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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 07 September 2021 |
| **Zoom details:** | Meeting ID: 88566263350  <https://mohnz.zoom.us/j/88566263350> |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.15pm | Confirmation of minutes of meeting of 03 August 2021 |
| 12.30pm | **New applications** |
| 12.30-12.55pm  12.55-1.20pm  1.20-1.40pm  1.40-2.05pm  2.05-2.30pm  2.30-2.55pm  2.55 – 3.20pm | 21/NTB/227  21/NTB/229  *Break (20 minutes)*  21/NTB/230  21/NTB/231  21/NTB/235  **Substantial amendments**  NTY/08/06/055/AM22 |
| 3.20-4.40pm  4.40-5.05pm | *(Break 1 hour 20 minutes)*  **New applications (continued)**  21/NTB/228 |
| 5.05pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 13/08/2021 | 16/08/2021 | Present |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Susan Sherrard | Lay (consumer/community perspectives) | 19/03/2018 | 19/03/2022 | Present |
| Mr Barry Taylor | Non-lay (intervention studies), Non-lay (observational studies) | 13/08/2021 | 16/08/2024 | Apologies |
| Ms Maxine Shortland | Lay (consumer/community perspectives) | 13/08/2021 | 16/08/2024 | Apologies |
| Dr Gabrielle Jenkin | Non-lay (intervention studies),  Non-lay (observational studies) | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The Chair opened the meeting at 12pm and welcomed Committee members, noting that apologies had been received from Maxine Shortland and Barry Taylor.

The Chair noted that the Committee would not be quorate for this meeting. The Chair proposed continuing with the discussion and making an interim decision, which will be peer reviewed by another HDEC member and the decision letter will contain the full confirmed decision. The Committee agreed with this approach.

The Committee noted and agreed the agenda for the meeting. However, it was agreed that applications 21/NTB/229, 21/NTB/230, and 21/NTB/231 were out of scope and could have been or could be considered by an institutional ethics committee (IEC). The Committee agreed to explain to the respective researchers the reasons why these studies were out of scope and provide an opportunity for the researchers to present their applications to an IEC instead.

## Confirmation of previous minutes

The minutes of the meeting of 03 August 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **21/NTB/227** |
|  | Title: | ECMT-154 for the Topical Treatment of Eczema |
|  | Principal Investigator: | Dr Gabby Shortt |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 August 2021 |

Dr Gabby Shortt and Alex Semprini 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 Study**

1. This study aims to test whether cream containing ECMT-154™, a mānuka-oil based extract, is effective at treating eczema. Pre-clinical experiments have demonstrated ECMT-154™ has anti-bacterial properties which could reduce the risk of eczema rashes becoming infected. ECMT-154™ extract may also have anti-inflammatory benefits to help treat eczema symptoms. A first-in-human study with 118 participants.

**Summary of resolved ethical issues**

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

1. The Chair stated that the request for a closed meeting is declined as commercial sensitivity is not sufficient justification under the New Zealand Public Health and Disability Act 2000. The Committee reassured the researchers and sponsor that the discussions are focused on the ethical issues of the study and will not disclose a trade secret. The researchers confirmed they would like to continue with the review under the open meeting conditions.
2. The Committee noted that screening and consenting is being done by pharmacies and queried how each pharmacy has been trained to consent to Good Clinical Practice (GCP) standards and can undertake the SCORAD assessments, etc. The researchers stated that the pharmacies must complete online and in-person GCP training to join the study. They advised that these pharmacies have experience in gaining consent as the researchers have used them for previous studies on similar skin conditions. They added that they will undertake SCORAD training with the pharmacies at the site initiation visit.
3. The Committee asked how the researchers can be sure that a pharmacy is not pushing recruitment due to receiving a participant finders-fee. The researchers clarified that the finders-fee is a small payment to cover the pharmacist’s time and will not cause undue pressure to participate.
4. The Committee noted the researchers’ confirmation that it is a phase 1 study and queried why the researchers are not using a placebo control. The researchers responded that they do not have the control because the previous study showed that those using the placebo cream had a marked improvement with their treatment and therefore, they are not sure if the study treatment has any benefit compared to placebo at this point.
5. The Committee queried if there is compensation for costs to participants (e.g. general practitioner (GP) visits) for study related injury and or ineffectiveness of the medication/control. The researchers confirmed that these study related injury costs will be covered by the study team.
6. The Committee queried if the participants who were receiving their (standard of care) treatment from their GP, will be disadvantaged by moving into the trial and no longer receiving the support from their GP. The researchers responded that to be enrolled the participants need to be relatively stable and will be monitored by the research team through a weekly diary.

**Summary of outstanding ethical issues**

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

1. The Committee raised concerns about the unusual phase 1 study design (i.e. randomised control trial, long duration, large number of participants) and the lack of clarity on how safety of the study treatment will be evidenced, given the study treatment is first-in-human. The Committee advised that while the patch test is a good start, more detailed steps are required to ensure a level of confidence that safety testing has occurred in phase 1 and 2 and that the treatment is safe to use before moving into phase 3 (randomised control trial). The Committee recommended the researchers break up the study design by stepping through the standard first-in-human processes Further, please document the risk mitigation activities in the protocol (e.g. sentinel dosing, stopping rules) and a write up of the testing data results (e.g. how tested, dosing, duration, any adverse events, etc.). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 10.11 – 10.14).* The Committee recommended the researchers get advice on how best to structure the phases and provided the following example:
   * Phase 1: treatment is tested on healthy volunteers. This could be the patch test with a more detailed data write up as described above.
   * Phase 2: treatment is tested on larger participant cohort with the condition in minor form. Sentinel dosing could be used in a small participant group in a controlled environment e.g. start with one participant and, if no serious side effects, move up to two participants, etc. through to five/six participants.
   * Phase 3: treatment is tested on participants with the true condition the cream is intended to treat. A randomised controlled trial to test efficacy of medicine provided the safety data from phase 2 supports the safe use of the treatment.
2. The researcher advised that any participants showing signs of infection or exacerbation will be referred to their GP or pharmacist by the research team. The Committee requested the escalation procedure in the protocol and the participant information sheet and consent form (PIS/CF) is amended to reflect that allergic reactions will be managed by the research team and not told to contact their GP if they experience issues. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
3. The Committee noted the researcher’s confirmation that the information on diagnosis and adverse events will be participant reported and will not be corroborated through medical records. It advised that the results reported will need a caveat that they are participant reported and not medically confirmed (i.e. will not be able to say participants were diagnosed with eczema). Likewise with adverse events and if any of these are extensive (e.g. burns) then medical reports will be required to ascertain if the cream caused the reaction. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.55).*
4. The Committee noted that pregnancy is an exclusion criterion and advised that, given the treatment is first-in-human and the effect on a foetus unknown, it is important to confirm the exclusion criterion with a pregnancy test rather than relying on self-reporting. Further, this plan should include managing a participant should they become pregnant during the study and clearly communicated to participants. For guidance, see the pregnancy and contraception statements on the [HDEC’s PIS/CF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc).
5. The Committee advised that the justification for not allowing participants to withdraw the data collected about them at the point of their withdrawal is not adequate. The Committee suggested ensuring participants are offered the option to withdraw their data up to the point of analysis.
6. The Committee noted the use of culturally significant Māori medicine for commercialisation and queried what consultation has been undertaken with Māori given Wai 262 which gives ownership of traditional Maori medicine to Māori. The researcher advised they have consulted Dr Matire Harwood and have a letter of support from her. She added that feedback from Dr Harwood was positive and that this type of treatment would be welcomed by whanau at her marae clinics as they are eager to use natural products over steroids. The Committee requested this letter of support is provided to HDEC.
7. The Committee requested that the word ‘experimental’ or ‘novel’ pre-empt the word ‘treatment’ on all advertisement material. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.11).*
8. The Committee were concerned that the insurance cover of $1m appears low for a first-in-human trial with 113 participants compared to what it would standardly see (i.e. $5m-$10m). Please reconsider the insurance cover to ensure it is proportionate to the potential risks. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.5a).*
9. The Committee noted the peer reviewer’s concerns that included training of pharmacists on eczema scoring and use of the SCORAD tool, and the clinical photo not being acceptable for scoring. The Committee requested the researchers provide a response on how they will address the scientific validity issues raised by the peer reviewers. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.25 – 9.32).*
10. The Committee noted that the data management plan and (PIS/CF mention future use of data, however it does not state what for. To support fully informed consent, please, be specific about what kind of future research the data may be used for in the study documentation (e.g. relating to this medication or eczema in general). (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.14c).*

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

1. Please add sponsor address to page 1.
2. Please provide more detail about what the electronic diary involves.
3. Participants are repeatedly told that they cannot take part if they are allergic to any ingredients in test formulation. Please explain what those ingredients are.
4. Please add a statement to reassure participants that existing facial routine and sunscreen are allowed.
5. Please state if the $200 payment at the end of study will be pro-rated if a participant withdraws early (e.g. due to allergic reaction).
6. Please distinguish whether the “study site” is the pharmacy (in the data section).
7. Aqueous cream is mentioned in inclusion criteria but there is no reference to it in study procedures section directly above. Please include an introduction of this requirement prior to the inclusion criteria.
8. Please amend the escalation procedure on page 4 and page 5 for an allergic reaction as this should be managed by the study team.
9. Please amend page 6 to include compensation for GP visits related to reactions to the trial medication/control.
10. It is unclear in the form if patients are not allowed to use other eczema treatments on that area during the trial, and if they do, that they will need to notify the study team. If this is the case this needs to be clearly outlined in the PIS/CF.
11. Please reconsider the use of green as this will be problematic for people who are colour blind.
12. Please explain what a study ID is and why it is not identifiable, in the data section.
13. Use of deidentified and coded interchangeably may be confusing, please use one or the other.
14. The Committee suggests that no identifiable study information is stored on the PIS/CF (e.g. participant ID) and the key codes are kept separately in a log for reidentification. Please remove.
15. The consent form clause talks about future research, please explain this in the body of the information sheet prior to the consent form.
16. Please ensure participants are made aware that they are required to stop all moisturisers and emulsion treatments as per protocol page 6. This requirement should be clear in study procedures (not just aqueous cream as per current inclusion/exclusion).
17. Please provide the Te Reo PIS/CF mentioned in the data management plan to the HDEC for review.

**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:** | **21/NTB/229** |
|  | Title: | Surgical antibiotic tissue concentration |
|  | Principal Investigator: | Dr Thomas Pett |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 August 2021 |

Thomas Pett 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 Study**

1. This study will investigate if tissue samples antibiotic concentrations correlate better to bioimpedance analysis compared to absolute weight and BMI to determine a more accurate way of calculating antibiotic dosage. Bioimpedance analysis is a method of calculating a person's lean and fat mass percentage by attaching electrodes to their limbs. The intended outcome of the study is to assist the prevention of surgical wound infections.

**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 the researcher’s comment of his intention is to undertake this study as part of a master’s degree. The Committee advised that this was not identified correctly when completing the application form and that masters projects are out of scope of HDEC review.
2. The Committee noted the researcher’s confirmation that he will not be retaining any identifiable data and it will be deidentified before analysis.

**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 an explanation of the study is added to the participant information sheet and consent form (PIS/CF) including pictures of electrodes on the body to help participants understand the study.
2. The Committee advised that Excel is not a secure location for storing research data and recommended the research database at the University of Auckland is used (e.g. Qualtrics).
3. The Committee advised it is communicated to participants in the PIS/CF that the study is being undertaken to obtain a masters qualification.
4. The Committee noted the researcher’s clarification that the amount of tissue used in the procedure is approximately 1-2 grams. The Committee suggested the amount of tissue required is communicated to participants in a way that will give them a sense of scale (e.g. 1-2 grams, the equivalent of a thumb tack).
5. The Committee queried if there are any risks of the procedure in addition to the surgery that the participant is already undergoing. The researcher confirmed that the removal of a thumb tack of extra tissue at the operation location will not cause an additional bruising or pain, etc as the muscle will already have been cut through. The Committee suggested that participants are reassured of this (e.g. that they will be sore, but their recovery is not expected to be delayed in any way).
6. The Committee advised that a sponsor needs to be identified for this study (e.g. University of Auckland’s research office or postgraduate office) and the study documentation updated accordingly.
7. The Committee advised that the data and tissue management plan (DTMP) will need to reference the data policy from University of Auckland (or Waikato DHB).
8. The Committee requested the DTMP and PIS/CF are much clearer on who the third-party MIR facility (Hamilton Radiology) accessing participants data is, what they are accessing and why.
9. The Committee noted the researcher’s clarification that data will be de-identified and there is no secondary use of data planned. Please correct the DTMP accordingly.
10. The Committee noted that the protocol mentions accessing hospital and/or GP records and requested this is also included in the DTMP and PIS/CF.
11. The Committed noted that application question 0 has been answered incorrectly as the device is not a test device, it is an approved medical device for measurement.
12. The Committee advised that laptop (question r.2.2) is not appropriate for data storage and research data must be stored on a secure server (i.e. at University of Auckland).
13. The Committee noted that both peer reviews are by early/mid-career people and that HDEC would prefer the study is peer reviewed by a senior academic.

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

1. Please proofread and remove typos (e.g. ‘withdraw all your data collect’).
2. Please identify a sponsor (i.e. University of Auckland) and add University of Auckland logo to documentation.
3. Please state what the treatment ingredients are, for allergy purposes.
4. Please be more specific about the information that is being accessed from hospital/GP records as per the protocol.
5. Please state that you will be seeking consent to access medical records for adverse event recording up to six weeks after surgery and include a consent item.
6. Please include information from section 11.1 of the DTMP in the PIS/CF.
7. Please state who will take the biopsies during surgery (e.g. your surgeon or an assisting registrar).
8. Please remove yes/no tick boxes from the consent form unless it is truly optional, such as GP contact.

**Decision**

This application was considered out of scope for decision by the Committee, as the study is being conducted principally for the purposes of a masters qualification. The Committee recommended the study is considered by the University of Auckland Human Participants Ethics Committee. *(Health and Disability Ethics Committees Standard Operating Procedures, para 31.2).*

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| **3** | **Ethics ref:** | **21/NTB/230** |
|  | Title: | Cognitive difficulties in OST service users |
|  | Principal Investigator: | Miss Tara Hayward |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 August 2021 |

Tara Hayward was present via videoconference for discussion of this application.

**Decision process**

The Chair advised that the Committee was not quorate. The Chair proposed continuing with the discussion and making an interim decision, which will be peer reviewed by another HDEC member and the decision letter will contain the full confirmed decision. The researchers agreed to this approach.

**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 Study**

1. This PhD research study will interview people receiving opioid substitution treatment (OST) about their experience of cognitive difficulties, and how they feel it affects their daily life (e.g. their thinking, memory, and concentration). The study will also seek feedback on the design of a future study. 10-15 New Zealand participants.

**Summary of resolved ethical issues**

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

1. The Committee advised that the population for this study have been incorrectly classified as vulnerable (in the context of medical research), as OST patients are not generally lacking capacity to provide informed consent. (*National Ethical Standards for Health and Disability Research and Quality Improvement, section 6 introduction*). Therefore, this level of research (low risk observational) should have been reviewed by the ethics committee at the University of Otago (UoO) rather than HDECs.
2. The Committee offered the researchers the choice to withdraw from HDEC and follow the UoO ethics process or continue with the more extensive HDEC process and monitoring. The researcher chose to follow through with the HDEC review in respect of the time and effort already committed by the Northern B HDEC and research team.
3. The Committee queried if any participants with cognitive impairment will have diminished capacity to consent and, if so, how these potential participants will be supported to give consent. The researcher responded that as potential participants are expressing their interest to attend (through advertising), he does not believe these potential participants, who are identifying as having cognitive impairment, represents diminished capacity to give consent.
4. The Committee noted that the study is based on self-reported cognitive complaints and the researchers will not confirm diagnosis. It queried the validity of this study design and why the researchers are not including an objective measure as participants may have pre-existing cognitive impairment or psychiatric condition prior to having methadone. The researcher responded that the research is based around subjective cognitive impairment, and they are more interested in the participants perceptions of their own cognitive abilities and how this influences how they function.
5. The Committee queried what OST data the researchers will be collecting. The researcher responded that only dose and duration information will be collected.

**Summary of outstanding ethical issues**

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

1. The Committee queried if there will be Māori mental health worker available for all participants and how confidentiality will be maintained. The researcher responded that there may be Māori support available at Hillmorton location to support the introduction process, but they would not attend the interview. The Committee advised that as this is not a true option for all participants, it would be better to state in the PIS/CF that this support will be offered to participants and they can choose to decline it.
2. The Committee advised that participants in a qualitative study should be given the opportunity to withdrawal their data if they leave the study (e.g. participants may regret information they disclose in an interview). Please amend the consent clause accordingly and explain this in the body of the information sheet (e.g. ‘If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw unless you withdraw after the study analyses have been undertaken’).
3. The Committee noted that the researches will need additional support with transcribing the interviews. Please ensure anyone not part of the research team has signed a confidentiality agreement and advise participants of this.
4. The Committee requested the supply of a data management plan for the lifecycle of the study to ensure the safety and integrity of participant data. This may either be incorporated into the protocol or a separate plan, but it must be study-specific and comply with *National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a.* For guidance, please see the [Data Management Plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) available on the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/).
5. The Committee advised that the protocol needs to be clear that the study will include anyone who thinks they have a problem rather than a diagnosed problem.
6. The Committee noted that an inclusion criterion is cognitively ‘stable’ and advised that this needs to be more clearly defined in the study documentation and advertising material. Please also provide more detail on what the exclusion criteria are (i.e. what you do want).
7. The Committee advised that the distress options outlined in the application (r.8.1) need to be detailed in the study documentation with a plan on how these will be managed. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
8. The Committee requested that a definition of cognitive impairment is included in the PIS/CF and advertising (e.g. ‘problems with thinking, such as problems with paying attention, remembering things, or planning for the future’).
9. Although a low risk study, there is no mention of how researchers would escalate any issues raised by a participant in terms of suspicion of depression/anxiety. Please include information in the protocol and Participant Information Sheet to cover this.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Pease make the inclusion criteria clearer that the study will involve people who self-report cognitive complaints including people with psychiatric conditions, etc.
2. Please add Māori health support contact details.
3. Please add a consent clause that sates that participants understand they can decline to answer interview questions.
4. Please state that people outside the research team will be transcribing the interviews and that they have signed a confidentiality agreement.
5. Please review the 'What happens to my information section' of [HDEC’s PIS/CF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) and incorporate relevant components into the PIS/CF. This section should align to the information in your data management plan.
6. Please consider including an open-ended question for gender rather than prescribed categories.
7. Please ensure the purpose of the study is clearer, i.e. explain the research question being asked and what kinds of questions about thinking, memory, etc will be asked.
8. Please state what kind of questionnaires are being used and how.
9. Please ensure no identifiable data is collected in the PIS/CF (i.e. remove phone number, etc).
10. Please outline the ethical issues addressed in the application (a.1.6) in the risks section.
11. Please make the risk section clearer about how researchers plan to manage participants should they become distressed. (e.g. ‘if you are distressed by any of the questions, you may see your GP or contact health line’, etc.).
12. Please ensure the study procedures are detailed for participants to understand what will happen during the study (including the consumer group hui and how they will be invited and contacted).
13. Please add the following statement to the PIS/CF, ‘If you have concerns about your thinking or your cognitive function, you may contact your GP, or Healthline’.
14. Please provide more information about the interviews including the optional locations.
15. Please add that the research is part of the researcher’s work towards a PhD.

**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 Ms Sue Sherrard and Dr Gabrielle Jenkin.

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| **4** | **Ethics ref:** | **21/NTB/231** |
|  | Title: | Children, young people and families experience of systemic lupus erythematosus |
|  | Principal Investigator: | Dr Julie Blamires |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 August 2021 |

Dr Julie Blamires 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 Study**

1. This preliminary feasibility study aims to explore the experiences and perspectives of children, young people, and their whānau living with and managing systemic lupus erythematosus (SLE). The methodology will be Interpretive Descriptive (ID) which is a qualitative research methodology aligned with a constructivist and naturalistic orientation to inquiry. The primary data sources will be in-depth semi-structured family group interviews.
2. This study will take place in Auckland and will consist of family interviews with six children/young people with lupus who have attended the paediatric rheumatology clinic.

**Summary of resolved ethical issues**

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

1. The Committee explained to the researcher that the application was out of scope for HDEC review. The application is for a low-risk qualitative observational study. Although it involves children, they are assenting and consenting in the context of whānau/family. While vulnerability was indicated in the application form, the Committee agreed that there are no particular vulnerabilities in this study which would require HDEC review. The application is therefore something that would be fairly routine for the Institutional Ethics Committee (IEC) i.e. the Auckland University of Technology Ethics Committee (AUTEC) to consider. The researcher agreed to have the application marked as out of scope and to instead submit it to AUTEC.
2. The Committee acknowledged that the researcher had nevertheless taken the time to submit an application and offered some points of feedback as below.
3. The Committee cautioned the research to consider the situation of possible participant withdrawal from the focus group. If one participant decides to withdraw from the focus group, pulling out their data, and in terms of analysis, may become difficult. Participants should be advised that given it is a group interview they cannot withdraw.
4. The Committee referred to the documents for participants under 16-years-old. These have been titled as consents but they should be assents. For the young person with SLE over 16-years-old, this addresses them as if they are a parent with a child. Further, the parental information sheet needs to address the fact that they are consenting on behalf of the young person, and also that they are participants themselves.
5. The Committee asked if video recordings are used as well as audio. The researcher confirmed it is just audio recordings and will amend the Protocol to reflect this.
6. The Committee advised that the researcher will need to provide letters of support from Arthritis New Zealand as a requirement for university ethics criteria.

**Decision**

This application was considered out of scope for decision by the Committee, as the study is a low-risk qualitative observational study. The Committee recommended the study is considered by AUTEC.

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| **5** | **Ethics ref:** | **21/NTB/235** |
|  | Title: | New Zealand Pregnancy Cohort and Baby Cohort annual updates |
|  | Principal Investigator: | Dr Sarah Donald |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 August 2021 |

Dr Sarah Donald and Dr Lianne Parkin were present via videoconference for discussion of this application.

**Decision process**

The Chair advised that the Committee was not quorate. The Chair proposed continuing with the discussion and making an interim decision, which will be peer reviewed by another HDEC member and the decision letter will contain the full confirmed decision. The researchers agreed to this approach.

**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 Study**

1. The researcher has used de-identified data from the New Zealand Ministry of Health’s National Collections to create two cohorts: (1) the New Zealand Pregnancy Cohort (NZPC), and (2) a linked Baby Cohort which includes all births associated with the NZPC. These cohorts were established as part of the researcher’s PhD work and to date she has used them to describe (1) the overall patterns of prescription medicine dispensing during pregnancy, (2) the patterns of dispensing of medicines which have the potential to cause harm to unborn babies, (3) the dispensing of antidepressants before, during, and after pregnancy, and (4) the maternal and infant outcomes associated with antidepressant use during pregnancy.
2. The current proposal is to update the NZPC and Baby Cohort annually (currently they have data up to 31 December 2015). Such updates are time-intensive, but if the cohorts are routinely updated on an annual basis this will enable the rapid investigation of emerging concerns about the use and safety of specific medicines (as well as medical devices and vaccines) during pregnancy using up-to-date data. For all future studies based on these cohorts, the researchers will make separate study-specific applications to HDECs for approval.

**Summary of resolved ethical issues**

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

1. The Committee acknowledged and commended the value of what the researchers are trying to achieve through the study, noting that pregnant women are excluded from drug trials in New Zealand.
2. The Committee noted that the study involves a significant amount of data and the researchers underwent a tough peer review. The researchers had responded to the peer reviews points admirably in terms of justifying by including people in the data set.
3. The Committee asked if it would be possible for someone to withdraw from the study. The researchers stated that it would be very difficult to withdraw someone individually because they would not know who they are, as the information available to the researchers will be indexed to an encrypted National Health Index (NHI) number. The researchers do not have the de-encryption algorithm.

**Summary of outstanding ethical issues**

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

1. The Committee referred to governance of the data and noted that the researchers had done well on this aspect of the study. The researchers had considered the main issues i.e. who would have access to the data and on what grounds etc. The Committee asked if the researchers had looked at the NEAC *National Ethical Standards for Health and Disability Research and Quality Improvement 2019* (the Standards), specifically [Chapter 12](https://neac.health.govt.nz/national-ethical-standards/part-two/12-health-data/) regarding governance of databanks. The researchers confirmed they had. The Committee advised that under the waiver of consent application it appeared that the researchers were leaning on the previous waiver granted in an earlier HDEC application that refers to the former NEAC guidelines. Please amend this according to the updated Standards for justifying a waiver of consent rather than relying on the previous waiver and former guidelines. It would be sufficient to provide the information requested explicitly in the Protocol.
2. The Committee noted that the only aspect of governance structure in the Standards missing in the Protocol was transparency. This is part of a social licence to use health information without consent (social licence is discussed further below). The study website is an appropriate place for transparency activities to occur. The Committee noted that the website is hosted by the University of Otago. The Framework on the website is available, however, some links do not lead to any pages/information when clicked and there is a lot more responsiveness to public interest required. The Committee encouraged the researchers to make the website more functional and update it regularly with study findings. The Committee also suggested providing a link to the data access protocols etc.
3. The Committee noted in the application and Protocol it was clear that the researchers were doing work with Māori and Pasifika. The Committee asked if the researchers are doing social licence work in the pregnant and babies cohort (as healthcare consumers) i.e. talking to those groups and having ongoing relationships with such groups. The Standards for waiver of consent now recognise that there needs to be an outreach and a process by which researchers engage with the community whose data they are using. The Committee requested that the researchers designate time in the next year to establish a programme of outreach work, similar to Māori consultation/engagement and meet with relevant groups e.g. a women’s network, women’s pregnancy groups, people who have had adverse medication experience etc. The researchers should have an engagement and communications plan available on the website as well, where they reach out to the groups and inform them about how the data is being used, what the impact of the research is, to figure out how the groups would like their information fed back to them, and to ask what issues they think are worthy of research direction in this space. When using data from large populations of people, there is an obligation to let them know their data is being used and inform them of the intention behind the study. Please implement this as an ongoing project and provide information to the Committee by the next annual report.
4. The researchers asked what the Committee would be looking for in terms of publishing items on the website e.g. the findings of the study. The Committee advised it would be looking for the latest advice for pregnant women and that this be communicated fairly directly to intending mothers. Further, please provide an ‘updates’ page or something similar under ‘news/events’. Please also fix the errors where page links do not lead anywhere e.g. the ‘publications’ page. Please provide clear information on which datasets are actually being held and provide a ‘what we do’ page in lay language with information about the study. The Committee also recommended referring to the [Stats NZ Integrated Data Infrastructure](https://www.stats.govt.nz/integrated-data/integrated-data-infrastructure/) website for a good example of transparency.
5. The Committee advised that the researchers will need to submit substantial amendments for HDEC review if any data requires reverse engineering on the encrypted NHI. However, researchers who apply to use the de-identified data will not need HDEC approval as long as they are accessing the data according to the data access protocols that have already been approved by the Committee. Accordingly, researchers who need to do reverse engineering on the NHIs will need to apply to HDECs as substantial amendments under this umbrella project. It does not need to be an entirely new HDEC application. It would just be the Protocol and Data Management Plan as substantial amendments. In terms of reporting to the Committee, the annual report can list the whole set of data access approvals that the governance group has granted to others.

**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 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).*

## Substantial amendments

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **NTY/08/06/055/AM22** |
|  | Title: | Growing Up in New Zealand |
|  | Principal Investigator: | Professor Boyd Swinburn |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 August 2021 |

Professor Susan Morton, Professor Chris Cunningham, Professor Yun Sing Koh,   
Ms Manisha Morar, and Ms Amelia Willems 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.

Leesa Russell declared a conflict of interest related to this application and did not participate in the discussion.

**Summary of Study**

1. Growing Up in New Zealand (GUiNZ) is a longitudinal study of many facets of child development from womb to potentially 21-years-old. N= 6853 at the baseline dataset, and it began in 2008. A number of amendments have previously been made.
2. This amendment relates to the Pilot phase (Phase 2) of the ‘Our Voices’ project which is a new component of the GUiNZ study. Phase 1 of this component involved co-design workshops in January 2021 (as described and approved in NTY/08/06/055/AM16). This pilot phase seeks ethical approval to trial the co-designed digital platform (app) that has been created as a result of engagement with a group of 25 members of the cohort. The app has been co-designed to appeal to the cohort (currently aged 12 to 13 years of age) and also to collect novel qualitative information to complement and augment the quantitative longitudinal information being collected in the core Data Collection Waves - DCWs (most recently the 12-year DCW received HDEC approval - NTY/08/06/055/AM20).
3. The Leading light interviews have recently been completed. As part of those interviews, the Leading Light participants were asked if they would be happy to receive information about this new component of the study and this amendment will invite those who agreed to be part of trailing the app prior to it being finalised for the main cohort.

**Summary of resolved ethical issues**

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

1. The Chair noted that this would have been a good opportunity for new members of the Committee to be updated on the Kaupapa of this study. However, the Chair advised the researchers that the Committee was unfortunately not quorate.
2. The Chair thanked the researchers for the substantial amendment and noted that they had addressed all matters from the previous decline letter. The Chair was satisfied that the question sets will not cause hurt or upset and was now more reassured in terms of the use of trigger words and photographs.
3. The Committee asked if the researchers know how many participants in the main cohort do not have internet access. The researchers stated that from the last data wave they know that over 90 percent of participants have access to a device at home. Ninety-five percent have internet access. The researchers are also following up these numbers. For the main cohort, one of the pre-call questions is whether the individual has access to a device and/or internet. The researchers are working with their technical partners in order to not exclude participants who do not have their own device or internet access. The researchers stated that a lot of the pre-work done for this particular study phase has been to work with the technical providers and ask how they can enable the voices of people who are least often heard to make sure they are engaged. The researchers have funding in their budget for people who do not have access to a device or internet, for the duration of the study. The researchers advised that they will have more information when they submit their next phase for the cohort.
4. The Committee asked what the researchers’ response would be if a participant reported any illegal activity. The researchers stated that in the child protection plans they have set out, illegal activity is something that they are setting out to look for. They would assess the different levels of risk involved and according to what they are required to under the Privacy Act 2020 and New Zealand law in terms of disclosure, they would decide on balance what they would be required to disclose. The researchers stated that at the serious end of their risk spectrum, they know they may have to disclose information to authorities. This would likely be very rare, but the researchers advised that they have a hierarchy in how to manage the situation.

**Decision**

The Committee agreed to the Chair ruling this as a substantial amendment that did not require full Committee review. This will be reviewed and processed as an approval by the Chair through the expedited review pathway.

## New applications (continued)

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| **6** | **Ethics ref:** | **21/NTB/228** |
|  | Title: | (duplicate) Safety and Effectiveness of Eye90 Microspheres™ in the Treatment of HCC and mCRC |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | ABK Medical Inc. |
|  | Clock Start Date: | 19 August 2021 |

Associate Professor Andrew Holden and Helen Knight were present via videoconference for discussion of this application.

**Decision process**

The Chair advised that the Committee was not quorate. The Chair proposed continuing with the discussion and making an interim decision, which will be peer reviewed by another HDEC member and the decision letter will contain the full confirmed decision. The researchers agreed to this approach.

**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 Study**

1. The study is a prospective first in human study to evaluate the effectiveness of radioembolization using Eye90 Microspheres™ (the study device) in the treatment of patients with unresectable hepatocellular carcinoma and metastatic colorectal carcinoma.
2. The study device has not been approved for sale or commercial use in any country. Participation will provide data that will help determine whether the study device is safe to use in humans and provide preliminary information as to how well it works. The study will enrol up to 10 patients at Auckland City Hospital, New Zealand.

**Summary of resolved ethical issues**

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

1. The Committee acknowledged the work put into this resubmission of the application that had previously been declined by a different HDEC.

**Summary of outstanding ethical issues**

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

1. The Committee asked about the safety of people in the operating room in regards to radiation exposure, and participant aftercare. The researchers stated that in the operating room, there is a one-metre distance rule. They also have a Geiger Counter available. The research team are required to wear full lead and double gown with shoe shields, and these are disposed of securely. Everyone in the operating room is scanned and cleaned. In terms of the aftercare, there are several aspects to this stated in the Protocol. For example, patients are required to sleep on their own for the first week, discard their own waste products, and not go near pregnant women and young children. Please put more information in the Participant Information Sheet and Consent Form (PIS/CF) about the aftercare for participants with some simple advice.
2. The Committee sought reassurance about the study device being put into the body forever – it cannot be removed. The Committee asked how the risks of the study device travelling to or blocking up non-target parts of the body will be managed. The researchers stated that the study device involves targeted embolization. The incidence of a later migration of the study device to another part of the body has not happened before. By contrast, non-target embolization involves the risk of migration. The study device is staged to minimise any risk of non-target embolization. Please provide an explanation in the PIS/CF to give participants reassurance that migration of the study device to non-target areas of the body after the procedure has never been reported internationally or in New Zealand. Further, that the study device could be inputted in an area that was not intended during the procedure, however, a two-stage approach and technique are used to double check where the study device is going. Please use lay language to detail this.
3. The Committee asked if the delivery system is being tested as well as the study device. The researchers confirmed this and stated that the Co-ordinating Investigator has training planned for the delivery system and that one of the advantages of livestreaming the procedure is that there will be a cross-check that the procedure is being performed correctly. Please make clear in the study documentation that it is not just the study device being tested, but also the delivery system, and that information about the delivery system will be collected too.
4. The Committee noted that the sponsor will be present during the procedure by video link. The Committee asked that the researchers be clear in the Protocol and PIS/CF what the livestream is for and who is involved. Further, that the livestream is secure and is not recorded.
5. The Committee noted that the Data Management Plan (DMP) in the Protocol was high level but sufficient. However, the information about what participant information from the hospital is being collected was broad. Please clarify in the DMP and PIS/CF what information is being collected from participants’ hospital records i.e. that it is just information about the participant and their cancer treatment (rather than their mental health/sexual health etc.) Given that information is being sent to the United States and there is future unspecified use of data in the United States, it must be made clear to participants what information is being used, and to provide reassurance that it is not their entire hospital record in perpetuity being sent overseas. In terms of the DMP, it is sufficient to provide the additional information as an addendum to the Protocol.
6. The Committee advised that the study cannot be stopped for commercial/financial reasons. Please remove this statement from the Protocol. Please remove ‘administrative reasons’ as a reason for withdrawing participants from the study as this is very broad. Please also note that withdrawal of participants due to safety/non-compliance cannot be discretionary so please amend this sentence.
7. The Committee noted that at p.4.1 of the application, the researchers noted the prevalence of the disease in Māori. However, study is implied to be on a first-come-first-served basis. This may lead to all participants being of European descent. Given that a large proportion of the patient population is Māori, please actively ensure that Māori are recruited to participate in the study as well. Please outline what will be done to support the recruitment of Māori participants in the response to provisional approval letter.
8. The Committee asked if participants will be compensated for their participation. The researchers advised that they do not routinely compensate participants. However, they compensate for costs incurred such as parking, travel etc. The Committee suggested stating the District Health Board’s policy on reimbursement clearly in the PIS/CF rather than referring to ‘reasonable costs’ as this implies that the reimbursement of costs is subjective.
9. The Committee noted that the PIS/CF is long and complex. The Committee and researchers discussed and acknowledged the difficulty in capturing all important information in a PIS/CF while also making it accessible/readable for participants. The Committee suggested inserting a colour-coded table of procedures with locations.

The Committee requested the following additional changes to the PIS/CF:

1. Please include the box from the HDECs [Participant Information Sheet and Consent Form template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) with the statement that this is a first in human clinical trial and there may be no benefit to participation etc.
2. Please define the Eye90 Microspheres™ when it is first mentioned i.e., ‘the Eye90 Microspheres™ (the study device)’. Then state ‘the study device’ for the remainder of the document. Currently, this is only explained halfway through the document.
3. Please distinguish between ‘treatment’ and ‘study procedure’ from all other procedures involved and standard of care. For example, these terms are used frequently in respect of the angiogram. However, it is important to distinguish what the actual research procedure is i.e., when the study device is inputted.
4. In addition to clarifying what information from the hospital will be obtained (as noted above), please also be clear about what information will be obtained from participants’ general practitioners.
5. Please clarify what information the researchers want to obtain from the participants’ general practitioner.
6. On page 2, it states ‘the microspheres have had an element added to them, to make them radiopaque’. This is a vague statement – please provide a clearer explanation and confirm the safety/risks of this ‘element’.
7. Please present the risks in a risks table and use whole numbers (e.g., one in 10), not percentages. Start with ‘very common’ risks and go down to ‘less common’ risks etc. Please also give an indication of severity/seriousness of risks.
8. Please address whether there is a possible risk of migration of the microspheres.
9. In the final paragraph under the ‘Possible Risks’ section, there is a statement that the frequency of risks for the study are no different to those of other cancer treatments. However, this is a first in human trial and investigational product. Please provide clarification that there are similar cancer treatments with similar risks, but there will be some specific risks to this being a first in human study and investigational product and that these risks cannot be certain until the study is undertaken.
10. Please clearly explain the post-implant restrictions for participants e.g., no alcohol consumption, avoiding pregnant women and young children etc.
11. Please add what will happen to samples i.e., that they are destroyed as per normal laboratory policy, not sent overseas or used for anything else.
12. Please remove the paragraphs from the compensation section that refer to Medicines New Zealand Guidelines. Study devices are not covered by these guidelines.
13. Please include the computed tomography (CT) scan in the post-procedures on page 3.
14. On page 8, please reword the alternative to treatment paragraph – remove the word ‘only’.
15. Please replace references to the Central HDEC with the Northern B HDEC.
16. There is a broad consent about ‘additional information’. Please either clarify the ‘additional information’ being sought or remove this.
17. Please remove the statement that the information has been read to the participant in their ‘first language’ as some populations will have a number of first languages.
18. Please remove the section for an official witness to sign the Consent Form. The researchers confirmed they are not recruiting participant with diminished capacity.

**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 PIS/CF, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, para 7.15 – 7.17).*
3. Please update the study protocol (addendum to the protocol/response to the HDEC decision letter are sufficient, as above), 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 Kate O’Connor and Leesa Russell.

## General business

1. The Committee noted the content of the ‘noting section’ of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting:

|  |  |
| --- | --- |
| **Meeting date:** | 05 October 2021 |
| **Zoom details:** | TBC |

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 5.05pm.