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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 July 2023 |
| **Zoom details:** | 973 875 6003 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00 - 12:30pm | 2023 FULL 15536 | Detection of Kingella kingae and Staphylococcus aureus infections in children using cell-free DNA. | Dr Amy Scott-Thomas | Mrs Helen Walker and Dr Patries Herst |
| 12:30 - 1:00pm | 2023 EXP 18081 | Comparison between Nail and Locking Plate in three-part proximal humerus fractures, A pilot trial | Dr Zohreh Jafarian Tangrood | Ms Jessie Lenagh-Glue and Mx Albany Lucas |
| 1:00 - 1:30pm | 2023 FULL 18330 | Comparison of betamethasone cream applied to the skin | Dr Noelyn Hung | Ms Sandy Gill and Mrs Patricia Mitchell |
| 1:30 - 1:45pm | BREAK (15 mins) |  |  |  |
| 1:45 - 2:15pm | 2023 FULL 18059 | Exploring rider engagement during horse riding | Dr Rachelle Martin | Dr Cordelia Thomas and Dr Patries Herst |
| 2:15 - 2:45pm | 2023 FULL 17949 | Clinical trial of MK-1242 compared to placebo for heart failure | Dr Bryan Mitchelson | Mrs Helen Walker and Mrs Patricia Mitchell |

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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) | 22/03/2020 | 22/03/2024 | Present |
| Ms Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | 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 27 June 2023 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2023 FULL 15536** |
|  | Title: | Development of a non-invasive “liquid biopsy” for Kingella kingae and Staphylococcus aureus infections in children using cell-free DNA. |
|  | Principal Investigator: | Dr Amy Scott-Thomas |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 13 July 2023 |

Dr Amy Scott-Thomas was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee noted the application indicated the study involved kaupapa Māori methodology but it was unclear how. Please clarify or revise the answer.
2. The Committee noted the adult participant information sheet (PIS) states participants aged 1 - 18 may participate and the protocol states up to 19. Please clarify.
3. The Committee queried whether a biostatistician would receive identifiable information and why this would be necessary. Please clarify or revise.
4. The Committee queried whether a Te Reo Māori version of the information form would be available and suggested creating one if not.
5. The Committee requested the Researcher adapt the [HDEC data and tissue management plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-tissue-management-template-Nov2022.docx) and complete all applicable sections. The Committee advised this does not need to be a standalone document and can be included in the protocol but all missing sections will need to be included.
6. The Committee queried whether parking and travel costs would be reimbursed. Please include information on whether this will be available or not in the information sheet.

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

1. The Committee suggested replacing 'bugs' with 'bacteria' in the 7-11 assent form to avoid confusion with insects. The Committee requested a simple definition of bacteria be included.
2. The Committee noted some children may be unfamiliar with the term 'wee' and suggested 'pee' or another age-appropriate word.
3. The Committee requested a line at the beginning of the 16-18 PIS to advise participants they are invited to join the study because they have a bone/joint infection.
4. The Committee requested information explaining to parents that children over 7 must give their assent to participate ("e.g. "If you consent for your child to take part and your child assents to take part..").
5. The Committee requested Māori health support be rewritten as Māori cultural support.
6. The Committee requested 'carriage' on page 3 be simplified e.g. "if present in your swab".
7. The Committee requested inclusion of the cultural statement from the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) in all information sheets.
8. The Committee requested the removal of the 'yes/no' boxes on the consent forms unless they are truly optional (i.e. a participant can answer 'no' and still participate in the study).
9. The Committee requested pictures of the swabs in mouths and noses in the information sheet so children understand what they will be used for.
10. The Committee requested a simplification for the assent process for 7-year-olds (e.g. circle a smiley face instead of writing the date).
11. The Committee requested a clarification on what is meant when the sheet states urine will be collected in the "usual manner" in all sheets. The Committee noted the 12–15-year-old sheet stated it would be collected in a pottle and the others did not.
12. The Committee requested the addition of "(if needed)" after the statement of nurses helping collect urine in the 16–18-year-old sheet.
13. The Committee requested information advising parents can help with the urine collection for the younger children.
14. The Committee requested removal of the statement regarding greater solidarity with other families.
15. The Committee requested additional information on the swabs when they are first mentioned and specify that they will go into the nose and mouth (the sheet currently states this further down).
16. The Committee requested the language in the sheet be gender neutral when it refers to a doctor ordering "his samples".
17. The Committee requested insertion of the ACC statement and the right to access and correct information from the HDEC template in the 12-15 year old PIS.
18. The Committee requested a clarification that both parent and child must agree to participate and the child may withdraw assent at any time.
19. The Committee requested a revision to check the language around consenting on behalf of children (e.g. to specify it is "consent for your child" to participate). The Committee noted the sheet is unclear in several places referring to "yours" when it should read "your child's".

**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 data management plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Dr Patries Herst.

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| **2** | **Ethics ref:** | **2023 EXP 18081** |
|  | Title: | Comparing Nail versus Locking Plate in displaced three-part proximal humerus fractures; A pilot randomised controlled trial (PHINZ trial), investigating the feasibility of a definitive RCT |
|  | Principal Investigator: | Dr Zohreh Jafarian Tangrood |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 13 July 2023 |

Dr Zohreh Jafarian Tangrood and Dr Richard Lloyd 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 noted home visits would be removed from the protocol and a safety plan would no longer be required.

Summary of outstanding ethical issues

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

1. The Committee queried how potential participants would be identified. The Researcher explained patient cases would be discussed at an orthopaedic meeting and if a patient with a three-part fracture was eligible to participate they would be approached with an offer to join the study. The Committee requested the initial approach be clarified in the protocol so the lead researcher makes the first approach to potential participants alone, and then if they are interested in participating in the study the surgeon can provide more information at a subsequent time. The Committee advised this is to avoid participants feeling undue pressure to participate if they first learn of the study from the surgeon who will be operating on them.*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.7).*
2. The Committee requested more information in the data management plan to specify what deidentified data will be collected and what it consists of (e.g. pain scores). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15 ).*

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

1. The Committee noted some of the language in the information sheet may be difficult to understand and requested a revision for ease of readability.
2. The Committee requested the '(PHINZ)' acronym be moved to after 'Proximal Humeri Intervention New Zealand' for clarify.
3. The Committee requested more information on what the post-operative physiotherapy will involve (e.g. one session per week progressively more strenuous) and what information the research assistant will collect.
4. The Committee requested the statement on receiving antibiotics be simplified to state "receive appropriate treatment".
5. The Committee requested the line "your surgeon will change the treatment based on his own medical experience" be amended to state "your surgeon will change the treatment based on their own medical experience".
6. The Committee noted several bullet points in the consent form that could be removed (e.g. the participant can continue to ask questions, putting the name at the end).
7. The Committee requested a bullet point in the consent form for participants to agree for their GP to be informed of their participation and any abnormal findings.
8. The Committee noted the table on page 5 was useful and requested additional text explaining what will happen at each appointment.
9. The Committee requested relevant information from the data management plan is transferred into the PIS under the "What happens to my information" section.
10. The Committee requested information in the sheet advising participants that they and their GP will be informed of any incidental or abnormal findings.
11. The Committee requested the phrase regarding long term collection of data to benefit surgeons in New Zealand be rewritten to state better patient care.
12. The Committee noted the language of the sheet shifts between "lead researcher" and "main researcher" and requested a revision for consistency.
13. The Committee requested an option for participants to receive study results on the consent form.
14. The Committee noted the statement "I authorise access to my health records as described in the information sheet" and noted this is not discussed in the sheet. Please add information in the sheet on what records will be accessed and for what purpose.
15. The Committee suggested rewording the sentence "there will be no negative effect on you" on page 2 as this cannot be guaranteed.
16. The Committee suggested rewording the phrase "we will improve our skills" on page 3 as this could be misinterpreted as implying the surgeon is practicing or unskilled in the operation.
17. The Committee noted the statement "the surgeons who perform the surgery are required to be experienced at least ten times for both nail and plate implant surgeries together (five surgeries for each type)" is confusing and suggested "whichever type of surgery you receive (nail or plate), your surgeon will be experienced in performing this surgery". The Committee noted if the number of times is important then "they have completed at least 5 (nail or plate) implant surgeries before" in brackets could be added.
18. The Committee requested removal of the statement "contribution to this research will give you a sense of self-satisfaction and enable you to gain valuable knowledge about the research process."
19. The Committee requested the phrase "this is because these problems may cause the treatment won't work properly" on page 6 be reworded.

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mx Albany Lucas and Ms Jessie Lenagh-Glue.

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| **3** | **Ethics ref:** | **2023 FULL 18330** |
|  | Title: | A pivotal in vivo bioequivalence study comparing betamethasone cream (Nova Chem, Australia) to Diprosone® cream (Organon, Australia), using the ED50 for Diprosone® cream calculated from the pilot dose duration-response study and using 90 responders with the expectation to have 40-60 subjects who meet the responder and detector criteria (“evaluable”). |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Zenith Technology Corporation Ltd and Nova Chem Australasia Pty Ltd |
|  | Clock Start Date: | 13 July 2023 |

Dr Noelyn Hung and Linda Folland 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.

Ms Jessie Lenagh-Glue declared a potential conflict of interest and recused herself. Ms Lenagh-Glue relinquished voting rights and did not participate in the discussion. Quorum was retained for the discussion.

Summary of outstanding ethical issues

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

1. The Committee queried why participants would be tested for HIV and hepatitis in screening. The Researcher stated it was a universal precaution for staff safety. The Committee noted standard procedure for a needle stick injury includes testing for HIV and hepatitis so the testing may not be necessary. The Committee requested a statement in the information sheet to advise participants the test is for staff safety as the current wording may lead a participant to believe it is to determine their eligibility to participate in the trial. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15).*
2. The Committee noted the information sheet states no interpreter is available and requested a correction if one will be available.
3. The Committee requested a flowchart to explain why investigations such as ECG would be undertaken and what they are.
4. The Committee requested pregnancy is added as an exclusion in the study advertising.
5. The Committee noted the information in page 2-3 of the PIS is dense and recommended simplifying it e.g. with a chart or table.
6. The Committee requested a statement advising that Māori cultural support contact information is available at the end of the sheet in the cultural statement.

**Decision**

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

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

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| **4** | **Ethics ref:** | **2023 FULL 18059** |
|  | Title: | Exploring how rider engagement within the therapeutic horse riding landscape can be optimised: a participatory action research approach |
|  | Principal Investigator: | Dr Rachelle Martin |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 13 July 2023 |

Dr Rachelle Martin and Lena Aewerdieck 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 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 as the study would involve research on a disability service the [Code of Health and Disability Services Consumers' Rights (the Code)](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/) would apply and opt-out consent would not be possible as this is inconsistent with the Code. The Committee requested the protocol be re-designed to seek opt-in consent. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.1).*
2. The Committee requested the inclusion of any relevant statistics or prevalence data in Māori (e.g. how many people who come to Riding for the Disabled are Māori) when answering C4 in the resubmission if this information is available. *National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.1).*
3. The Committee queried whether participants who turn 16 would be reconsented into the study. The Researcher confirmed they would and would provide them with the appropriate form. The Committee advised that participants who turn 16 with competence to provide their own informed consent can be reconsented and participants who do not have capacity to provide their own consent can have parental consent to participate until they turn 18. The Committee recommended doing research on competence assessments. The Committee advised consulting a participant's clinician may be appropriate for this purpose though it would require their consent in order to do so. *National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.26).*
4. The Committee recommended revising the inclusion criteria to a maximum of 18 years old. The Committee advised that from age 18 parents could no longer give consent on behalf of their child to participate in research. The Committee advised that adults who lack capacity to provide informed consent cannot legally participate in research unless they have a welfare guardian to consent on their behalf or their inclusion is in their best interests to be consistent with Right 7(4) of the Code. *National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.70).*
5. The Committee noted the person who would sign the site information sheet would not be a study participant and would only be authorising use of the site. The Committee advised it is sufficient to receive a letter from the individual authorising the site and their consent as a participant is not required. The Committee requested the letter specify the person authorising the site is the elected president of the group.
6. The Committee noted the data management plan stated information would be held for 'up to' 10 years and advised data must be retained for at least 10 years. The Committee requested this be updated in the data management plan. *National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*
7. The Committee requested section 10 of the data management plan be updated to include information on the study's consultation process. The Committee noted it currently states consultation will be undertaken "with the following relevant communities/stakeholders" and then the section ends.
8. The Committee noted section 12 of the data management plan stated a participant could withdraw their data but noted this may not be possible from the anonymised field observation notes. The Committee requested the data management plan and PIS be updated to reflect this.
9. The Committee recommended splitting the assent forms based on level of understanding rather than age and to have one predominantly visual for participants with lower understanding and one primarily verbal for participants with greater capacity.
10. The Committee requested information in the researcher safety plan to detail what the Researcher would do if something inappropriate or unsafe is observed. The Committee requested information explaining this process be included in the participant information sheets.
11. The Committee noted the response to question C5 in the application form and advised whakamā may be present in Māori participants. The Committee recommended the Researcher become familiar with this concept.
12. The Committee recommended submitting the resubmission back to the Central HDEC. The closing date for the Central HDEC's August meeting is **Thursday 10 August** and the closing date for the September meeting is **Thursday 14 September.**

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

1. The Committee requested the Researcher adapt the HDEC information sheet and consent form template as this contains all necessary prompts to comply with [Chapter 7 of the National Ethical Standards.](https://neac.health.govt.nz/national-ethical-standards/part-two/7-informed-consent/) *National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 ).*
2. Please explain the NZRDA acronym the first time it is used in all sheets.
3. The Committee requested a statement advising how much time the focus groups / interviews will take and that anyone who wishes to take part can do so in the information sheets.
4. The Committee requested footers and page numbers be included in all information sheets.

Under 14 PIS:

1. The Committee noted the under 14 PIS states "no one can identify who you are" on the second page. The Committee noted other people in the group will be able to identify the participant and requested an update to reflect this. The Committee suggested amending the phrase to state the study's publication will not identify who individual participants are.
2. The Committee noted assent will be sought for under 14s and parents/guardians will provide consent on their behalf. The Committee requested an update to the PIS to reflect this.
3. The Committee noted the statement advising that a "parent or caregiver can be part of the conversation" and suggested including "or anyone else you trust".   
   The Committee requested the inclusion of Māori cultural support contact information
4. The Committee requested a safety plan for Researcher home visits. An alternative would be to remove home visits from the protocol and have all study processes take place on-site.
5. The Committee noted information in the assent form checklist that is not covered in the preceding information (e.g. "I know that I won't be paid for taking part in this interview.") The Committee requested an update to include information on all items in the checklist.

Youth 14-16 PIS:

1. The Committee requested a revision to simplify language such as "optimise" and "engagement processes" for ease of readability.
2. The Committee requested the addition of "or anyone else you trust" when the sheet advises participants to discuss with relatives.
3. The Committee requested the inclusion of the ACC statement from the HDEC template.
4. Info in assent not in PIS,
5. The Committee requested the inclusion of Māori cultural support contact information.
6. The Committee requested an update to include information on all items in the assent checklist in the information sheet.

Parent / Guardian PIS:

1. The Committee noted the sheet begins with "Dear caregiver" and requested this be updated to state "parent / guardian".
2. The Committee requested the addition of "or anyone else" when the sheet advises to discuss with relatives.
3. The Committee noted the sheet states "whether or not your child participates" and requested this be amended to state "whether you agree for your child to participate".
4. The Committee noted both the parent and child would have to agree to participate and requested the sheet be updated to refer to "you and your child" (e.g. "You and your child can withdraw consent").
5. The Committee requested more information regarding the recordings and transcriptions such as where the data will be stored, how long it will be stored for, what will happen to the deidentified data and what will happen to identifiable information. The Committee recommended adapting the section from the HDEC template.
6. The Committee requested the inclusion of the ACC statement from the HDEC template.
7. The Committee requested the inclusion of the right to withdraw statement from the HDEC template.
8. The Committee requested the inclusion of the right to access and correct information statement from the HDEC template.
9. The Committee requested the reference to a brochure be amended to state information sheet.
10. The Committee requested the inclusion of Māori contact details.

Advisory group PIS:

1. Please include how much time will be involved.
2. Please include the ACC statement from the HDEC template.
3. Please state that information will be retained for a minimum of 10 years.
4. Please include Māori health contact details.
5. Please include the prompt from the HDEC template advising participants of their right to access and correct information about themselves.
6. Please include the prompt from the HDEC template advising participants they can withdraw from the research at any time and what will happen to their information.
7. Please include a confidentiality clause for participants to agree to not to discuss what others say.
8. Please specify that a support person can be present during both the interview and the focus groups.
9. Please clarify whether recordings are audio or visual. The Committee noted there may be ambiguity when discussing field observations and participants may think they are being video recorded.

**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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| **5** | **Ethics ref:** | **2023 FULL 17949** |
|  | Title: | A Phase 2/3 Randomized, Placebo-Controlled, Double-blind, Clinical Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Vericiguat in Pediatric Participants with Heart Failure due to Systemic Left Ventricular Systolic Dysfunction (VALOR) |
|  | Principal Investigator: | Dr Bryan Mitchelson |
|  | Sponsor: | Merck Sharp & Dohme |
|  | Clock Start Date: | 13 July 2023 |

Dr Bryan Mitchelson, Margaret Joppa, Valerie Carlioz and Rafael Souza 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 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 participants who turn 16 during the course of the study will be reconsented. The Researcher stated they would reconsent them on the adult PIS. The Committee suggested adding a paragraph to explain the participant's parents had consented for them to be in the study and now they are being approached for reconsent.
2. The Committee queried how privacy would be ensured for the Tanner and breast exam. The Researcher confirmed there was opportunity for a chaperone and the exam would take place in a private clinical room. The researcher confirmed participants would have the opportunity to specify a preference for the clinician conducting the exam's gender. The Committee requested information explaining this and a prompt to specify a gender preference be included in the information sheet and consent form.
3. The Committee requested a proof-read of all participant facing documents to ensure all Māori words have correct spelling and macron usage.
4. The Committee recommended including a koha for rangatahi / tamariki participants in addition to the reimbursement of expenses for parents / caregivers.
5. The Committee suggested splitting the assent forms based on level of maturity and understanding instead of age.
6. The Committee noted the oral suspension storage instructions were unclear referring to store "at 15°C and 25°C" on the first page and requested this be clarified to 'between'.

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

1. The Committee requested all potential side effects be added to the information sheet. The Committee advised this could be attached as an appendix at the end of the sheet.
2. The Committee note the sheet states participants would need to be abstinent and requested a plain language explanation explicitly stating what they must abstain from. The Committee requested the Researcher adapt the gender-neutral wording from the [HDEC reproductive risks template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-v.4.0-april2023.docx)
3. The Committee noted some adolescents under 16 do have sex and requested age-appropriate information regarding contraception and positive pregnancy tests in the 12-16 PIS.
4. The Committee requested the phrase 'able to have a baby' be changed to 'able to become pregnant' on the main PIS and 12 - 16 PIS.
5. The Committee requested a description of ECG when it is first mentioned in the form as it is currently not described until further down the sheet.
6. The Committee requested tea and energy drinks be added when the sheet states participants should not smoke or drink coffee.
7. The Committee noted participants aged 16-18 could complete the quality-of-life questionnaires themselves and would not require their parents to do so on their behalf.
8. The Committee requested the statement that participants would be withdrawn if they are not 'able' to follow instructions be changed to 'do not' follow instructions.
9. The Committee noted pages 12 and 13 refer to 'doctor', 'GP', 'your doctor', 'usual doctor' and requested a revision to clarify and be consistent about who the sheet is referring to.
10. The Committee noted the information about the Health Information Privacy Code in the PIS was not necessary and could be removed.
11. The Committee suggested simplifying the younger assent form by replacing 'parent or guardian' with mum or dad.
12. The Committee requested the inclusion of the full cultural statement in all information sheets.

**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 Mrs Helen Walker and Mrs Patricia Mitchell.

## General business

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

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| **Meeting date:** | 22 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 2:45pm.