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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 18th July 2023 |
| **Zoom details:** | 973 875 6003 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:30pm-1:00pm | 2023 FULL 18214 | AB-101-001: A Study to Investigate the safety and tolerability of AB-101 in healthy participants and in participants with Chronic Hepatitis B Virus. | Prof Ed Gane | Ms Catherine Garvey & Dr Andrea Forde |
| 1:00pm-1:30pm | 2023 FULL 18069 | A Study of Oral Decitabine/Cedazuridine in Combination With Magrolimab in Subjects With Intermediate- to Very High-Risk MDS | Dr Merit Hanna | Mrs Helen Walker & Dr Sotera Catapang |
| 1:30pm-2:00pm | 2023 EXP 18005 | Personality, Beliefs, and Wellbeing | Miss Rebecca Salzano | Ms Helen Walker\* & Mr Barry Taylor |
| 2:00pm-2:30pm | 2023 FULL 17793 | The ASPIRE-AF trial | Professor Harvey White | Ms Catherine Garvey & Ms Jade Scott |
|  |  | **BREAK 30 MINUTES** |  |  |
| 3:00pm-3:30pm | 2023 FULL 18268 | YCT-529-01-NZ: A Study to Investigate the Safety of single doses of YCT-529 In Males as a Potential non hormonal contraceptive. | Dr Alexandra Cole | Ms Helen Walker\* & Dr Andrea Forde |
| 3:30pm-4:00pm | 2023 FULL 18195 | Recommendations for school-based health and wellbeing interventions for young people in the Wairarapa | Mr Joshua James | Mrs Helen Walker & Mr Barry Taylor |
| 4:00pm-4:30pm | 2023 FULL 13151 | ROPAC-Registry Of Pregnancy And Cardiac disease | Dr Chethan Kasargod | Ms Catherine Garvey & Dr Sotera Catapang |
| 4:40pm-5:00pm | 2023 FULL18275 | Evaluation of STEPS-A DBT in schools programme | Dr Liesje Donkin | Ms Catherine Garvey\* & Ms Jade Scott |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mr Derek Chang | Non-lay (Intervention studies) | 08/07/2022 | 08/07/2025 | Apologies |
| Dr Kate Parker | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Apologies |
| Dr Andrea Forde | Non-lay (Intervention studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey | Lay (the Law) (Chair) | 19/03/2019 | 19/03/2022 | Present |
| Dr Sotera Catapang | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Apologies |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |
| Mrs Helen Walker (Co-opt) | Lay (Consumer/Community perspectives) | 22/05/2020 | 22/05/2023 | Present |
| Mr Barry Taylor (Co-opt) | Non-lay (Intervention/Observational studies) | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The Chair opened the meeting at 12pm and welcomed Committee members, noting that apologies had been received from Dr Kate Parker, Mr Derek Chang and Mr Jonathan Darby.   
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mrs Helen Walker and Mr Barry Taylor confirmed their eligibility and were co-opted by the Chair as a members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 20th June 2023 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2023 FULL 18214** |
|  | Title: | A Double-Blind, Randomized, Placebo-Controlled, Single and Multiple Dose Study Evaluating the Safety, Tolerability,  Pharmacokinetics, and Pharmacodynamics of AB-101, an Oral PD-L1 Inhibitor, in Healthy Subjects and Subjects with Chronic HBV Infection |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | PPD, part of Thermo Fisher Scientific |
|  | Clock Start Date: | 6th July 2023 |

Professor Ed Gane, Grace Tougher, Holly Thirwall, and Courtney Rowse 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.

Dr Andrea Forde declared a potential conflict of interest and the Committee decided to proceed with Dr Forde included in the discussion.

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 pregnant people were not being included in this study until there was sufficient research on reproductivity toxicity in indicator species to prove that there would be no reproductive risk to humans with the capacity to become pregnant.
2. The Committee clarified the exclusion of rabies vaccine recipients in the participant information sheet.
3. The Committee clarified that viral genome sequencing and human genome testing would be carried out.
4. The Committee clarified that there would be gender collection for parts 1 and 2 although people assigned female at birth are excluded from these studies.
5. The Committee clarified the dosing of cohorts.
6. The Committee clarified the amount of blood that would be taken and when.

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 insurance certificate expires before the expected end of the study which will need updating prior to that occurring.
2. The Committee noted that the radio script should reflect that this is a first in human study with inherent risks. The Committee requested that the advertising place less emphasis on the entertainment available for trial participants during overnight stays and include reference to risk associated with the study.
3. The Committee requested that the researchers provide a submission for part three of the study as an amendment prior to commencement.
4. The Committee requested that it be provided with the currently ongoing pre-clinical studies on reproductive toxicity as the studies are concluded.

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

1. Please change the language around exclusion of rabies vaccinated individuals to state that there would be no exclusion based on this but that the receipt of the study drug would render the vaccine inactive and therefore this would become a contraindication to participation.

**Decision**

This application for parts 1 and 2 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 provide the advertising materials back to the Committee for approval prior to starting the study.

Part 3 of the study will need to be submitted at the time this part of the study has been deemed safe to conduct. No approval has been given to this third part.

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| **2** | **Ethics ref:** | **2023 FULL 18069** |
|  | Title: | A Phase 2 Study of Oral Decitabine/Cedazuridine in Combination With Magrolimab for Previously Untreated Subjects With  Intermediate- to Very High-Risk Myelodysplastic Syndromes (MDS) |
|  | Principal Investigator: | Dr Merit Hanna |
|  | Sponsor: | IQVIA |
|  | Clock Start Date: | 6th July 2023 |

Dr Francisca Reed was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the treatment plan and withdrawal plan of participants with DLT.
2. The Committee clarified the archival use of bone marrow tissue.

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 protocol reflect that should participants have archival bone marrow tissue from a biopsy within an acceptable time period that this will be used instead of requiring an additional biopsy.
2. The Committee requested clarification as to any restrictions (such as fasting or blood sampling) that may be placed upon the participants in relation to the pharmacokinetic determination of Magrolimab. This may also need to be clarified in the participant information sheet/consent form (PIS/CF).
3. The Committee clarified that information would be deidentified prior to analysis.

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

1. Please clarify that participants may not need an additional bone marrow biopsy as per the protocol.
2. Please clarify the amount and frequency of blood sampling.
3. Please include a table of procedures for participants to have a better and more simplified idea of expectations.
4. Please include information as to the mitigation in place for participants with regard to the cross matching and transfusion related risks associated with Magrolimab, to align with the protocol and provide reassurance.
5. Please note that “DAT” and “ADA” are not notifiable diseases and should be removed from this section.
6. Please note that barrier methods of contraception are not considered particularly effective methods and should not be sole methods and the time-period referred to of each seems to not be relevant for these methods. Please amend.
7. The Committee recommend not relying on barrier methods given the potential for reproductive toxicity. Please also provide clarification as to the different timeframe for contraceptive requirements for different sexes based on drug clearance as listed.

**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 Mrs Helen Walker and Dr Sotera Catapang.

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| **3** | **Ethics ref:** | **2023 EXP 18005** |
|  | Title: | Evaluating the Efficacy of Positive Episodic Future Thinking (EFT-P) to Increase Positive Beliefs about the Future and Decrease  Suicidal Ideation in University Students |
|  | Principal Investigator: | Miss Rebecca Salzano |
|  | Sponsor: | The University of Otago |
|  | Clock Start Date: | 6th July 2023 |

Rebecca Salzano and Dr Richard Linscott were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the recruitment process of participants from a previous study.
2. The Committee clarified that there was no commercial interest in the online study platform and that the study would not incur any cost to 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 queried if it is assumed that individuals invited into this study would have ongoing suicidality. The researcher noted that there was an expectation that these potential participants had reported suicidal ideation in the months prior to invitation and therefore may experience suicidal thoughts again. The Committee noted that suicidality can be incredibly situational, and the potential participants may be at increased risk of becoming suicidal again. The Committee noted that there could be considerable risk to the potential participants as some are likely vulnerable. The Researcher noted that the former study did not assess the extent to which the ideation may be associated with a clinical syndrome. The researcher also noted that there would be a mix in this cohort of potential for risk. The researcher noted that they believe it unlikely that the invitation to the study will raise the risk already present for the individuals but that it would increase the potential for this to be discovered. The researcher recognised that there is potential for discomfort. The Committee requested a safety protocol that takes into account the current state of the potential participants and perhaps consider ongoing suicidality as an exclusion criterion. The Committee noted that this plan needs to contain sufficient plan for follow up response in the event of disclosure of active suicidality. This should include some correspondence that asks the person if they are receiving help currently and a plan to refer should there be a disclosure event.
2. The Committee queried why course credits would be received by those participating in the intervention. The researcher noted that there would be the opportunity to receive either a koha or course credits for all participants, depending on year level. This needs to be clarified across all study documentation and participant information sheets.

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

1. Please clarify for participants that this is a randomised trial and that should they not be randomised to receive the intervention that they can receive this post-trial.
2. Please describe the intervention clearly for participants.
3. Please clarify for participants that declining to participate in the study will not negatively impact their results or ability to achieve in their studies.

**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 Mrs Helen Walker and Mr Barry Taylor.

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| **4** | **Ethics ref:** | **2023 FULL 17793** |
|  | Title: | Anticoagulation for Stroke Prevention In patients with Recent Episodes of perioperative Atrial Fibrillation after noncardiac surgery - The ASPIRE-AF trial |
|  | Principal Investigator: | Professor Harvey White |
|  | Sponsor: | Population Health Research Institute |
|  | Clock Start Date: | 6th July 2023 |

Caroline Alsweiler 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 study was investigator-led.
2. The Committee clarified that the drugs used in the study were not novel and are currently in use in New Zealand as Standard of Care in non-surgical patients.
3. The Committee clarified that the insurance certificate was provided for completeness but not indicative of the trial being commercially sponsored.
4. The Committee clarified the recruitment process.
5. The Committee clarified that the higher risk of a cardiac event is discussed as part of standard of care for these patients when diagnosed with an AF arrythmia

Summary of outstanding ethical issues

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

1. The Committee noted that there were posters mentioned in the protocol that would not be used without approval. Please provide these should they be required
2. The Committee queried the rationale of exclusion of pregnant and lactating women given that this group can develop AF arrythmia and the study drug is licensed for infants

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

1. Please clarify reimbursement for travel and parking.
2. Please clarify that the sponsor is in Canada.
3. Please amend the blood amounts to state the millilitres collected rather than the teaspoon amounts.
4. Please remove the ETHICS 0800 number as this is no longer active. This can be replaced with the Ministry number provided in the [HDEC templates for PISs](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).

**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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| **5** | **Ethics ref:** | **2023 FULL 18268** |
|  | Title: | Double-blind, placebo controlled, first in human study to evaluate safety, tolerability, pharmacokinetics, and pharmacodynamics of  single ascending oral doses of YCT-529 |
|  | Principal Investigator: | Dr Alexandra Cole |
|  | Sponsor: | YourChoice Therapeutics Inc. |
|  | Clock Start Date: | 6th July 2023 |

Dr Alexandra Cole, Holly Thirwall, and Courtney Rowse were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the recruitment process, via advertising, site databases and Urology referral.
2. The Committee clarified the age range of those in the study with particular interest in those who are younger and not vasectomised, and how the assessment is done to determine the certainty of the decision not to have children in the future. The researcher clarified the process to ensure that this is being managed in the participants best interests.
3. The Committee clarified that the sponsor is paying for the storage of participant sperm samples for as long as required.
4. The Committee queried if it is possible to recruit from a narrowed age bracket or from those who have completed a family, undergone a vasectomy or awaiting a vasectomy. The Researcher clarified that the focus of participants is such participants and on a pool of those who have already had a vasectomy and estimate 40% of participants will already have a vasectomy/completed family. They noted they would target older men and those who have already had a vasectomy.
5. The Committee clarified the process of storage and for how long this may be in multiple situations.
6. The Committee asked about reimbursement and why there is a difference between vasectomised and non-vasectomised participants. The Researchers explained this is because the vasectomised participants do not need to provide sperm samples, whereas the non-vasectomised participants will need to attend a fertility clinic for this purpose.

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 upload the CV and medical indemnity of the co-investigator of the trial.
2. Please amend/rephrase the wording of the advertisement “are you seeking a potential form of non-hormonal oral contraceptive”

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

1. On page 11, please review/remove reference to the Covid pandemic for relevancy.
2. Please include more information in lay language about the storage of the sperm sample and that if participants do not return to baseline, the sample is still stored and will be continued to be stored at the Sponsor’s expense until baseline levels have returned.

**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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| **6** | **Ethics ref:** | **2023 FULL 18195** |
|  | Title: | Recommendations for school-based health and wellbeing interventions for young people in the Wairarapa |
|  | Principal Investigator: | Mr. Joshua James |
|  | Sponsor: | Te Whatu Ora Wairarapa |
|  | Clock Start Date: | 6th July 2023 |

Joshua James was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the intervention typing and codesign aspect of the study. The Committee also clarified the outcomes or output focus of the study.
2. The Researcher noted that there will be a Te Whatu Ora Wairarapa Public Health co-ordinator outreach employee accompanying the Researcher.
3. The Committee asked why Public Health are involved in this study. The Researcher explained this is because Public Health has contracted the Researcher for their services for this study.

Summary of outstanding ethical issues

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

1. The Committee queried the consenting process and specifically the consenting of participants over the age of 16. The Researcher noted Te Whatu Ora Wairarapa have requested that informed consent from both the student and parent are obtained, even if the student is over the age of 16. The Committee noted that those over the age of 16 should not require consent from parents. The Committee suggested that Te Whatu Ora Wairarapa recognise that there is no increased ethical risk from allowing these participants to consent for themselves without parent/guardian consent. The Committee suggested to the researcher that it may be a possible work-around to provide the parents/guardians an information sheet but not seek their consent.
2. The Committee requested the provision of a robust safety plan. This should require another adult who works with the school to be present to monitor the situation such as a school councillor and also detail what will happen with an involuntary disclosure and how participants will be supported.
3. The Committee noted confirmation of permission to access school facilities for the research conduct should be acquired for completeness.
4. The Committee requested provision of the letter that will be sent to the schools.

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

1. Please include more information about the co-design process that will occur, and what participants are expected to do throughout all stages of the co-design process.
2. Please include a reminder to the participants of the confidentiality expectations of group settings and clarify that the Researcher will be recording and transcribing.
3. Please clarify how long the data will be kept and who has access to said data.
4. Please include more information about potential data breach and what systems are in place to prevent and address any breach.
5. Please include the four topic areas that are described in the submission so that participants have a good idea of the nature of questions.

**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 Mr Barry Taylor and Mrs Helen Walker.

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| **7** | **Ethics ref:** | **2023 FULL 13151** |
|  | Title: | ROPAC-Registry of Pregnancy and Cardiac disease |
|  | Principal Investigator: | Dr Chethan Kasargod |
|  | Sponsor: |  |
|  | Clock Start Date: | 6th July 2023 |

Dr Chethan Kasargod 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 data collected is for the overseas Registry. For New Zealand participants demographic and ethnicity data will also be collected and will remain in New Zealand in a separate data set retained by the researchers.
2. The Committee clarified that participants would not undergo any assessments outside of standard of care for the purposes of data collection for the Registry.

Summary of outstanding ethical issues

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

1. The Committee noted the outline of recruitment processes in in the submission at D.9, but requested confirmation that this would be used for participants who have given birth since 2017 and ensuring only living participants are approached. Please include a copy of the invitation letter.
2. In the data management plan, please remove unnecessary reference to tissue in headings and the body of the sections including sections 5, 7.2, 8.1.
3. In the data management plan, please ensure all requirements are discussed, e.g. the prompt in 11.1 regarding Māori data has not been addressed, please amend.
4. Please review the data management plan and answer only questions that are applicable to the study.
5. Please amend section C3.3 and explain how the study uses Kaupapa Māori methodology, as the database is based in Europe.
6. Please include information how data is obtained from birth and death registers.
7. Please include a New Zealand specific appendix for the protocol or similar document that explains the secondary data collection for NZ specific data (ethnicity and demographic information), specifying what this is, where it will be stored and how, who has access to this and the purposes it will be used for. This information should also be included in the Data Management Plan.

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

1. Please include what data is de-identified and sent to the registry based in France.
2. In the child data collection form please include all of the data that is collected alongside data relating to congenital heart disease.
3. On page 2 please include more information in lay language about the assessment of changes in maternal cardiac function as a consequence of pregnancy if echocardiography cannot be obtained.
4. Please note that if there is a plan on collecting information from third parties, such as primary care practitioners, midwives, nurses etc, please include the questionnaires
5. The Committee noted that the study could impose significant third party costs and questioned how this would be reimbursed.
6. The consent form does not provide space for name of witness to consent process, please amend.
7. Please include an Assent form for younger pregnant women.
8. Please amend the Child PIS/CF, storage of health data should be for 15 years.

**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 Ms Catherine Garvey and Dr Sotera Catapang.

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| **8** | **Ethics ref:** | **2023 FULL 18275** |
|  | Title: | An exploration of the effectivess, feasability and acceptability of a DBT in schools (STEPS-A) programme in Aotearoa New Zealand |
|  | Principal Investigator: | Dr Liesje Donkin |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 6th July 2023 |

Dr Liesje Donkin 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 peer review was independent.
2. The Committee clarified that the psychometric health data obtained as part of the STEPS-A programme will be kept and stored by Te Whatu Ora and as such the data management plan stating the retention of study-specific data will be for 6 years is adequate.
3. The Committee clarified that the collection of psychometric data would be for all participants in the STEPS-A programme not only study participants, and that it will be deidentified before the researcher has access to it in accordance with consent given by parents/caregivers when young people engage with the programme.
4. The Committee clarified that hard copies of the participant information sheet/consent forms (PIS/CFs) will be sent where required.
5. The Committee clarified that there will be oral consent.
6. The Committee clarified that school years 9-11 only will be participating in the studies.

Summary of outstanding ethical issues

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

1. The Committee requested a protocol for the study as the protocol provided relates to the STEPS-A programme, not the evaluation (this research). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7a & 9.8)*
2. The Committee requested a clear process for participation in the focus group. A consent form for parents to consent on behalf of their children and an assent form for those children in the younger group is required. Please review the [HDEC assent form template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/hdec-assent-form-instructions-and-checklist-may18.doc) for guidance on what these should include. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.25)*
3. The Committee requested clarification as to what the process may be should the parent wish to participate but the children did not or vice versa. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7a & 9.8)*
4. The Committee requested provision of the parent surveys for review.
5. The Committee requested that the protocol thoroughly outline the consent processes. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7a & 9.8)*

The Committee requested the following changes to all Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please include the HDEC, Māori cultural support and advocacy contacts. Examples of these can be found in the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
2. Please identify the sponsor for participants.
3. Please add yes/no options for all consent forms where there are options.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

## General business

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

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| **Meeting date:** | 16th August 2023 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 5pm.