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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25th October 2022 |
| **Zoom details:** | 96507589841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12.00-12.30pm | 2022 EXP 13538 | Pharmacological Regulation of Optical Properties of the Lens (PROPeL) Study | Dr Alyssa Lie | Mrs Helen Walker & Mx Albany Lucas |
| 12.30-1.00pm | 2022 FULL 12587 | Normal Swallowing Measures in Children | Ms Louise Bax | Dr Cordelia Thomas & Ms Julie Jones |
| 1.00-1.30pm | 2022 EXP 13386 | Whitu For School Randomised Controlled Trial | Dr Hiran Thabrew | Ms Sandy Gill & Dr Patries Herst |
| 1.30-2.00pm |  | Break (30 minutes) |  |  |
| 2.00-2.30pm | 2022 FULL 13144 | A trial to assess whether substituting A2VD for ABVD in early-stage Hodgkin lymphoma improves survival - RADAR | HD13 | Dr Leanne Berkahn | Ms Jessie Lenagh-Glue & Ms Patricia Mitchell |
| 2.30-3.00pm | 2022 FULL 12676 | Eastern Porirua Community Gout Project | Mr Ajay Kumar | Dr Cordelia Thomas & Mx Albany Lucas |
| 3.00-3.30pm | 2022 FULL 13732 | The long-term impacts of Covid-19 infection in NZ children | Dr Julie Bennet | Mrs Helen Walker & Ms Julie Jones |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/05/2018 | 22/05/2020 | Present |
| Mrs Sandy Gill | Lay (Consumer/Community perspectives) | 22/05/2020 | 22/05/2023 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Dr Cordelia Thomas | Lay (the Law) | 20/05/2017 | 20/05/2020 | Present |
| Ms Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Ms Julie Jones | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2022 | Present |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that no apologies had been received.

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 27th September 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 EXP 13538** |
|  | Title: | Pharmacological Regulation of Optical Properties of the Lens (PROPeL) Study |
|  | Principal Investigator: | Dr Alyssa Lie |
|  | Sponsor: |  |
|  | Clock Start Date: | 13th October 2022 |

Dr Alyssa Lee 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 undertaking of cultural consultation would be done after the ethics application; the Researcher voiced intent to do this within the optometry school at the University.
2. The Committee clarified that consenting would be done prior to pre-screening.
3. The Committee clarified the clinical exam schedule and specifically that the pre and post-drop testing would be done in one visit and then the MRI scans would be done in a follow up session/visit.
4. The Committee clarified that the administration of eyedrops in different age groups would be done both to ensure that the data is consistent for scanning given the age groups are characterized by differential ability for the eye to constrict and dilate, and to keep within budget for the 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 noted the koha would be different based on completion of the study. The amount would be consistent across participants at around $20 per hour. The Committee noted that paying for anything other than time would be taxable and that this should be the responsibility of the Researcher to pay. If the voucher was a reimbursement, it would not be taxable. The Committee noted that Westfield vouchers would not appear as a reimbursement and that cash would be more appropriate if possible. The Committee suggested that the phrasing be considered in consideration of taxation.
2. The Committee noted that there were limited human aspects covered in the peer review, please submit a new review as per the HDEC Peer Review Template.
3. The Committee noted that the protocol was not adequately detailed and did not list the inclusion and exclusion criteria or safety risks adequately. Please refer to the National Ethical Standards (9.7 & 9.8) for guidance on the detail required for review.
4. The Committee queried the risk for use of the eyedrops in pregnant and breastfeeding women. The researcher noted that the drug was not approved for use in this population. Please include safety risks in the participant information sheet (PIS).
5. The Committee requested that the protocol include details on assessments regarding ability to drive and more information regarding driving.
6. The Committee requested that participants be required to bring a support person, or a driver eye safety assessment provided before driving, or alternative transport be offered.

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

1. Please clarify the statement concerning “standard care” as this is currently unclear perhaps wording it “the standard care you may receive”.
2. Please define what “lying supine” is for participants.
3. Please define the sponsor of the study and state who this is for the participants. A change in phrasing may be required.
4. Please amend the reimbursement statements as required.
5. Please clarify whether participants can participate if they do not consent to inform the General Practitioner (GP).
6. Please amend the withdrawal opt-out to ensure that participants are aware if there is analyses already performed on the data they cannot withdraw fully.
7. Please firmly state that participants should not drive directly after having received the eye drops.
8. Please change the contact for Māori “health” support be amended to Māori cultural support.
9. Please include a statement to explain that pregnant participants will not be able to continue in the study.
10. Please amend the blinding statement as this is not correct and may cause undue panic in an optometry setting.
11. Please amend the blinding statement as the explanation is not correct.
12. Please include a statement informing participants that they will be assessed as safe to drive and how long they may have to wait before driving, i.e. up to 2 hours as indicated by the investigator.
13. Please clarify the sponsorship and auditing statements.
14. Please review statements around avoiding eye-makeup etc to be specific and less vague.
15. Please clarify the requirement to change out of clothing containing metal prior to scans.
16. Please amend mention of “usual doctor” to be a GP and ensure that reference to optometrists as doctor are amended.
17. Please remove consenting and information for data to be sent overseas and future unspecified research if this will not happen.
18. Please include a statement recognising the head being tapu such as the following: *We understand that Māori consider the head tapu and the researchers will be mindful of this and act respectfully. Should you have any concerns regarding appropriate practice/ tikanga to address cultural issues please let us know.*
19. Please remove the yes/no tick boxes from the consent form for all statements that aren’t truly optional, i.e. those where a participant could select ‘no’ and still participate in the study.
20. Please clarify when optical coherence tomography will be performed.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).
4. Please supply an independent peer review for the current version of the study protocol. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mx Albany Lucas and Mrs Helen Walker.

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| **2** | **Ethics ref:** | **2022 FULL 12587** |
|  | Title: | Normal Swallowing Measures in Children |
|  | Principal Investigator: | Ms Louise Bax |
|  | Sponsor: |  |
|  | Clock Start Date: | 13th October 2022 |

Louise Bax and Dr Anna Miles 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 that the children are the 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 noted that if the data is in use after a participant turns 16 that they will need to be reconsented and that this can be supplied as an amendment to the study should this occur.
2. The Committee requested that any questionnaires that will be used be provided for review.

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

1. The Committee suggested referring to the [HDEC template for the participant information sheet (PIS](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v3.0july2022.doc)) to ensure there is sufficient detail in the documentation for review.
2. The Committee noted that as the children will be the participants, the PISs will need to be amended to be addressed as “your child” or may contain some statement to note that “Where we refer to ‘You’, we are referring in all cases to you and your child”.
3. The Committee requested that there be a statement noting the ethical aspects of the application have been approved by Central HDEC as is in the HDEC PIS template.
4. The Committee requested that there be a statement, not only for the participants’ right to access but also to correct information
5. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: “If you were injured in this study, which is unlikely, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”
6. The Committee noted that there was not sufficient information as to the storage, access, and security of data and that this will need to be addressed in all information sheets.
7. The Committee requested a Māori cultural statement and that this includes recognition of information as taonga and the head as tapu.
8. The Committee requested that the contact details as per the HDEC template be provided in all information sheets, including contacts for Māori cultural, advocacy and HDECs.
9. Please ensure that there are headers and footers for version numbers, page numbers and dates.
10. Please review the section for requesting a summary of the study for typos.
11. Please review the statement “we don’t think anything bad will happen to you.”
12. Please review for repetitions.
13. Please detail what will occur should there be an issue with swallowing identified during the study.
14. Please note that reference to “we” needs to be removed as it should be either the child withdrawing or the parents.
15. Please note that there is a legal requirement for the health data to be stored 10 years from the time the youngest participant turns 16.
16. In the CF, please remove reference to “resident by proxy” or amend as required if this is to denote the parents consenting for their children.
17. Please specify who the support person would be where necessary in the CF.
18. Please expand on the abbreviation where referencing the additional ‘min’ (minutes) required for the X-ray.
19. Please specify who will be withdrawing participation. ‘We’ is not appropriate. The parents can either withdraw on behalf of the child, or the child can withdraw their assent.

The Committee requested the following changes to the Assent Form:

1. Please review and simplify for lay-friendly language.
2. Please review the yes/no statements for accuracy.
3. Please remove the mention of the “extra x-ray” and specify that this x-ray is simply slightly different.

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

1. Please note on page 7 there is a typo in the statement “When *you* child has their fluoroscopic…” This should be amended to refer to the child directly and not contain overly technical language such as ‘fluoroscopic’, i.e. “When you have your swallowing test.”.
2. Please consider amending the image with the toothbrush as this is potentially confusing.
3. Please define the term “cumulative” and review for lay language.
4. Please review for who is being addressed.
5. Please review for sentences without ends.
6. Please review for spelling.
7. Please review “something wrong with your swallowing” as this is a judgemental phrase.
8. Please review on page 10 the use of the phrase “hard parts of the project” and the further statement “we do not think anything bad will happen to you.” This could lead to children being scared to participate or believe that there may be ‘bad’ consequences to participation. Please remove repetitive information.
9. Please review for the repeat mention of flying to Australia.
10. Where there is mention of “we will tell you if there is something wrong with your swallowing”, please clarify that there will be informing of more than just the child of these issues, such as their parents and their general practitioner.
11. Please note that there is a legal requirement for the health data to be stored 10 years from the time the youngest participant turns 16.

**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 Cordelia Thomas and Ms Julie Jones.

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| **3** | **Ethics ref:** | **2022 EXP 13386** |
|  | Title: | Whitu For School Randomised Controlled Trial |
|  | Principal Investigator: | Dr Hiran Thabrew |
|  | Sponsor: |  |
|  | Clock Start Date: | 13th October 2022 |

No one from the research team was present via videoconference for discussion of this application.

Potential conflicts of interest

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

Ms Patricia Mitchell identified and disclosed a potential conflict of interest however the Committee felt that this was only a perceived conflict and therefore they were not excluded from the discussion.

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 this application was exceptionally valuable research but that the risks had not been correctly assessed for this age group.
2. The Committee requested how peer pressure would be managed in this age group.
3. The Committee queried how the researchers intended to control spread of information between intervention and control groups. *National Ethical Standards* para *9.7*
4. The Committee requested a detailed safety plan be in place for the questionnaires, specifically with how quick the turn-around will be with assessing these and ensuring that there was enough support in place should distress be identified. A risk assessment plan should also be provided. *National Ethical Standards* para *8.3, 8.4, 9.7 & 9.8*
5. The Committee requested that parents be informed by reliable means of this study. This could be a school app, pamphlet or email but should be direct to the parents and not via the children. *National Ethical Standards* para *9.7*
6. The Committee requested that there be a website or place for the parents to go to see the content that their children will be exposed to.
7. The Committee queried what the phases specifically of this study were and what would be occurring in each phase.
8. The Committee requested that the researchers refer to the templates for the [Participant Information Sheets,](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v3.0july2022.doc) the [Data Management Plan](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx), the statements for ACC (as in the PIS templates), [Māori cultural considerations](https://ethics.health.govt.nz/guides-templates-and-forms/cultural-questions-guidance/) and [Independent Scientific Peer Review](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx). *National Ethical Standards* para *9.7, 7.19, 7.15, 7.16, 3.1, 3.10, 12.15, 9.25- 9.32 & 6.25- 6.27*
9. The Committee requested that the researchers refer to the National Ethical Standards 9.7 & 9.8 with respect to the protocol as currently this is not adequate in detail for HDEC to review.
10. The Committee noted that the researchers would do well to bear in mind that many suicidal or severely mentally unwell youths are not attending school.
11. The Committee queried if the provision of phones would include the provision of data. *National Ethical Standards* para *9.7*
12. The Committee noted that the request for children in one of the groups to not access any other wellness apps in the 3 months after the study was a potential safety concern as other apps may be providing them with support that they need. *National Ethical Standards* para *8.3 & 8.4*
13. The Committee noted that providing a phone to children who may not already have one could open them up to additional risks of things such as cyber-bullying etc. that had not been accounted for by the research team. The provision of a phone could also be construed as an inducement to a child whose family could not afford one. *National Ethical Standards* para *8.3 & 8.4*
14. The Committee noted that the statement concerning the provision of this app to all children in the school after the 3-month period post-study completion “so that no one misses out from any potential benefit from a well-being intervention” showed significant bias towards this app working and should be reworded to be more neutral.
15. The Committee noted that there could be stigmatisation of children whose parents would not allow them to participate and that this needs to be accounted for in the safety plan.
16. The Committee noted that many cultures do not recognise mental health issues and that there may be shame or Whakamā involved in this that has not been adequately addressed by the researchers.
17. The Committee noted that the principal cannot give consent for the researchers to approach the students. This is still the remit of the parents/guardians and children to consent and assent respectively to.
18. The Committee requested the following changes to the Data Management Plan (DMP) *National Ethical Standards* para *12.15*:
    1. Please only include information relevant to this study.
    2. Please clearly identify who will have access to the data.
    3. Please clearly identify the sponsor and if they will have access to data.

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

1. Please review Page 1: parents should also discuss with their children if they want to take part. A sentence should be added to state that children will also need to give their assent to be in the study.
2. Please clarify on page 2 the statement “your child can decide to take part in the study…” to state that both the parent and the child need to consent and assent respectively.
3. Please rephrase the statement concerning random assignment into groups to not state “split into two”. This wording is not appropriate.
4. Please use the ACC statement as in the [HDEC PIS Template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v3.0july2022.doc)
5. Please include details for a Māori cultural support contact.
6. Please consider using a diagram to show the two groups as the text in the description of the study groups is confusing.

**Decision**

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

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| **4** | **Ethics ref:** | **2022 FULL 13144** |
|  | Title: | A trial to assess whether substituting A2VD for ABVD in early-stage Hodgkin lymphoma improves survival - RADAR | HD13 |
|  | Principal Investigator: | Dr Leanne Berkahn |
|  | Sponsor: | ALLG |
|  | Clock Start Date: | 13th October 2022 |

Dr Fadiya Al-abuwsi and Dr Leanne Birkin 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 offshore genetic testing would not identify any incidental findings and would only investigate certain blood levels of biomarkers.
2. The Committee clarified how data would be shared and where the genetic samples would be analysed and what data would be linked to this.
3. The Committee clarified that the deductible in the insurance certificate was not necessary as part of this application.

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 initial approach for recruitment be undertaken by someone not responsible for the primary clinical care of the participants i.e. their clinician.
2. The Committee requested removal and amendment of reference to district health boards.
3. The Committee queried whether there was support possible for applicants around travel expenses/koha. This will need to be detailed in the PIS/CF as possible.

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

1. Please note that the PIS is long and should be amended to reduce redundancies and be easier to understand for the participants.
2. Please explain what a PET-CT scan is, the first time it is mentioned, as some people will not be familiar with this procedure.
3. Please clarify who can take part in the study based on former cases of cancer.
4. Please consider utilizing a flow chart or table for the tests and procedures that will be part of participation.
5. Please specify if the pregnancy or parentage of children should be for the duration of the study or just the chemotherapy.
6. Please remove reference to “the AIDS virus” as this stigmatizing terminology.
7. Please modify "notify the local medical office in New Zealand " - to say 'The Medical Officer of Health'.
8. Please review to ensure the document is entirely in the first person.
9. Please clarify that barrier contraception is only to be used in addition to one of the highly effective or effective methods outlined – as it is currently worded (“may also”) it could be misinterpreted to mean that is a standalone option.
10. To the statement, "If you choose to participate in this trial, you will need to come to hospital for some extra visits to have tests done"; Add “Please see the diagram below which explains this further.” This allows the reader to be directed to the flow chart which is clearer to read.

**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 Patricia Mitchell and Mrs Jessie Lenagh-Glue.

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| **5** | **Ethics ref:** | **2022 FULL 12676** |
|  | Title: | Eastern Porirua Community Gout Project |
|  | Principal Investigator: | Mr Ajay Kumar |
|  | Sponsor: | Cannons Creek Pharmacy |
|  | Clock Start Date: | 13th October 2022 |

Ajay Kumar 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 if the researcher is still a trainee at the start of the study, that as per the code of rights this would need to be explained to the participants in the study.
2. The Committee clarified that the research would have implied consent should the survey be completed.
3. The Committee clarified that the koha was only for Group C.
4. The Committee clarified the purpose of the demographic questions in the survey about the number of people and or the number of adults in a household.

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 how the participants would be approached. The researcher noted that he had experience doing this. The Committee was concerned that this is a stigmatising condition and that there may be others present who may overhear this. The Researcher noted that there would be a side room in the pharmacy that would be available. The Committee suggested being as discreet as possible.
2. The Committee requested the participant information sheets (PISs) for Group A and B be provided for review.
3. The Committee requested that there be a face-to-face option for participants to speak with the researcher.
4. The Committee requested that the information sheets be combined for Group C.
5. The Committee requested an independent scientific peer review as per the [HDEC Template](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx).
6. The Committee suggested that there may be a need for interviewers of different genders to help in the interview process and making the participants more comfortable.
7. The Committee suggested having a flyer for potential participants for busy periods.
8. The Committee requested that the researcher use the [Data Management Plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) to ensure necessary details are provided to HDEC for review.
9. The Committee requested that the participants not be approached with the statement “it will help the community” as there could be some undue pressures attached to this.
10. The Committee suggested that an informal script be provided for the approach of potential participants.

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

1. Please include headers and footers to ensure there is versioning and dates for the sake of document control.
2. Please use the standard wording for the HDEC ethical approval as per the [HDEC PIS Template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v3.0july2022.doc).
3. Please include the standard HDEC cultural statement as per the PIS Template.
4. Please include a statement recognising data as a taonga.
5. Please include Māori cultural support contacts.
6. Please remove the tick-box for the yes/no question around the sharing of medicine.
7. Please ensure that statements for withdrawal and correction of data are included, specifically note this for the withdrawal after the data has been used/analysed.
8. Please include that participants have a right to correct their data, not only to request access to it.

**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 Cordelia Thomas and Mx Albany Lucas.

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| **6** | **Ethics ref:** | **2022 FULL 13732** |
|  | Title: | The long-term impacts of Covid-19 infection in NZ children |
|  | Principal Investigator: | Dr Julie Bennet |
|  | Sponsor: |  |
|  | Clock Start Date: | 13th October 2022 |

Dr Julie Bennett, Angela Chong, Neil Tee and Dr Amanda Kvalsvig 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 would be used immediately and not able to be re-identified then no reconsenting needs to be undertaken.

Summary of outstanding ethical issues

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

1. Please ensure that it is clear who is participating, specifically please be careful with use of “you” and “yours”.
2. Please remove all mention of being “happy” to do things and amend as ‘willing’.
3. Please specify that one child will be selected per household.
4. Please include Māori cultural support contact details to all PISs.

The Committee requested the following changes to the Children 11-15 Participant Information Sheet and Consent Form (PIS/CF):

1. Please make it clear in the statement "The telephone interview will take a maximum of 20 minutes." that this call is with the parents/guardians.
2. Please amend the sentence, "All information will be stored for ten years or until the youngest participant turns 16 years of age and then destroyed”, as the requirement for this is 10 years after the age of 16, not when the last person turns 16.
3. Please remove mention of “no one will be angry with you…” as this is not something the researchers can promise.

The Committee requested the following changes to the Children 16+ Participant Information Sheet and Consent Form (PIS/CF):

1. Please review the sentence "Answers given in the phone interview will be combined with other people’s information their name and contact information will be stored in a separate secure file so no one will know who said what." as it is currently hard to parse and may need some grammatical changes to be easier to understand.
2. Please specify what ‘de-identified’ means in relation to the de-identification of information.
3. Please remove the words “your child” from the sentence "If you do want to take part now, but change your mind later, you can pull your child out of the study at any time."
4. Please amend the HDEC ethical approval statement as only the ethical aspects of this study are approved by this Committee.

The Committee requested the following changes to the Children Under 10 Participant Information Sheet and Consent Form (PIS/CF):

1. Please clarify that some of the participants will have had Covid and that some will have not. This could be confusing for some.

**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).*

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 22nd November 2022 |
| **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 3:20pm.