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| **Committee:** | Northern A Extra HDEC Meeting Health and Disability Ethics Committee |
| **Meeting date:** | 30 May 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11:30am - 12:00pm | 2023 EXP 17861 | Zesty Kids Study: Studying the relationship between fruits, vegetables, and children’s mental well-being. | Dr Nicola Gillies | Mrs Helen Walker and Dr Patries Herst |
| 12:00pm – 12.30pm | 2023 FULL 15613 | CO44668: IMbrave152: Atezolizumab and Bevacizumab, with or without Tiragolumab, in patients with untreated, unresectable hepatocellular carcinoma | Professor Edward Gane | Ms Sandy Gill and Dr Devonie Waaka |
| 12.30pm - 1.00pm | 2023 FULL 15596 | A study to evaluate the efficacy and safety of combination immunotherapy in patients with surgically resectable Hepatocellular Carcinoma prior to surgical intervention. | Professor Edward Gane | Mrs Helen Walker and Ms Amy Henry |
|  |  | BREAK 30 MINUTES |  |  |
| 1.30pm – 2.00pm | 2023 FULL 15401 | RAIN-3202 (MANTRA-2): A study of Milademetan in solid tumours | Dr Jane Yeojeong So | Ms Catherine Garvey and Dr Patries Herst |
| 2.00pm - 2.30pm | 2023 FULL 16790 | Phase 3 Study of Adjuvant V940 and Pembrolizumab in Resected Melanoma (V940-001) | Dr Gareth Rivalland | Ms Kate O’Connor and Mr Barry Taylor |
| 2.30pm – 3.00pm | 2023 FULL 15192 | Services Your Way | Dr Jessica Stubbing | Ms Sandy Gill and Ms Amy Henry |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Kate O’Connor | Lay (Ethical/Moral reasoning) | 13/08/2021 | 16/08/2024 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Dr Devonie Waaka | Non-lay (Intervention studies) | 18/07/2016 | 18/07/2019 | Present |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) | 22/05/2018 | 22/05/2020 | Present |
| Ms Catherine Garvey | Lay (the Law) (Chair) | 19/03/2019 | 19/03/2022 | Present |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Mrs Sandy Gill | Lay (Consumer/Community perspectives) | 22/05/2020 | 22/05/2023 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The Secretariat noted that this was a special meeting organised to assist with the extra volume of applications received. Ms Catherine Garvey was selected to be acting chair for the meeting. All applications approved will be transferred to Northern A for post-approval monitoring.

The Chair opened the meeting at 11.00am and welcomed Committee members co-opted across the HDECs.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## New applications

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| **1** | **Ethics ref:** | **2023 EXP 17861** |
|  | Title: | Zesty Kids Study: Studying the relationship between fruits, vegetables, and children’s mental well-being. |
|  | Principal Investigator: | Dr Nicola Gillies |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 18 May 2023 |

Jeanette Rapson and Clare Wall were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee asked about the relationship with Zespri International and the study. The Researcher explained that Zespri approached the researchers about starting a pilot study into any impact of increasing fruit and vegetables in schools, delivered as whole foods, on cognitive health and general mental health. The researchers conducted a narrative review to ascertain if such a study had been done previously and what tools to use to assess change in the study parameters.
2. The Committee asked for clarification whether this pilot study is commercially sponsored and were satisfied that this pilot is investigator-led. The Researcher explained that while Zespri is supplying the study fruit and vegetables, they have no influence over data collection, publication or study design and kiwifruit is not the focus of the study.
3. The Committee asked about the recruitment process, noting the study aims to recruit four classrooms at four primary schools. The Researcher explained that the recruitment will be a multistage process, starting with getting the consent of the school Principals and Board of Trustees, then the teacher of the classroom selected by the school. Children and their parents/guardians will be recruited, using consent from parents/guardians and assent from the child participants. The Researchers explained they will work collaboratively with the schools for a smooth process. As well as receiving information packs, parents and children will have the opportunity for face-to-face discussion with a researcher if they require more information about the study.
4. The Committee clarified that the researchers would seek assent from the child participants and noted the complexity of the information and assent forms.
5. The Committee asked about the steps the researchers will take to ensure the children understand the process of the study and the study documentation. The Researcher explained that they will be talking to the classroom about the study as a whole and within that session and other sessions if needed sitting down with the children and making sure the children understand what the study is, what they will be doing and the different types of data the researchers will be collecting.
6. The Committee asked about the questionnaires and if assistance is given to children who require help with answering. The Researchers explained that assistance will be available to those who need it and that the questionnaires have been validated for use in this age group.
7. The Committee suggested the researchers consider the study title given a possibility participants may have a different understanding of the study title because of social media.

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 section D9, please note that supported consent is not the same as assent. It does not seem likely that, even with support, most children in the target age range will understand the implications of issues such as sending samples overseas or completing mental health questionnaires. Please amend.
2. In section D9 it references 'participants' when it appears the statements may be talking about the parent/guardian. Please amend if needed.
3. Please clarify whether Māori consultation has confirmed that stool samples are considered tissue - feedback from Māori consultation in some previous applications is that faeces is considered waste rather than human tissue and that karakia is not appropriate, however the researchers should proceed in accordance with the Māori consultation they have undertaken/will undertake on this issue.
4. For koha please consider that the teacher will have several responsibilities during the study requiring a significant amount of in-class time, away from usual classroom activities. Please consider recognition with an appropriate koha on study completion.
5. For the Facebook group please ensure privacy limitations are explained in the DTMP and PISCFs.
6. Locality authorisation is required at each locality (school) where the intervention is being conducted. Please ensure locality authorisation is obtained prior to commencing any study activity at the locality. The person providing authorisation should be aware of what needs to be assessed to grant locality authorisation; this information is available in the HDEC SOPS.
7. Please state if assistance would be provided for children who cannot read or understand the study questionnaires independently.
8. Please upload all questionnaires to HDEC that are planned to be used in the study.
9. Please upload the NIH toolbox that is being used.
10. Please upload the evaluation surveys.
11. On protocol page 6, table 3 questionnaire to measure dietary intake please ensure all questionnaires are culturally suitable and ensure the food pictures presented are suitable for the participants.
12. Please state if the vegetable boxes and recipes consider, different traditional veggies for Pasifika, Māori, Asian and other ethnicities, please include if halal/kosher recipes will be provided.
13. Please ensure that there is a clear plan for managing students within a participating classroom who are not taking part in the study, and whose parents have not consented or who themselves have not assented to take part including in study activities that do not involve data collection.

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

1. Please provide a PIS for the control group.
2. Please amend the advocacy email.
3. Please create and provide a dual assent/consent form for all children, the information in the current assent forms is complicated for children to read and contain points that the children may not understand fully.

All Adult PICFS:

1. Please clarify what the 'simplified intervention' consists of for the waitlist (control) group.
2. Please state whether the results of the cognitive or mental health tests will be shared with the teacher.
3. Please make it clear it is for the adult and the child; the adult is also participating via questionnaires and using the home-based resources and vegetables provided.
4. Please address what plan is in place if any of the questionnaires give rise to a need for follow up.

PISCF Whanau:

1. Please state if vegetable boxes are delivered weekly or at another interval.
2. Please review for complex words or sentence structure and simplify where possible.

PISCF Child:

1. Please note that not all children will be able to read this, the age range is from 7 to 11, there are too many complex words, especially for the lower age range. Please use lay language and appropriate language for the age range of 7- to 11-year-olds.
2. Please simplify the lay title.
3. Please clarify that "a simplified version of the intervention" means they get the fruit, vegetable boxes, school lessons and home resources but not assessments/data or stool collection, and the timing of this.

Parent PISCF:

1. From the application, it appears that non-consenting children will also take part in some of the study activities. Please clearly state which study activities the child will participate in regardless of consent, and whether there is any option to opt out of those activities.
2. Please make it clear that this is also providing consent on behalf of the parent/caregiver’s child.

Teacher PISCF:

1. Please review for statements that appear to have been copied from the parent PISCF.
2. The voluntariness of teacher participation is not clear, particularly with statement such as 'the principal .... have consented for your classroom to take part in this study'; please amend.
3. Please make it clear that the teacher's decision to participate will have no impact on evaluations, career prospects within the school etc.
4. The information regarding tissue management does not mention sending of samples to China, please include.
5. Please give an estimate of the total time commitment the study is likely to represent for teachers.

Tamariki Assent Form:

1. Currently the assent form is not appropriate for the likely comprehension levels of the child participants, and requires a thorough revision, please amend.
2. The statement: 'Because your principal and teacher have agreed for your classroom to take part....' makes it seem like the child needs to say yes. Please make it clear that it is fine to say no regardless of the parent, teacher or principal saying yes.
3. Please do not include mention of a koha or gift; this may be sufficient incentive to result in children providing assent.

**Decision**

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

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| **2** | **Ethics ref:** | **2023 FULL 15613** |
|  | Title: | CO44668: IMbrave152: Atezolizumab and Bevacizumab, with or without Tiragolumab, in patients with untreated, unresectable hepatocellular carcinoma |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | F. Hoffmann-La Roche Ltd |
|  | Clock Start Date: | 18 May 2023 |

Professor Edward Gane 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 registration with a WHO approved clinical trial registry. The Researcher explained that the study will be on clinicaltrials.gov and is a global study.
2. The Committee asked for reassurance that palliative care will be discussed with participants prior to them receiving and reading this in the PIS. The Researcher provided reassurance and explained that it is likely the participants will also be receiving palliative care alongside the study.
3. The Committee asked about the biopsy sections of the information sheet. The Researcher explained that the biopsy is not mandatory as this study is a phase 3 study, explaining that if somebody has a radiological diagnosis of HCC, they will not need a biopsy.
4. The Researcher explained the intention to have three study sites to provide for participants outside of Auckland, and the planned recruitment within NZ is 20.

**Summary of outstanding ethical issues**

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

1. The Committee asked about the data linking statement in the PISs and what data the researchers are anticipating will be collected and linked that is not study data.. The Committee asked the researchers to review the data linking statement. And explain clearly what datasets would be linked.
2. For the clinical trial registry please ensure the study is registered with a WHO-approved CTR prior to commencing the study in NZ.
3. Please amend references to ADHB policies.

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

PISCF Main:

1. On page 3 please state approximate number of New Zealand participants.
2. On page 7 please delete the reference to 'legally authorised representative'.
3. On page 12 please give an idea of how many people have been exposed to tiragolumab, and whether this includes long-term exposure.
4. The font used for the risk tables is 10 point and difficult to read. Please use the same size font as the rest of the document.
5. Please combine the risk information in the same place in the document (Sections 1.5 and 2.1/2.2) and delete repetition.
6. On page 18 please replace teaspoon with mL measurements to describe blood volumes.
7. Please explain what a biomarker is in lay language the first time this term is used.
8. On page 19 the description of mandatory genetic testing is broad and inconsistent with the description provided in F4.1 of the form; it is identical to the description provided in the optional FUR PISCF ('HCC 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 directly related to the study drug or disorder.
9. Please delete or amend the final bullet point regarding Māori data sovereignty; it is currently an instructional template statement.
10. Please remove caps lock of the lay title to make it easier to read.
11. Please ensure references are to Te Whatu Ora not DHBs.
12. For data linking on page 22 of the PISCF states that ‘your study data may be …. linked to other data collected from you'. Please explain what datasets are intended to be linked and how this will occur, given study data will be de-identified prior to being provided to the Sponsor.

PISCF Optional FUR:

1. On page 3 please amend font size in table to match remainder of document.
2. On page 8 the text states genome sequencing results will be made available 'if permitted by local law'. Please find out what the law permits locally and amend the statement to be applicable to New Zealand.
3. Several bullet points regarding access to identifiable information are not applicable to participation in the RBR itself (laboratory staff, compensation claims, GP etc). Please review and delete where applicable.
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.

PISCF Additional Biopsy:

1. On page 3 please amend font size in table to match remainder of document.
2. Please review consent clauses and retain only those applicable to this optional PISCF.

PISCF Treatment Continuation:

1. Please review consent clauses and retain only those applicable to this optional PISCF.

**Decision**

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

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

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| **3** | **Ethics ref:** | **2023 FULL 15596** |
|  | Title: | A study to evaluate the efficacy and safety of combination immunotherapy in patients with surgically resectable Hepatocellular Carcinoma prior to surgical intervention. |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | F. Hoffmann-La Roche Ltd |
|  | Clock Start Date: | 18 May 2023 |

Professor Edward Gane 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 pre-screening and the retention of data and/or tissue for those who are either ineligible or do not enrol. The Researcher explained that if participants do not continue in the study for whatever reason their tissue is retained. The Researchers further explained that if the participant is screened and the screen fails, blood samples are sent to central labs but no liver tissue. Liver tissue is only taken in this study after the participant is eligible and enrolled in the study, after which a biopsy will be taken.
2. The Committee asked why there are tracked changes in the forms when submitted to HDEC. The Researcher explained that this is an internal researcher error, and this application has not been reviewed by an HDEC before this meeting.

**Summary of outstanding ethical issues**

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

1. F5 of the application form states no genetic analysis will be undertaken; the treatment PISCFs discuss mandatory broad genetic testing. Please clarify and ensure that mandatory genetic analysis is restricted to research related directly to the disorder / drugs under study.
2. The application form references optional uses of tissue, whereas Section 10.2 of the DTMP states tissue use is restricted to mandatory uses specified in the study protocol only. Please amend to include optional research.
3. The text in Section 11.2.2 of the DTMP references data rather than tissue; please correct.
4. Please ensure the trial is registered with a WHO-approved CTR prior to commencing recruitment activities in NZ.
5. The PISCFs state data-linking will be undertaken. Please clarify what if any datasets external to data collected specifically for the purposes of the study will be linked.
6. Please state who will make the initial approach to the potential participants if approached directly or by phone.

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

1. The specific treatment arm PISCFs could be significantly shortened and simplified by not repeating a great deal of information already presented in the Screening / Treatment Assignment PISCF. A statement that 'the information provided in the Screening and Treatment Assignment PISCF continues to apply' (or similar) would be sufficient.

Mandatory PISCFs:

1. Please delete 'have liver disease' from the exclusion criteria; participants are likely to consider their HCC is a liver disease.
2. Please delete 'or legally authorised representative'; this is not relevant in New Zealand.
3. Please replace tablespoon with mL volumes for blood volumes.
4. Please put each use of tissue on new line for readability and explain 'antibodies' and 'biomarkers' in lay language the first time these terms are used.
5. The explanation of potential genomic analysis is too broad to be mandatory, as it includes 'and other diseases, possible links among diseases, variations in the sequence of genes and how they might affect a disease or a person's response to treatment, and new avenues for drug development and personalised therapies'. Please limit mandatory genomic research to analyses directly related to the disorder / study drugs and amend the PISCFs to reflect this.
6. Please state whether there is an any risk that an individual's genetic data could potentially be matched across databases (e.g. commercial or criminal genetic databases).
7. The PISCF states that exploratory biomarker analysis results will not be made available 'unless required by law'. Please find out whether release of results is legally required in New Zealand and amend the statement accordingly.
8. GP notification of study participation / abnormal results, and continued use of data post study withdrawal, are mandatory components of study participation (per the application form). Please remove optional tick boxes from the consent form.
9. State explicitly if genetic analysis is mandatory, this is not made clear in the PIS or across the documentation approved.

**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 Ms Sandy Gill.

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| **4** | **Ethics ref:** | **2023 FULL 15401** |
|  | Title: | RAIN-3202 (MANTRA-2): A study of Milademetan in solid tumours |
|  | Principal Investigator: | Dr Jane Yeojeong So |
|  | Sponsor: | Rain Oncology Inc |
|  | Clock Start Date: | 18 May 2023 |

Dr Jane Yeojeong So 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 how broad the scope of genetic analysis is for this study. The Researcher explained that the mandatory test is a genomic test on the tumour sample not the blood test to confirm eligibility.
2. The Committee asked if Medsafe has approved the study or the study drug. The Researcher explained that Medsafe has approved the study drug for use in the clinical trial only, the drug is not routine, not approved for use and is not Pharmac funded.
3. The Committee clarified the scope of the planned FUR.
4. The Committee asked if data being sent overseas will be coded. The Researcher confirmed that data being sent overseas will be coded.
5. The Committee asked if any samples will be tested locally. The Researcher confirmed that safety blood tests will be analysed locally, and other tissue will be sent to the central labs.

**Summary of outstanding ethical issues**

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

1. For section C16, please ensure local ethnicity data is collected for NZ sites, in addition to that specified per protocol.
2. Please amend the tissue retention time in the application form (F5) and DTMP (Section 10.1) for consistency.
3. Please amend section F5: the application form states all samples will be de-identified; the DTMP states some samples will be identifiable (e.g. Section 8.1). Clarify what is intended and ensure all documentation is consistent and amend as required.
4. Please add the sponsor, Rain Oncology Ltd, to the submission.
5. Please reference the NZ CRO (Infinity Consulting) in Section 2 of the DTMP if international CRO responsibilities have been delegated.
6. Participants should be given the option of refusing all further collection of data (including the researcher obtaining data from the GP). Please amend the PISCF consent to include this option.
7. Please amend the risks section it should not refer to the main study, there are no further benefits and risks only pertain to loss of confidentiality.

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

Pre-screening PISCF:

1. Please explain what gene amplification is in lay terms, in relation to eligibility for enrolment in the study.
2. Please make it clear that no other genetic testing will be performed.
3. If only historical / existing tissue is to be used, please delete the Compensation in Event of Injury statement.
4. Please delete 'identifiable' from the following sentence: 'you can request for your participant identifiable/deidentified samples to be destroyed'.
5. Please include what happens to tissue and data if the participant is not eligible or decides not to enrol.
6. Please include that the samples are coded prior to being sent overseas.

Main PISCF:

1. On page 2 please reference Medsafe rather than EMEA and FDA when discussing investigational status.
2. On page 3 please delete the first paragraph.
3. On page 4 please replace race with ethnicity.
4. On page 6 please explain what 'exploratory biomarkers' are in lay language the first time they are referenced.
5. On page 9 it is unclear whether the text about genetic biomarkers is describing optional or mandatory analyses. Please clarify what is intended and ensure this is plainly conveyed in the PISCF.
6. On page 10 please include uncommon / rare but potentially important adverse effects of the study drug.
7. On page 12 additional consent is required to collect pregnancy outcome information, please amend accordingly.
8. On page 12 please include the HDEC contraceptive paragraphs from the HDEC template.
9. On page 12 please reference Ethics Committee, rather than IRB.
10. On page 16 please state if testing for communicable diseases will be done and if so, please add this to page 16.
11. Please shorten the PIS by not repeating the information for each cycle-describe procedures once then use the table that has been included.
12. Please state that some samples will be analysed locally and that the results will be identifiable.

**Decision**

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

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

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

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| **5** | **Ethics ref:** | **2023 FULL 16790** |
|  | Title: | Phase 3 Study of Adjuvant V940 and Pembrolizumab in Resected Melanoma (V940-001) |
|  | Principal Investigator: | Ms Khay Leong |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited (MSD) |
|  | Clock Start Date: | 18 May 2023 |

Ms Khay Leong 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 discussed the need for PI oversight of an application, noting in this case an ethics start-up agency had been utilised. The Committee discussed the need to ensure all sections of the application were answered with relevant information.
2. The Committee asked where participants would be recruited from, noting the site is a private hospital. The Researcher explained that the site has been chosen for control of the logistics of the study, and that a clinical trials new site was under construction and intended to be used. The researcher confirmed that participants would be identified through the normal channels at Te Whatu Ora.
3. The Committee asked if the locality has a Māori research review process. The Researcher confirmed that the locality is Southern Cross and they do not currently have an internal Māori research review process, however the researcher will use a private Māori review process.
4. The Committee asked for clarification about the statement in the PIS as to the possibility of the vaccine containing an infectious organism. The Researcher explained that there is no specific risk of this vaccine when compared to any other vaccine and is a generic vaccine warning relating to a risk of contamination during production. The researcher confirmed the vaccine would be administered by suitably trained staff. The researcher confirmed a test for sterility would be conducted on the first vial, with procedures in place for destruction and replacement if required.
5. The Researchers made a note on ethnicity data, explaining that they are collecting it and that it is based on the New Zealand standards.

**Summary of outstanding ethical issues**

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

1. Please note that the indemnity certificate for the PI Dr Rivallands has expired.
2. Please fill in the organisation name throughout the document.[?]
3. Contact details especially cultural contacts should be completed before submitting, please amend.
4. The Committee has requested the GTAC approval, and any conditions imposed.
5. Please note that for doctor-patient relationship in section B21.1 where the researcher also provides clinical care to the participant, please ensure the participant speaks to a member of the research team not directly involved in his/her clinical care at some point in the recruitment process so as to provide the opportunity to decline participation outside the existing doctor-patient relationship.
6. Please ensure additional relevant ethnicity data is collected at New Zealand sites, should CRF-specified ethnicity groups not reflect the New Zealand population.
7. Please revise the submission. Reference to other submitted documents for further detail is accepted, however this should be supplemental. Affected sections of the form include:
8. Study Procedures (D19): no summary of study procedures / time commitment / number of visits.
9. Physical Risks (E1): no risk information provided. It is expected at a minimum that information regarding the most serious or common risks of the investigational product are summarised.
10. Primary Health Care Provider Notification (E5.1): the response provided does not answer the E5.1.
11. Tissue labelling and identifiability (F5): the response includes a cut and paste of large sections of the Data and Tissue Management Plan, most of which is not applicable to the question asked.
12. Please amend the collection of data post study withdrawal section, some of the submitted material states no further data will be collected post withdrawal from study; other documents state information will continue to be collected unless the participant contacts the researcher to state no further data is to be collected. If this is intended, please include a study withdrawal form with an optional tick box for ongoing collection of data post-withdrawal.

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

1. On page 4 please explain terms such as 'assay validation' and 'biomarker' the first time they are used or replace with lay language.
2. On page 5 please delete tablespoon blood volume measurements.
3. On page 7 please include which Māori cultural option is being used and remove the other template options and tidy up form.
4. On page 9 please state how many people have received V940 in previous trials, including how many individuals with melanoma.
5. On page 10: please review the statement regarding the risk that the first dose of V940 containing an infectious organism. Please include a statement for reassurance that the handling is the best clinical practice and safe.
6. On page 14 please explain that information regarding pregnancy outcome will be collected if the pregnant participant provides additional consent.
7. Currently the extent of genetic analysis is not well described, please clearly state whether the participant's entire genetic code will be analysed, and any additional risks associated with WGS.
8. Please provide reimbursement amounts in $NZD and enter agreed amount into the PISCF.
9. Please decide which travel reimbursement option will be used by the site and remove other options. and remove requirement to supply receipts.
10. On page 18 please include the Māori cultural option used by the site and remove the other template options.
11. On page 18 please adapt to New Zealand context and include the full name of the HDEC committee.
12. Please space out the consent statements.
13. Please provide more information about the questionnaires, especially the mental health questions, and have a safety plan in place if participants are distressed. This information should be included in the PIS/CFs.

Limited Screening PISCF:

1. On page 2 please clearly state what the blood sample will be used for..
2. On page 4 please explain terms such as 'assay validation' and 'biomarker' the first time they are used or replace with lay language.
3. Please delete tablespoon blood volume measurement.
4. Because genetic testing is being undertaken, please provide information about the extent of analysis as requested for the main PISCF.
5. Please review the entire section about use of information and delete all text not relevant to the limited screening the potential participant is consenting to. Entire paragraphs should be amended and/or removed.

**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 Ms. Kate O'Connor.

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| --- | --- | --- |
| **6** | **Ethics ref:** | **2023 FULL 15192** |
|  | Title: | Services Your Way: Evaluating a Youthline national counselling program |
|  | Principal Investigator: | Dr Jessica Stubbing |
|  | Sponsor: | Youthline Auckland |
|  | Clock Start Date: | 18 May 2023 |

Anna Williams 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 for clarification whether the application for approval relates to the pilot study alone or includes the full study. The Researcher explained the application seeks approval for the full study.
2. The Committee asked about the voluntary nature of participation for existing and newly recruited Youthline staff in delivering the SYW programme and the evaluation of it. The Researcher confirmed that participation is voluntary, and for those who are to deliver the programme training will be provided.
3. The Committee asked how many participants are planned for the pilot study. The Researcher explained that the pilot will conduct over the first 6 months of recruitment and will at the Auckland sites and they anticipate about 400 young people will be included in the programme during the 6-month period, anticipating over 1400 young people over the duration for the full study. The pilot study and the full study will include the staff surveys and qualitative interviews.
4. The Committee asked what other pathway is available for people seeking Youthline’s services who are not eligible or do not wish to participate in SYW. The Researcher explained that Youthline has a range of services that are offered to young people, and in relation to those for whom the SYW programme is not suitable, they have established procedures to support those young people to receive appropriate services.

**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 submit the following documents that are required for HDEC review and approval prior to use:
2. PISCF for staff
3. PISCF for youth interviews
4. Staff survey
5. Interview outline
6. Advertising material
7. Invitation script
8. Please attach the appendix for the protocol.

Protocol - Staff Participants:

1. The protocol states 'the implementation survey is 'to be completed by all key head office staff, management, and supervisors for each site, and at least 3 clinicians per site'. Please revise the protocol to ensure that it reflects the voluntary nature of participation.
2. Please include how many staff you plan to recruit.
3. Please include how staff will be approached regarding study participation.
4. Please include potential conflicts of interest and how they will be mitigated.
5. Please include whether there is a risk of re-identification due to the number of staff participants, if information is collected regarding role / other demographics.

Youth Recruitment:

1. Section D5 of the application form references a script to be used to invite young people to participate; this will require approval by HDEC prior to use.
2. In section D5 it states that 'potential participants will be informed about wait times across services to allow them to make informed decisions'. Please clarify whether the wait times on joining the study will be significantly different to standard care - and if so, whether this may unduly influence study participation (where the young person may participate in order primarily to get timely access to services).
3. Disability data is apparently not collected (submission C.17) yet the participants are asked about disability in the survey. Please consider whether you will collect disability data given a stated aim of the study is to assess whether diverse populations will engage with the SYW programme.

Data Management:

1. Please note that certain health data needs to be retained for at least 10 years. Please check whether this applies to any data generated in the current study and amend documentation if required.
2. Please ensure participants are made aware that any data entered into the clinical record cannot be withdrawn.
3. While the response to G6 states that participants can withdraw their data at any time, Section 12 of the data management plan (DMP) states 'Data collected prior to the participant’s withdrawal will continue to be used and analysed'. Please amend the DMP to reflect that data will be used if the withdrawing participant agrees to this.

Sponsor Authorisation:

1. As this is a new application to HDEC, Sponsor authorisation is required. Please amend to reflect this and ensure Sponsor authorisation is given prior to resubmitting.

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

1. Please make it clear that clinical records will be kept and form part of the participant's clinical records.
2. State the therapy sessions will not be recorded, and the clinician will not provide clinical notes to the research team.
3. Please clarify whether the SYW counselling programme itself is investigational, or whether it is available to non-participants at participating sites (i.e. whether the participant has to take part in the study to receive SYW counselling or will be able to access it as a client of Youthline).
4. Please state approximately how long the in-treatment and follow-up surveys will take to complete.
5. No information is provided about wait time across services, contrary to the response to D5. Please clarify what is intended and insert information if applicable.
6. Please state that there may be no benefits to participation.
7. Please address obligatory reporting requirements (circumstances where identifiable information may be shared with others, and whether this will be with / without the consent of the participant).
8. Please state what if any clinical data will become part of the research dataset, other than the questionnaire and survey responses.
9. Please amend data retention period to 10 years, if applicable.
10. For an observational, uncontrolled study, it is difficult to see why access to on-study personal health information would impact the scientific integrity of the trial. Please review and amend.

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

The meeting closed at 3.00PM.