thoroughly and effectively.
5. The Committee asked for clarification on how participants without internet access will complete the assessment and if they will be provided with a paper form. The Researcher explained that they will be moved straight to the clinic visit with an assessment done there.
6. The Committee asked about de-identifiable data and storage of information. The Researcher explained that storage will be de-identified under Redcap but will be able to be linked back if 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 queried whether health care provider notification of clinically significant findings is optional; submitted documentation regarding this is inconsistent.
2. The Committee noted that all advertisements need to be provided for review prior to use. Please provide this prior to commencement.
3. The Committee asked if any home visits will occur. The Researcher explained that at this stage home visits could happen, and have happened in previous iterations due to families without transport etc. The Committee requested a safety plan for researchers should home visits occur.
4. The Committee requested the following changes to the Data Management Plan (DMP):
   1. The data management plan states data will not be de-identified. Please amend to reflect that data will be de-identified, as clarified by the Researcher.
   2. Given that voice is a biometric identifier, please specifically address how the data from audio recordings will be managed.
   3. Please provide more detail about the networks being used and what is meant by using Well Child Tamariki Ora “databases.”

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

Main PIS/CF:

1. Please provide parent and caregiver participant information sheets in a hard copy on request.
2. Please include that the research team will travel to different locations if needed such as Plunket etc.
3. Please include that if risks and/or health issues are detected in a child, the appropriate people are informed to ensure follow-up and care supplied if required. Furthermore, please remove the sentence “with their consent”.
4. Please include the ability of participants to request withdrawal of data from the study data sheet before analysis is conducted if they wish to do so.
5. Please include and acknowledge that there are resource delays and significant wait times may occur for participants who have been identified as requiring further follow-up.
6. Please include that once the audio recordings are transcribed, they will be deleted by the researchers.

Parent PIS/CF:

1. Several components of the study, including health provider notification, entry into the clinical record, 12-month follow-up etc appear to be optional due to the language used in the PIS (the addition of 'with your consent' for these specific components suggests they are optional extras). Please delete ‘with your consent’ from these statements as all components are mandatory.
2. Please state approximately how long the interview component will take.
3. Please address ability to request withdrawal of collected data from the study database and amend as applicable.

Professionals PIS/CF:

1. Please state approximately how long the interview component will take.
2. Please state whether the interview will be audiotaped.
3. Please provide full information regarding management of data.
4. Please address ability to request withdrawal of collected data from the study database.

**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 provide a researcher safety plan addressing the concerns raised by the Committee (National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).
5. Please update the data management plan to ensure the safety and integrity of participant data *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15, 14.16&14.17).*

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

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| **3** | **Ethics ref:** | **2023 FULL 13945** |
|  | Title: | Effect of smartphone screen surround colour on childhood myopia progression |
|  | Principal Investigator: | Dr John Phillips |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 27 April 2023 |

Dr John Phillips 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 informed consent and if some participants could provide their own informed, independent consent. The Researcher explained that the participants are young children and could be coerced by the idea of having their own smartphone. The Researcher also explained they believe the parents must be involved for monitoring purposes due to the large range of online issues the young children may face when given the smartphone.
2. The Researchers asked about the process if there is a conflict between the parent and child in relation to the individual informed consent. The Committee explained that if there is a significant conflict and it cannot be resolved, the researchers have discretion on who to enrol and can decide to not enrol a child if it looks like the social fallout and the conflict it will cause will be contrary to the child’s best interest.
3. The Committee asked why the Researchers are conducting this study in the age group and why not conduct the study in an older age group. The Researcher explained that the study is about myopia and that children’s regression of myopia is rapid in the early stages around the ages 8 – 10 years old and have good scientific reasoning to conduct the study.
4. The Committee asked what will happen if a participant loses or breaks a study phone. The Researcher explained that another will be purchased and provided to the participant.
5. The Committee asked if participants could use their own phone during the study. The Researcher explained that the app they are using requires a specific version of Android and has been made specially for this study, the participants will have to use the study phone for the duration of the study and will be advised not to use their own one if they have one, participants can still use the normal applications such as snapchat, etc.
6. The Committee asked about how withdrawals due to rapidly progressive myopia will be handled in the data analysis. The Researcher explained that they do not expect to have children withdrawing from the study due to rapidly progressive myopia, however, they would include their data in the study analysis and encourage ongoing follow-up in the study.
7. The Committee asked how much of an idea the research team will have at the end of phase 1 about which light has greater effects on myopia progression. The Researcher explained that after 1 year there will not be a clear indication of which light is better.

**Summary of outstanding ethical issues**

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

1. The Committee requested that the researchers note the risk inherent in the handing of a phone to a young child in the process of assessing them for the purpose of consent. The Committee deemed it reasonable for dual consent to be obtained on the proviso that the individual being asked is competent.
2. In the application, the answer to D8 is incorrect, as it is not anticipated that all participants will give informed consent. The Committee noted that this cannot be corrected at this point, but this should be made clear in the researcher’s response.
3. Detail as to how withdrawals due to rapidly progressive myopia will be handled in data analysis (as per point 6 above) should be included in the protocol.
4. The Committee queried whether participants in a comparative study of this nature should be able to withdraw data on request; this may impact scientific validity and needs to be accounted for in the protocol and data management plan.
5. Formal consultation outside of the research group is required for the current study. The Committee requested that this be undertaken prior to commencement.
6. Per NEAC Standard 9.20, all researchers conducting health research in New Zealand must collect good/quality ethnicity data. Please amend study documentation to ensure ethnicity data is collected according to Stats NZ ethnicity groupings.
7. The Committee requested that the web page be provided to HDEC for review once it has been developed.
8. The Committee requested that all advertising be consistent and that the Facebook advertising be amended to match the other submitted advertisements.
9. The Committee requested the following changes to the Data Management Plan (DMP):
   1. Please correct the time frame for holding data from 10 years to 10 years after the youngest participant turns 16.
   2. Please update the contents page to be accurate.

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

Main PIS/CF:

1. Please clarify the process should a participant's phone be lost or damaged, and that participants can contact the research team for provision of a new phone if needed.
2. Please include that numbers dialled using the study phones will not be recorded or kept.
3. Please clarify what happens to the device at the end of the study.
4. Please outline that dual-phone usage is not planned and the participants must use only the study phone that is given to them.
5. Please clarify the role of the app creator (the Spanish company) and outline any data collected by that company, confirming absence of commercial interest for participants/researcher.
6. Please soften the wording about treatment benefit, as participants may experience no change at all.
7. Please review for use of technical and medical terms ('systemic abnormalities', 'ocular', 'adverse events', 'repository' etc) and replace with lay language.
8. On pages 1 and 7 please delete repeated information regarding withdrawal of data.
9. On pages 3 and 8 please describe information collected by the app once only.
10. On page 4 please note that participants should be reimbursed for travel costs, etc.
11. In the consent form please delete optional tick boxes for mandatory consent clauses.
12. The assent form provides no information for the child participant. Please provide an age-appropriate version of the participant information sheet.
13. For participant data withdrawal please include that already collected data will be kept and analysed.

Parent PIS/CF:

1. Please include that dialled numbers on the phones will not be collected.
2. Please address the parent/caregiver participant information sheet to the parent/caregiver.

**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 to ensure the safety and integrity of participant data *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15, 14.16&14.17).*
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 Mr Dominic Fitchett and Mr Jonathan Darby.

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| **4** | **Ethics ref:** | **2023 FULL 13454** |
|  | Title: | Māori approaches to communication support: Living well with mate wareware (dementia) |
|  | Principal Investigator: | Miss Megan Eustace |
|  | Sponsor: | University of Canterbury |
|  | Clock Start Date: | 27 April 2023 |

Megan Eustace 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 consent process and what the Researchers plans are for getting consent. The Researcher explained that the process will have the researcher assess potential participants following a protocol which includes several questions assessing the level of the participant’s dementia and whether the participant could understand what the study includes.
2. The Committee asked about the possibility of stigmatism during the study. The Researcher explained that they will be gathering ethnicity data and reporting on the experience of Māori and aim to report those findings in a way that is supportive of Māori & have undergone Māori consultation.
3. The Committee asked about the audio/visual recordings and how they will be used for educational purposes. The Researcher explained that the idea is the recordings could be used for lecturing purposes or workshops, to share the results to the communities and groups that are involved. The Researcher confirmed that the participants will be able to review their recordings and videos before results are shared and are allowed to delete them or request changes to the recordings as they see fit.
4. The Committee asked about the security of drop-box for storage of study data. The Researcher explained that it is normal practice, is managed by the University of Canterbury and has several layers of security.
5. The Committee asked about the recruitment process and the possibility of coercion of potential participants. The Researcher explained that the plan is for the neurologist to identify potential participants, who would be referred to the research team. The neurologist will not be involved in interviews or focus groups. The Research team is aiming to have full transparency, letting the participants know what the neurologist’s and other research team members’ roles are in the study.
6. The Committee asked about the statement that demographic data could be identifiable and asked why it cannot be adequately de-identified. The Researcher explained some of that data could be indirectly identifiable if it was stored together as the population group is small. The Committee agreed this is acceptable but requested that data be sufficiently aggregated to mitigate the risk of identification in any presentations or publications.
7. The Committee asked if there will be a Māori translator available for participants during the consenting and assessments. The Researcher explained that the person conducting the consenting and assessments has intermediate Māori language skills.
8. The Researcher assumed that most people that partake in this study will also speak English, though the plan is to use Te Reo Māori where possible.
9. The Committee asked about participant privacy and the locations available for the assessments to take place such as cafes, explaining that cafes are not private especially in smaller cities/towns. The Committee also noted that some people with dementia find it hard to focus in areas such as cafes due to noise and people around them. The Researcher explained that the intent was to give participants as much choice as possible but agreed that public places are not suitable for participants and that interviews will be restricted to places where the participants feel safe and can focus.
10. The Committee asked if the Whānau units in the protocol will participate in both the interview and the focus groups, or if different units would be used for each. The Researcher explained that they will use the same whānau units for both.
11. The Committee asked if the participant information sheets could be translated into Māori for those participants that prefer that. The Researcher explained that the participant will most likely speak English, and at the current stage the research team does not have anybody in the research team who can translate a full participant information sheet.

**Summary of outstanding ethical issues**

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

1. The Committee requested that the payments and travel costs to each individual/group be consistent. There is inconsistency between B21.1 and D22.1.
2. The Committee requested that where possible, friends/whānau are allowed to assist the participants with consenting.
3. The Committee requested that the advertising material make it clear that the advertisement is for participation in research.
4. The Committee requested provision of the outline of the semi-structured whānau unit interviews.
5. The Committee requested that the researchers provide a formal researcher safety plan for home visits.
6. Locality authorisation should be provided from the facility at or from which the procedures outlined in the protocol of the study are to be conducted. Please ensure locality authorisation is obtained prior to commencing the study.

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

1. Please provide more details about the intended process to disseminate study results; if hui is planned, please ensure participants are informed of this in the PISCF and provided with the opportunity to attend.
2. Please include that participant can participate in the interviews and not participate in the focus groups, however not the other way around.
3. On page 4 it states that only the research team will have access to the audio-visual recordings, this contrasts with other statements. Please amend where applicable.
4. On page 5, the paragraphs about the right to withdraw information and under ‘what happens if I change my mind’ are contradictory. Please amend for consistency.
5. Please describe clearly what is meant by 'communication supports' and provide examples.
6. Please note that once ‘mate wareware’ has been translated initially, use either the Māori or English term consistently (not both).
7. If there is an applicable Māori term to describe the ‘communication supports’ referenced in the study, please consider using this in the document.
8. Please state if paramanawa will be provided at the focus groups.
9. The sharing of photos and audio-visual recordings is introduced in the consent form only. Please ensure this is discussed in the body of the PIS. Information should be provided regarding the format of the images, whether they will be identifiable, and exactly what they will be used for. Please also state that participants will be given the opportunity to approve specific images / video prior to use.
10. Some language may be too difficult for a person with dementia to understand e.g., stigmatise. Please use lay-language where possible or simple terms in brackets.
11. For the focus groups please include a statement to consent to ensure all group members' privacy is maintained.
12. Data from focus groups cannot be withdrawn, as this may impact the context of other contributions. Please amend accordingly.

**Decision**

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

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

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

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| **5** | **Ethics ref:** | **2023 FULL 13824** |
|  | Title: | Use of home blood pressure monitors for remote optimisation of cardiac medications (Home MED Study) |
|  | Principal Investigator: | Dr Tze Vun Liew |
|  | Sponsor: | Waikato Medical Research Foundation |
|  | Clock Start Date: | 27 April 2023 |

No researcher 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. In S9 of the application form: use of human tissue, this question has been answered incorrectly in the negative (whereas blood samples are being taken), hence several questions have not been addressed in the application. Answering the question correctly will provide the relevant questions for the researcher to respond to. Answering yes to use of human tissue will open the form up with the correct questions.
2. In section H1 of the application form, registration of the study with a WHO-approved clinical trials registry must be done prior to commencement.
3. The Committee requested clarification as to whether participants are provided with information regarding whether and how to repeat their blood pressure recording, in the event of a significantly abnormal result.
4. The Committee requested clarification about whether participants will be provided with information about blood pressure recordings (high or low) that should be reported to the research team promptly.
5. Availability of a research contact during normal working hours only is suboptimal for a research study. The Committee queried who participants can contact, should they have urgent questions, concerns, or adverse events outside working hours.
6. The Committee noted that sponsor authorisation is required as the previous submission was declined. Ensure this is undertaken as part of the response to provisional approval.
7. The Committee requested provision of the invitation letter and device instruction leaflet referenced in the application form.
8. The Committee requested the following changes to the Data Management Plan (DMP):
   1. A sponsor has been included on the application but not in the data management plan, please amend.
   2. In Section 7.2, please note that data is not de-identified if it carries the participant’s NHI number and date of birth. Please ensure all identifiers are removed from de-identified data.
   3. Please review and remove ‘note to researchers’, instructional text, square brackets and template statements not applicable to the current study.
   4. As the Investigator will retain a log linking participant ID with identifiers (Section 7.2), the statement regarding linking consent forms with study data is not correct; neither is the statement regarding return of individual results. Please amend accordingly.

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

1. For participants unable to use the BP device due to dexterity, eyesight etc. please clarify if there will be alternative devices available.
2. For participants who benefited from the trial, please clarify options available at the end of the trial for ongoing blood pressure monitoring.
3. Please indicate whether karakia will be available at the disposal of blood samples or not.
4. Please explain how study staff will find out about adverse events and if that is dependent on self-reporting.
5. On page 4 and 5 please underline subheadings for consistency.
6. Please consider adverse events associated with medication titration in 'risks' section.
7. Please make it clear under 'identifiable information' that participation in the study, blood test results and medication changes and potentially blood pressure / heart rate recordings will be added to the participant's clinical record.
8. Please clarify that data added to the clinical record cannot be withdrawn, should the participant withdraw consent.
9. The statement regarding review of identifiable information for audit should not be introduced in the consent form. Ensure this is noted in the body of the participant information sheet.
10. Please clarify if a Te Reo Māori version will be available.

**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 Devonie Waaka and Mr Dominic Fitchett.

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| **6** | **Ethics ref:** | **2023 EXP 15582** |
|  | Title: | Intergenerational Conflict in immigrant Chinese families in New Zealand: A Qualitative Study of Mental Health Service Users |
|  | Principal Investigator: | Dr Richard Yu |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 April 2023 |

Dr Richard Yu and Dr Gary Cheung 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 queried why the study is not being conducted in a healthy population first. The Researcher responded that they want to research how these conflicts influence the course of the patient’s illness.
2. The Committee confirmed with the Researcher that only those over 18 years and able to provide fully informed consent will be enrolled and was reassured of the Researcher’s ability to determine capacity to consent.
3. The Committee clarified that recruitment is through other clinicians, who would seek patient permission to pass on details to the researcher.
4. The Committee queried if there would be any need for interpreters. The Researchers responded that it will be conducted in English in most cases, however the lead researcher is fluent in Mandarin. If there are participants who do not speak English or Mandarin, they will seek additional dialect interpreters, but the majority from experience of the Researchers should speak English or Mandarin. The Committee were satisfied of 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 the following changes to the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8*):
   1. The protocol submitted was more of a form than a formal protocol. Please provide a formal protocol, taking into account the suggested inclusions outlined in [Standard 9.8.](https://neac.health.govt.nz/national-ethical-standards/part-two/9-research-development-and-design/) Examples can be found via the footnotes of that Chapter.
   2. Please detail exclusion and inclusion criteria.
   3. Please make it clear that the primary objective is to get the perspective of the patient, and that inclusion of a family member is additional but not mandatory.
   4. Please outline managing recruitment and participation of the family member, detailing how any potential conflicts will be managed. The Committee noted to ensure that the patient passes on the information sheet, and to make it clear what is confidential about the other’s participation.
   5. Please include a specific safety management plan for responding to distress or concerns raised during the interviews. Please also include a summary of this in the participant information sheet (PIS).
2. The Committee noted that access to participant’s medical records is quite broad in the study documentation. Justification for what is needed and why should be detailed in the data management plan (DMP) and PIS.
3. The Committee requested more detail in the submission who the Sponsor is.
4. The Committee requested that if online interviews are an option, information regarding how interviews are recorded and transcribed, and how audio or video data will be stored and deleted be included in the DMP and PIS. If conducting interviews online, be sure to also include guidance on finding somewhere private for their interview to participants.
5. Some parts of the DMP state that data may be retained for future related research, subject to additional optional consent. Clarify what is intended and either add an optional consent clause to the PIS/CF, or amend statements in the DMP and body of the PIS/CF.
6. The Committee noted inclusion of draft documents in the submission such as the interview schedule, stating that final versions should be included in the response to provisional approval.

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

1. A separate PIS should be available for family members of the patient.
2. A review by a lay person, potentially with English as their second language, is advised. Please also review for a few grammatical errors that make it more difficult to read.
3. The participant needs to understand what they are required to do as part of their participation, and the PIS needs to be rewritten to outline this as it is currently not clear. The Committee recommended the Researcher adapt the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
4. Please amend inclusion criteria – both participants in the family pair do not need to be mental health service users. Please address eligibility criteria for family members.
5. Under Risks, it is not necessary to refer to fatigue or boredom.
6. Please explain precisely what health information might be wanted from medical records and for what purpose-currently far too broad. Also clarify whether this refers to both participant categories.
7. The text switches between 2nd and 3rd person. Please use a consistent point of view throughout the PIS/CF.
8. Please review for unnecessary technical language ('intervention', ' qualitative observational', snowballing', 'randomisation', 'convenience sampling', 'demographic', 'acculturation gap', 'index patient' etc); replace with simple lay terms or delete extraneous information.
9. Please clarify that the interviews are conducted on a one:one basis.
10. Please clarify that the index participant's consent will be sought prior to contacting family members.
11. Please clarify whether statements made during the index participant's interview will be raised / discussed during the family member interview (or vice versa).
12. Please address obligatory reporting requirements.
13. Please delete template statement regarding retention of minors' health information.
14. Please delete statement regarding access to other study-specific information; this is not relevant to the current study.
15. Please delete repetitive statements regarding study withdrawal.
16. Please clarify whether Chinese cultural support will be available if required.
17. Please remove template prompts
18. Please remove the optional tick box for contacting GP in the consent form in the event of significant abnormal results, this should be mandatory.
19. Please provide information regarding interview recordings, as noted in Point 8 above.

**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 & 9.8).*
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 Catherine Garvey and Associate Professor Mira Harrison-Woolrych.

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| **7** | **Ethics ref:** | **2023 FULL 13521** |
|  | Title: | A PHASE 2A, RANDOMIZED, PLACEBO-CONTROLLED, DOSE-RANGING STUDY TO EVALUATE THE SAFETY AND EFFICACY OF PTC518 IN SUBJECTS WITH HUNTINGTON'S DISEASE |
|  | Principal Investigator: | Professor Tim Anderson |
|  | Sponsor: | PTC Therapeutics, Inc. |
|  | Clock Start Date: | 27 April 2023 |

Laura Paermentier 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 Pharmasols is the local CRO.
2. The Committee confirmed with the Researchers that sufficient steps had been taken at managing the conflict of interest of the CI’s clinician role and were comfortable with the proposed recruitment approach.
3. The Committee confirmed with the Researcher that receipts are not required for reimbursements, and that expenses are handled by the coordinators on behalf of 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. The Committee noted that in New Zealand, minimum retention of health data is 10 years. Please amend across documentation accordingly.

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

1. Please make it clear no genetic testing will be undertaken on samples for future related research.
2. The Committee noted the contraceptive section should have more lay-friendly language and examples applicable to a New Zealand population. Please amend accordingly. The Committee recommended use of the [HDEC reproductive risks template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
3. The consent form refers to unrelated/unspecified research, which conflicts with the statement regarding future Huntington’s-related research outlined in the body of the PIS. Please amend to clarify that only research related to the study disorder will be undertaken.
4. Please amend the footer to ensure a space between it and the main text is more defined to aid in readability.
5. Please refrain from using teaspoon measures for blood; millilitre volumes only is sufficient.

**Decision**

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

* please address all outstanding 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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| **8** | **Ethics ref:** | **2023 FULL 16764** |
|  | Title: | A soft pressure-sensitive skin to measure lymphoedema treatment efficiency. |
|  | Principal Investigator: | Dr Anna Rolleston |
|  | Sponsor: | Medulla Health |
|  | Clock Start Date: | 27 April 2023 |

Dr Anna Rolleston and Desiree De Spong 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 queried the answer to D4 of the application form which states that the CI has no clinical relationship with potential participants. The Researcher clarified that the first approach and introduction to the study is not done by the CI, who will not see them as an investigator until they’ve fully consented to participate.

**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 participation is limited to only Māori and Pasifika while there is no justification for the scientific rationale for this in the study submission. Most trials of new devices carry risks, so the Committee required a justification of burdening specific groups for a healthy participant study. The Researcher stated that Māori and Pasifika did not have equal access to trials and that it was an equity issue. The Committee agreed with the issue of equity but had reservations for this being applied to trials of healthy participants where there is no prospect of therapeutic benefit and the potential for risk. The Committee noted that given the locality of the study, it is likely that only Māori and Pasifika will be available for recruitment, but there does not appear to be a rationale for specific restriction of eligibility based on ethnicity in the protocol. Please provide study-specific justification for the restrictions on ethnicity.
2. Eligibility criteria isn’t mentioned anywhere in the protocol. It is not stated whether the study is enrolling participants affected by lymphedema or healthy adults. Please address this. Exclusion criteria based on increased risk or inability to undergo required study procedures should also be detailed.
3. The Committee noted that peer review is required by an independent expert in the field. The Committee referred the Researcher to the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) for use if needed.
4. The study is being undertaken with a commercial collaborator who has access and involvement in data analysis and reporting of results and owns the IP of the device. For the Committee, that suggests this study should be covered by commercial sponsor as there is probable financial benefit for the sponsor. The Committee requested evidence of CI indemnity and sponsor insurance. The participant information sheet (PIS) will need to be amended too to include this. The template statement on the [HDEC PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) can be used.
5. The Committee noted that because the commercial partner’s representative is part of the research team, the conflict of interest needs to be declared in the protocol and in the PIS. The protocol should also outline the steps taken to mitigate this conflict.
6. The Committee noted the following about the recruitment material:
   1. The material claims the benefit of enhancing overall health. This needs to be modified, as this is not proven for the device under study.
   2. The statement that the device is natural, implies it is made from natural materials. Please amend to state it is a device based on natural therapeutic practices.
   3. Please delete the term ‘interfacial pressure’, or state what it means in lay language.
7. The Committee noted the following about the Data Management Plan (DMP):
   1. Please provide final version of document and not the draft.
   2. Dr Samuel Rosset is named as PI on cover page. This should be Dr Rolleston only.
   3. Please address the management of documents carrying identifiers (consent forms, contact lists etc).
   4. Please clarify whether all researchers and Medella staff are NZ-based (Section 5.2)
8. All intervention studies in New Zealand should be registered with a WHO-approved clinical trials registry. Please ensure this is done prior to commencing recruitment.
9. The application form indicates locality authorisation is not required. The study requires authorisation from the facility where the study is being conducted. If there is a COI between the study team and who would usually authorise this, someone else senior and independent from the study may assess and authorise this instead.
10. As this is targeting Māori and Pasifika, the Committee queried if there the availability of interpreters.

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

1. The title of the information sheet states the study is assessing lymphedema treatment efficiency, which is not correct. Please amend.
2. In lay language, please outline who can take part and who is excluded.
3. Please explain the skin in lay language and include a photo.
4. Please explain all the assessment tools in lay language, including any potential risks or inconveniences.
5. Please indicate how much time participation will take, who will do the assessments and where they will be done.
6. Please clarify whether participants will be reimbursed for travel expenses to and from the research centre in addition to the $50 voucher. Note that participants should not be left out-of-pocket as a result of study participation.
7. Please outline who is funding the study.
8. Please make it clear there may be no benefits to participants.
9. Please provide more information around data management, such as what will happen to the consent forms and data, who has access, how data will be de-identified, how long data will be kept for, whether it will be used for future research, rights of ownership, risk of privacy breach, etc. The HDEC PISCF template may be a useful reference.
10. In a clinical trial, its preferable that health care provider notification of clinically significant abnormal findings requiring follow-up be mandatory. Please amend the PIS accordingly.
11. It is useful to explain physiological effects to participants to reassure them of what would be considered a risk of the device.
12. Please review for technical jargon, and either replace or explain in lay language.
13. Please delete repeated statements.
14. The CF statement about withdrawing data is not consistent with the statement in body of the PIS. Please ensure they are consistent.
15. Please check the contact details for HDEC and the HRC are correct as per the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).

**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 Dianne Glenn and Dr Devonie Waaka

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| **9** | **Ethics ref:** | **2023 EXP 17847** |
|  | Title: | Testing a Wellbeing App on New Zealand High School Students |
|  | Principal Investigator: | Dr Hiran Thabrew |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 09 May 2023 |

Dr Karolina Stasiak and Mir Mahrukh 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.

**Summary of outstanding ethical issues**

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

1. This is a resubmission of a study declined by the Southern HDEC after the response to Provisional Approval didn’t quite meet expectations surrounding the informed consent of minors. The Committee needed to see a simplified information sheet for children that were unable to consent for themselves (assent form). The Committee had also required confirmation that the Researchers were able to assess each child’s capacity to provide their own informed consent. The Committee noted that the approach to assess capacity to provide informed consent has been revised in the resubmission, however the protocol does not indicate how this would be done. Currently, it leaves the assessment in the hands of the individual to assess their own capacity. The Researcher clarified that the students and families would be provided with information about the study ahead of time and be aware of it by the time it came to seeking participation. The Researcher is anticipating people would self-select and by understanding the content of the advertisements, would understand what the study is about and come forward to participate. Due to the low risk of the study, the Researcher agreed that almost everyone taking part is expected to have capacity to understand their participation. The Committee acknowledged this and noted that if someone didn’t have capacity to participate, they may not be a good fit for this study as they have to be able to understand how to use the Wellbeing App. After discussion, the Committee stated that in the unlikely event someone is determined as lacking capacity to provide their own fully informed consent, an information sheet with assent form (which is a simplified version of the participant information sheet) will be read and signed by the participant, with a parent providing consent.
2. The Committee also noted that self-selecting for participation may not be indicative of sufficient understanding of the study and its associated risks and benefits, as this age group may be prone to going along with what their peers are doing. The Committee emphasised the importance of the one:one on-boarding discussion to assess whether each child understands the information, and to make sure sufficient time is allocated to each discussion.
3. The Committee queried the addition of school staff interviews and whether this impacts the privacy of the student participants. The Researcher clarified the interview will be confined to asking how an app like this could be used and implemented post-study, such as linking to a curriculum. This is entirely process-focused and devoid of asking staff to divulge anything about students. The Committee noted that no recruitment material was submitted for school staff.
4. The Committee noted that if a participant has capacity to provide informed consent for the study, they should have the right to access their individual results on request. Budget constraints are not a justification for withholding results. Please ensure participants have the right to access individual study results on request.
5. The data management plan currently refers to reconsenting those who turn 16 (unlikely in year 10 and left out of the participant information sheet). Please review whether this is required and address in the participant information sheet if needed.

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

All:

1. The Committee noted that the Ethics phone number has changed to 0800 400 569 (Ministry of Health general enquiries). See the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) if required.
2. Please address risk of privacy breach

Assent

1. Please provide a simplified participant information sheet for participants who as stated above have been deemed as lacking capacity to provide their own fully informed consent.

Staff PIS/CF:

1. Please state if the interviews are group or individual. If group interviews, discuss how privacy will be protected
2. Please state how the interview will be recorded.
3. Please state what will happen if participants withdraw from the study

Main PIS/CF:

1. Please address potential risks of the study
2. Please state that questionnaires will be reviewed by research staff and follow-up arranged if there is concern regarding the responses given; that the participant's parent / guardian will be informed, and that the participant's GP or other relevant health professional will be notified if clinically indicated. Please also clarify what will happen if a participant states they do not want their parent notified.
3. Please make it clear that this is a randomised control trial and some participants will not use the app for the first 4 weeks, and will then have access to it rather than just saying they ‘will have access at different times’. Please also clearly state that those in the second group should not download or discuss the app with the first group if possible.
4. Please outline how the follow up questionnaires are administered – hard copy or electronic, how are they delivered to the participants and submitted once completed etc.

**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 Mr Dominic Fitchett and Ms Amy Henry.

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| **10** | **Ethics ref:** | **2023 FULL 15347** |
|  | Title: | A Phase III, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of Astegolimab in patients with chronic obstructive pulmonary disease |
|  | Principal Investigator: | Andrew Edwards |
|  | Sponsor: | Roche Product Pty Limited |
|  | Clock Start Date: | 09 May 2023 |

Rebecca Sisterson 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 confirmed with the Researcher that there are plans to bring the open-label extension to New Zealand.

**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 raised the following about the application form:
   1. B21 states no investigators will provide clinical care to participants. The Researcher confirmed that some investigators will be recruiting patients. The Committee requested an outline of the steps taken to mitigating the potential for undue pressure on patients to participate as a result of the existing doctor: patient relationship.
   2. C4 provides no information regarding whether COPD is a particular issue for Māori. Please ensure this is addressed in future submissions.
   3. C11 is incomplete. Please describe Pasifika consultation undertaken for the study.
   4. F4.1 talks about genetics analyses and restricts mandatory genetic analyses to analyses related to the study. This is not reflected in the main participant information sheet (PIS) which is very broad and is identical to text in the optional PIS. Please confirm that the answer in F4.1 of the application form is correct for mandatory genetics and amend the main PIS to restrict that use accordingly.
   5. The Researcher has selected that Sponsor authorisation is not required, which is incorrect. Please amend and seek Sponsor authorisation of the submission.
2. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP)
   1. All site principal investigators referred to as CI on cover page. Please name the Coordinating Investigator for New Zealand only.
   2. Section 8.7 refers to data linking but states that all identifiers are removed prior to linking. The intended data use described by the researcher to the Committee is not data linking (linking an individual’s data from the study set to other sets of that individual’s data). Please amend.
   3. F7 of application form says karakia is not available, but section 11.1 of DMP says there are options that will be discussed. Please clarify in the DTMP that information will be provided in site-specific PISs
   4. F8 of application form says collected tissue will not be continued to be analysed if a patient withdraws, but section 13 of DTMP says it will be analysed. Please clarify which of these two statements is correct and amend accordingly.
3. The CV of CI indicates no specialist training in respiratory medicine, and a total of 2 years’ experience in clinical research. The Committee noted that other secondary sites have more appropriately qualified principal investigators. In a therapeutic trial conducted in a patient population, the Committee would expect the CI to have specific expertise in the disease indication under study and significant clinical research experience. Please provide further confirmation that the CI appropriately experienced and trained.

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

Main PIS/CF:

1. Please review first sentence (page 1).
2. Please state the approximate number of New Zealand participants next to total number of participants worldwide.
3. Please explain what antibodies are in lay language (page 8).
4. The description of mandatory genetic testing is very broad and inconsistent with the description provided in F4.1 of the application form; it is identical to the description provided in the optional FUR PISCF ('COPD and other diseases, possible links among diseases, genome variations and how they might affect a disease or a person's response to treatment, and new avenues for drug development and personalised therapies'.) Please amend to limit mandatory testing to that described in the application form (page 8)
5. Please state approximately how many people have been exposed to the study drug, and whether this includes long-term exposure (page 9).
6. GP notification of study participation should be mandatory; please amend the statement regarding this (page 12).
7. Please review whether the statement regarding withdrawal of data is correct (page 14); it does not match the application form or DTMP.
8. Page 14 has an apparent conflict between statements on pages 14 and 15 – as below:

*"If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken." (Page 14),* and   
  
*"However, Roche will still be able to use information that was collected prior to stopping, including information from samples that were tested prior to stopping." (Page 15)*

1. Please delete reference to 'legally authorised representative' (p15)
2. The application form states participants can request their genome sequencing; the PIS/CF states this will not be made available. Clarify what is intended and amend documentation accordingly (page 16)
3. Please amend the consent form to reflect that GP notification of study participation and significant abnormal results is mandatory (page 19).
4. Please amend the consent form to include a clause about mandatory genetic testing (page 19).
5. Please specify city and country of all overseas labs used for testing
6. Please specify what happens to samples at end of storage period (i.e., destruction)

Optional Future Unspecified Research (FUR) PIS/CF:

1. The form states only residual samples will be donated to the RBR; the PISCF describes collection of a new sample. Please clarify what is intended and amend study documentation accordingly (page 2).
2. The text states samples will be retained for a 'defined period as described below', however no further information is provided. Clarify what is intended and amend the PIS/CF accordingly.
3. The text states genome sequencing results will be made available 'if permitted by local law'. Please clarify what the law permits locally and amend the statement to be applicable to New Zealand.
4. Please ensure participants who withdraw from the main study are specifically asked whether they wish to withdraw consent for ongoing use of RBR samples.
5. The first mention that participants can elect to limit future analyses to related research, or agree to indefinite use of samples, is in the consent section. Please discuss options in the body of the PIS.

Optional Physical Activity PIS/CF:

1. Please describe what the device is actually monitoring (steps, heart rate, arm movement, etc.) (page 2).
2. Please state whether the device involves GPS (location monitoring) (page 2).
3. Please describe whether 3rd parties have access / rights to use of device data (page 2).

**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 and tissue 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, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Catherine Garvey and Dr Devonie Waaka.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 13 June 2023 |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting.

* Ms Neta Tomokino
* Ms Amy Henry

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 4.15pm.