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| **Committee:** | Northern A |
| **Meeting date:** | 15 March 2022 |
| **Zoom details:** | Zoom details:  Meeting ID: 965 0758 9841  Meeting URL: <https://mohnz.zoom.us/j/96507589841> |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12.30-1.00pm | 2022 EXP 12176 | Text based support following a suicide attempt | Dr Lillian Ng | Mr Jonathan Darby & Dr Kate Parker |
| 1.00-1.30pm | 2022 EXP 12086 | Experiences of injuries to the head as a consequence of domestic violence | Professor/Dr Alice Theadom | Ms Catherine Garvey & Ms Jade Scott |
| 1.30-2.00pm | 2022 FULL 11317 | Novel white crowns for drill-free treatment of dental caries in NZ children | Dr Joanne Jung Eun Choi | Dr Leonie Walker & Dr Andrea Forde |
| 2.00-2.30pm | 2022 FULL 11962 | TRITON glaucoma or ocular hypertension (Resubmission) | Professor Anthony Wells | Mr Jonathan Darby & Dr Sotera Catapang |
| 2.30-3.00pm |  | *Break (30 mins)* |  |  |
| 3.00-3.30pm | 2022 FULL 11767 | Finding a better nasal anaesthetic | Dr. Samuel Hale | Ms Catherine Garvey & Dr Kate Parker |
| 3.30-4.00pm | 2022 FULL 11630 | Preventing preschool wheeze hospital admissions | Professor Cameron Grant | Dr Leonie Walker & Ms Jade Scott |
| 4.00-4.30pm | 2022 FULL 12294 | Reboot KIDS - Healthy Eating for childhood cancer survivors | Dr Amy Lovell | Mr Jonathan Darby & Dr Andrea Forde |
| 4.30-5.00pm | 2022 FULL 12266 | A Study of SZN-043 in Healthy Volunteers and Patients with Liver Cirrhosis | Principal Investigator Prof Ed Gane | Ms Catherine Garvey & Dr Sotera Catapang |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Karen Bartholomew | Non-lay (Intervention studies) | 18/07/2016 | 18/07/2019 | Apologies |
| Dr Kate Parker | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey | Lay (the Law) | 19/03/2019 | 19/03/2022 | Present |
| Dr Sotera Catapang | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Dr Leonie Walker | Lay (Ethical/Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Dr Karen Bartholomew

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 15 February 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 EXP 12176** |
|  | Title: | Text based support following a suicide attempt |
|  | Principal Investigator: | Dr Lillian Ng |
|  | Sponsor: |  |
|  | Clock Start Date: | 03 March 2022 |

Dr Mike Ang, Dr Lillian Ng, and Danielle Diamond 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. The study evaluates the use of digital text-based intervention following a suicide attempt. These texts will be trialled, and service users will be interviewed afterwards about their experience.

Summary of resolved ethical issues

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

1. The Committee clarified that this HDEC application was for part 2 and part 3 of the study.

Summary of outstanding ethical issues

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

1. The Committee stated that the protocol needs to be much clearer (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7, 9.8, 9.22).* The changes requested include:
   1. Split procedures clearly into part 2 and part 3.
   2. Outline further the inclusion / exclusion criteria for service users. The Committee suggested that some who would be excluded due to disability could be included in the study by the use of supported decision-making techniques to support their ability to consent.
   3. Explain how participants will be identified before they are invited to participate. Waiver of consent should be sought to obtain health information without consent (7.47). The Committee noted that while the research team have access to this data as part of their clinical role, this is not the same as accessing it for research. More information is required on how this conflict is managed (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.5-11.6).*
   4. More information is required for part 3 around what standard of care involves for service users presenting acutely following a suicide attempt, including whether texting is already used.
   5. More information is required as to the access to health information that the researchers require to conduct the study after the initial assessment of eligibility.
2. The submission currently states there is a partnership between the area’s District Health Board (DHB) and an unnamed helpline, but how this relates to the provision of the text messaging is not explained in the protocol or participant-facing documentation. Further information about how participants are supported should also be outlined (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.1-8.6).*
3. The Committee stated more information in the Data Management Plan (DMP) is required to satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) is not mandatory but is encouraged to be adapted or used as a guide for level of detail required. The Committee noted in particular that health information needs to be stored for 10 years, and that detail around how data will be shared between researchers and confidentiality maintained is required (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.13, 12.15a).*
4. The Committee noted that peer support workers are also participants and therefore need their own participant information sheet (PIS) to outline what their participation involves (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.1).*
5. The Committee noted that it appears consent from service users is being sought after actual participation begins (receiving the text messages as that is the intervention being trialled). Consent is being obtained for the feedback portion currently and needs to include consent to receive the texts. Written consent should be sought before the participants receive texts. If the researchers intend to adapt the consent process to take into account the participants’ acute presentation and likely distress, please document justification for this in your protocol. This should include a justification for verbal consent, how this will be obtained and documented. The Committee discussed an abridged information sheet and noted that informed consent in some manner should be obtained initially as medical records are being accessed for the purposes of the text messages. Separation of clinical and research access to information should be made clear. The Committee suggested this could be a brief PIS given before discharge *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.8,7.8a, 7.14-7.17).*
6. The Committee requested a script of the content of the texts, even if they are drafts.

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. Ensure everything is first explained in PIS before it appears in the CF.
2. PIS is missing key aspects such as an explanation of why the person has been asked to be involved, and information about data collection, use and storage. The Committee recommended the Researcher refer to the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
3. Please update to state that the ethical aspects are reviewed and approved by the HDEC, not the University ethics committee.
4. Please include more information around risks, benefits and privacy.
5. Please inform participants that their GP will be informed.
6. Please outline how a participant can withdraw.
7. Information on the content of texts should be provided

**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:** | **2022 EXP 12086** |
|  | Title: | Experiences of injuries to the head as a consequence of domestic violence |
|  | Principal Investigator: | Professor Alice Theadom |
|  | Sponsor: |  |
|  | Clock Start Date: | 03 March 2022 |

Magdalena Durrant and Dr Claire O’Donovan 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. The study aims understand the experiences of adults who have experienced a Traumatic Brain Injury (TBI) in their lifetime as a consequence of domestic violence using a community-based qualitative design using interpretive descriptive methodology. Approximately 20 adults (10 in New Zealand, 10 in the United States) will be interviewed.

Summary of resolved ethical issues

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

1. The Committee clarified that the collaboration with a US-based researcher involves that researcher doing the same study and the de-identified findings will be compared after analysis.
2. The Committee clarified that information on the injury will rely on participant information in response to interview questions and the Researcher is not going through medical records nor are they diagnosing anyone with a TBI.
3. The Researcher clarified they are not restricting Domestic Violence to intimate partner violence.

Summary of outstanding ethical issues

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

1. The Committee noted that the Protocol requires clarification regarding inclusion of participants who may not have suffered a TBI, including an explanation that participants who do not disclose a history of this will not be excluded from the study. Following from this, the Committee noted that the interview questions indicated in the Protocol may require revision.
2. The Committee noted that clarification is needed on determining who meets the exclusion criteria, such as how and who determines whether a potential participant has an unstable mental or physical condition which renders them unsuitable to participate. Please clarify what the inclusion criteria is and the procedure for the screening process (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.9a*).
3. The Committee noted the following issues with the advertisement (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12)*:
   1. Participants are to be 18 years or over at the time of participation, however the advertisement refers to 16. Please clarify this means they may have suffered the relevant injury younger.
   2. Please clarify whether the study is looking for participants who experienced an injury to the head/brain (strangulation is included, this should be worded so it is sufficiently inclusive but does not attract participants who suffered other types of injury) or will include participants who may not have suffered a TBI.
   3. Please ensure the ethics reference number will be included.
4. Please ensure the CV for the Researcher conducting the interviewers is provided (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.23)*.
5. The Committee asked the Researcher to consider how else participants may be supported outside of the use of a crisis team for those who may need different levels of support or need support in follow-up after the interviews. This should be documented in the protocol and material provided to the participant (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.1-8.6)*.
6. Please refine in the protocol who are excluded from participation due to disability/mental health reasons, and how those with disabilities could be supported to participate (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7 & 9.22)*.

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. Under the heading "What is the purpose of the study?" please clarify this is for people affected by injuries to the head.
2. Under the heading "What will my participation in the study involve?" it currently states “you will be asked to complete an interview with a researcher”. Consider adding some general information about what topics may be covered in the interview so the potential participant is aware of what topics will be discussed. They will be discussing topics that may be sensitive and upsetting.
3. The [PIS template available on the HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) has specific wording when using identifiable information to pass on in the event of serious risk to health or safety. Please use this and clarify who is in the crisis team.
4. Please state whether participants can access their transcript before its deidentified to allow for corrections. Participants should be given the opportunity.
5. Please add an expected time frame for study results.
6. Make it clear this is for obtaining a PhD.

**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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| **3** | **Ethics ref:** | **2022 FULL 11317** |
|  | Title: | Novel white crowns for drill-free treatment of dental caries in NZ children |
|  | Principal Investigator: | Dr Joanne Choi |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 03 March 2022 |

Dr Joanne Choi, Dr Susan Moffatt and Samuel Carrington 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. The purpose of this study is to compare the effectiveness of a novel white shell crown system with the conventional metal (stainless steel) preformed crown for drill-free caries management (Hall Technique) in New Zealand children to establish whether these crowns could be viable alternatives to (or replacements of) the metal crown. The effectiveness of the novel shell crown system will be determined by the failure rates and requirements for re-treatment over a one-year period.

Summary of resolved ethical issues

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

1. The Committee clarified with the researcher that they are seeking HDEC approval for the feasibility study only.
2. The Researcher explained the composition of the white study crown, that it is suitable for use in the mouth and advised it will be manufactured locally by a manufacturer who meets GMP standards.

Summary of outstanding ethical issues

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

1. The Committee noted that the University needs to be named as the Sponsor and that insurance for the study is through the University in both the protocol and participant information sheet (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.17 & 9.8*).
2. Please provide information regarding the protocol/handbook for training and the hands-on training to be given to the dental therapists and oral health therapists who will be administering the crown (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.23*).
3. Please ensure that the protocol includes timeframes for assessing that the dental and oral health therapists are conducting the procedure correctly and, assessing the safety of the study crown(*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7 & 9.8*).
4. Please detail in the protocol the recruitment process and how much time a participant has to consider enrolling in the study, as well as when they provide their consent. Please also provide a copy of the invitation letter for participation (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.7, 9.7, & 9.8*).
5. The Committee noted that the peer reviewer made excellent comments but not all were addressed in the study (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8 & 9.32*).
6. Please remove irrelevant sections/sentences in the Data Management Plan (DMP) such as 8.4 (data overseas) and data linking. Ensure that information collected should be kept 10 years after someone turns 16 (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.28, 12.13 & 12.15a*).

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. The information sheets have technical descriptions. Please amend these to be lay-friendly.
2. The Committee noted there are missing sections of the participant information sheet in order to obtain fully informed consent such as a compensation statement. The Committee recommended the Researcher adapt the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
3. State that the white crowns have not been used previously in children or adults, and who has developed them.
4. Explain standard of care.
5. Explain that the participants will be randomised and why this is important.
6. State the number of children to be enrolled.
7. Please state what happens if either of the crowns fail in a particular child. State if they receive only the metal crown or would the trial crown be replaced with another.
8. Refer to fact that a participant will have no commercial interest in the white crown if it is developed for use.
9. Please clarify follow up. There is reference to 6 and 1 month follow up-is this in-clinic assessment, with X-rays and so on. Please state and ensure any variation from standard of care is noted.
10. The assent is too complex for some children aged 5-7years. Consider diagrams, and much briefer explanations.

**Decision**

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

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| **4** | **Ethics ref:** | **2022 FULL 11962** |
|  | Title: | TRITON glaucoma or ocular hypertension (Resubmission) |
|  | Principal Investigator: | Professor Anthony Wells |
|  | Sponsor: | Allergan Ltd. |
|  | Clock Start Date: | 03 March 2022 |

No Researcher was 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 Study

1. A multicenter, open label, Phase 3b study to evaluate the duration of intraocular pressure (IOP)-lowering effect and safety of up to three pro re nata (PRN) administrations of 10 µg Bimatoprost sustained release (SR) in the study eye of participants with open-angle glaucoma (OAG) or ocular hypertension (OHT) who are not adequately managed with topical IOP-lowering medication for reasons other than medication efficacy (e.g., due to intolerance or nonadherence). The purpose of this study is to obtain data on as needed administration of Bimatoprost SR.

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 lactating or pregnant women would not receive the standard of care being changed.
2. The Committee did not consider the peer review independent. Please provide an independent peer review.
3. The Committee noted the response to Point 3 in the resubmission. The Committee requested clarification of the plan for recruitment by reference to approaching people who have “previously consented to be contacted for clinical trials, have been in clinical trials with the site previously, or who have consented to contact through the clinics registration form.” Please confirm that potential participants from prior trials have consented to being contacted.
4. Please provide justification for collecting information on pregnancy of withdrawn participants. This can be consented separately if it happens but needs to be accounted for in the protocol.
5. The Committee queried if the implant site for PRN treatments is the same site as the original and what implications this may have for participant’s tissue.
6. Please clarify that no New Zealand participant has received the now-discontinued higher dose and if so, some rewording in the participant-facing information may be appropriate.
7. Please clarify the number of New Zealand participants as this is referred to as different numbers across different documents.
8. The Committee noted the explanation for needing a washout period and the brief explanation in the participant information sheet (PIS); participants should be advised what to expect with regard to any risks especially if it is a long period of time depending on what their current treatment is. Further, clarify if the participant becomes eligible for study treatment in the fellow eye, if this also has a washout period, and whether this can only be offered after the treatment in the study eye is complete.
9. The Committee noted the error in the application form (C.10) that still retains reference to genetic testing that has now been removed in the resubmission.
10. Please amend the Data and Tissue Management Plan (DTMP) in relation to notifying participants of a privacy breach, by reference to the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/). All breaches should be notified to a participant unless there is good reason not to do so (that is, the duty to notify a participant is not limited to breaches that are notifiable to the Privacy Commissioner).

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

1. Please remove the quotation marks around the word karakia.
2. Please outline likely frequency of assessments or insert a table of visits and what happens at each.
3. Please consider rearranging the order of ‘what to expect’ so it is logical for participants in order of procedures.
4. Please clarify what is meant regarding collection of safety information following withdrawal of consent.
5. Please clarify availability of study treatment after the study to New Zealand participants.
6. Please clarify the Fellow eye treatment and PRN treatment schedule and indication for participants.

**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 Mr Jonathan Darby and Dr Sotera Catapang.

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| **5** | **Ethics ref:** | **2022 FULL 11767** |
|  | Title: | Finding a better nasal anaesthetic |
|  | Principal Investigator: | Dr Sam Hale |
|  | Sponsor: |  |
|  | Clock Start Date: | 03 March 2022 |

Dr Sam Hale 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. Nasal endoscopy is a common procedure in otolaryngology (ear, nose and throat surgery). Cophenylcaine (a combination of lignocaine and phenylephrine, a local anaesthetic and decongestant respectively) is commonly used as a spray to make the inside of the nose numb prior to this procedure. However, other local anaesthetics like tetracaine are more potent than lignocaine and are likely to give greater patient comfort in this setting. Further, phenylephrine tastes very bitter, whereas other decongestants like oxymetazoline are essentially tasteless. On this basis, we wish to objectively determine the potency and rate of onset of tetracaine/oxymetazoline as an anaesthetic spray compared to cophenylcaine. We will subsequently enrol patients from tertiary rhinology (sinus and nose surgery) clinics who are having nasal endoscopy as a part of their care, and compare these sprays in terms of the comfort of the procedure and the tolerability of the sprays themselves

Summary of resolved ethical issues

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

1. The Committee asked about the healthy volunteers and the methods used to test sensation in the nose during the study. The Researcher explained and showed an example of the tool that is being used to test the sensation in the nose, being a filament that is touched onto the participant and gives a standardized pressure on that spot that was pressed. This is used to test the participants’ sensory threshold. This would give the Researchers an objective measure of the depth of anaesthesia at a given point in time.
2. The Committee asked about how potential participants for the first part of the trial are going to be recruited. The Researcher explained that they will recruit by word of mouth within the faculty but would be limited partly due to working at home and COVID-19 but are confident in finding 6 volunteers. The Committee noted if wider recruitment was necessary, then further recruitment documentation could be uploaded.
3. The Committee asked how the participants from the main study will be identified. The Researcher explained that they will be from both a private clinic list and a clinic running in the Auckland District Health Board (DHB). The Researcher’s intention was for the clinician doing the procedure to approach the potential participants, however acknowledged the Committee’s preference that recruitment is not by the treating clinician-researcher. A research nurse will be available to undertake recruitment.
4. The Committee asked about equity and why smokers and pregnant woman are being excluded from the study. The Researcher explained that smoking can potentially affect the lining of the nose, so exclusion was based on minimizing any potential unknown effect on the results. The Researcher explained there is a minor risk that pregnant people can be negatively affected by the nasal constrictor, leading to issues for the placenta and uterine lining, but noted that a nasal endoscopy would usually be performed during pregnancy if required.
5. The Committee asked if blinding is going to be possible given the taste and reaction many participants have. The Researcher explained that it may be difficult to blind but they will use a random number generator to assign which bottle would go into which nostril prior to each to clinic, the clinics would then give the sprays not knowing what spray which was. The Researcher explained that spray taste may not happen straight away and if the sprays are administered in quick succession the participant may not know what spray was responsible for the unpleasant taste.

Summary of outstanding ethical issues

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

1. Please amend the protocol and participant information sheet (PIS) to reflect how long the questionnaires will take, as even if brief, this will extend usual appointment time.
2. Please include consideration of rights to access and correct information for participants, and the steps that will be taken in the event of a privacy breach in the Data Management Plan (DMP).
3. Please be clear in the DMP whether any non-study information is held at the university (taken from medical records) and if study data is retained in the medical record.

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

1. Please provide what different doses of the combination of tetracaine and oxymetazoline are being used and what this is based on.
2. Please remove the statement in the healthy volunteer study PIS under the heading "Will any cost be reimbursed" as this says no costs will be involved and so no reimbursement. However, there are two visits and potentially a few hours involved-please consider appropriate reimbursement for volunteers who are required to travel to the site and pay for parking.
3. Please include a reimbursement for participants section such as paying for parking and travels costs etc. in the PIS for the participants undergoing nasal endoscopy.
4. Please amend the main participant information sheet as it currently refers to the involvement of doctoral candidates. Please explain what aspects of this are being used for a PhD and include this in the participant information sheet.
5. Please include what will happen upon finding potential significant abnormal findings in the participant information sheet first, not just in the consent form.

**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 Dr Kate Parker and Ms Catherine Garvey.

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| **6** | **Ethics ref:** | **2022 FULL 11630** |
|  | Title: | Preventing preschool wheeze hospital admissions |
|  | Principal Investigator: | Professor Cameron Grant |
|  | Sponsor: |  |
|  | Clock Start Date: | 03 March 2022 |

Professor Cameron Grant 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 is to determine if an orally administered bacterial lysate (OM-85) prevents hospital admissions for acute wheezy illnesses in children aged 1-5 years. The primary objective is to determine the efficacy of OM-85 for prevention of hospital admission due to an acute wheezing illness over a 12-month period in preschool aged children with recurrent wheeze compared with placebo. Secondary objectives are to assess the effect of OM-85 on subsequent recurrent wheeze events in preschool aged children with reference to: the number, severity and duration of wheeze episodes; health resource utilisation, lost productivity, and cost-effectiveness; and quality of life.

Summary of resolved ethical issues

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

1. The Committee asked about potential exclusion due to internet access being needed for the study. The Researcher explained that the weekly diary can be accessed through a cell-phone and that they are able to take devices into the family homes for the interviews to be conducted and then uploaded to the study data base to avoid participant exclusion.
2. The Committee asked about research staff and how recruitment will occur in terms of approach. The Researcher explained that they have a process where the research nurses can review the daily hospital admissions and from that information determine who is potentially eligible. For potentially eligible participants the research nurse will then discuss approaching the family with the clinical nurse. The research nurse then has a discussion with the family about the study and most of the recruitment will happen once the child has gone home from the health care centres.
3. The Committee asked about prompts for taking of medication for 10 days a month for 12 months and how the study medication is sent. The Researcher explained that they are planning to send it out every 3 months and will be using phone/text reminders to encourage medicine taking.
4. The Committee asked about potential sensitivity for parents and asked about the content of the planned information video. The Researcher explained that they will make questions and answers very clear for parents.
5. The Committee asked about e-Consent to ensure the appropriate person is providing consent. The Researcher explained it will be done with a tablet while study staff are with the family.

Summary of outstanding ethical issues

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

1. Please submit an Investigator Brochure for OM-85
2. Please amend D7 of the application form: if ads are being used, please submit them, as no advertisements were submitted.
3. Please submit the study video and study brochure used during recruitment mention in application (D9).
4. Please ensure the protocol describes the electronic consent methods *(National Ethical Standards for Health and Disability Research and Quality Improvement, para* 7.25).

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

1. Please provide more detail explain that the study medication will be sent every three months with a note for storage and dosing and missed dose instructions.
2. Please amend to let parents & caregivers know there will be text reminders sent.
3. Please include who retains the linking log and who is responsible for this.
4. Please include what steps would be taken if a privacy breach occurs.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7*).
4. Please upload the advertisements, taking into account the feedback provided by the Committee. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12*).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Leonie Walker and Ms Jade Scott.

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| **7** | **Ethics ref:** | **2022 FULL 12294** |
|  | Title: | Reboot KIDS - Healthy Eating for childhood cancer survivors |
|  | Principal Investigator: | Dr Amy Lovell |
|  | Sponsor: |  |
|  | Clock Start Date: | 03 March 2022 |

Dr Amy Lovell 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. Reboot-Kids is a parent-focused, web-based healthy eating intervention developed and piloted in a small number of families in Australia, that aims to help family/whānau understand how cancer treatment can affect children’s sense of taste, food preferences, and eating habits. It also aims to assist family/whānau in identifying and implementing helpful, practical strategies to improve fruit and vegetable intake and gives evidence-based approaches to managing fussy eating.

Summary of resolved ethical issues

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

1. The Committee asked about the application form and the risks involved with the inclusion of the lifeline numbers help services and asked if Pasifika help lines could be included alongside food disorder help lines. The Researcher explained that they have taken this information on board and will try to include more health lines that are more relevant to New Zealand.
2. The Committee asked about the questionnaires and a possible change of the questions themselves. The Researchers explained that they can change the order of the questions and have taken this information on board.
3. The Committee asked about the risks of stigmatisation associated with the study, in particular the cost of purchasing fruit and vegetables in New Zealand. The Researcher explained the study will include information sheets that will include all the foods that are available and how they will fit in their family dynamic such as canned foods and frozen foods. The researcher also explained that the dietitian will work with families based on what they have, rather than stipulate specific food purchases or meal plans.
4. The Researcher explained that this study is a pilot for New Zealand using information gained from the Australian study, rather than an arm of an Australian study.

Summary of outstanding ethical issues

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

1. Please amend the submission page 3: provide how many active human participants are included.
2. Please clarify the LEAP database.
3. Please remove Australian contact numbers and add New Zealand contacts if available.
4. Please let participants know that their interactions will be with a PhD student.
5. The minimum period to keep identifiable health data is 10 years following someone turning 16. This should be amended across all study documentation.

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

1. Please state the value of the koha.
2. Please provide details of the mental health safety plan, in terms of the protocolised steps that may be taken if concerns arise for participants during the study based on responses to the “emotional thermometer” or otherwise.
3. Please make it clear whether the study data is held in Australia or New Zealand.
4. Please clarify on page 6 that data will be stored for the minimum period required by New Zealand law (currently 10 years following children turning 16 for health data that relates to an identifiable individual)
5. Under "What happens if I change my mind"; please provide more information from the protocol about planned follow up if responses to the "emotional thermometer" indicate a need for help.
6. Please clarify whether any identifiable data is stored in Australia (namely the dietary recall in Foodworks).
7. The Committee suggested additional support services being listed in the PIS, specifically Pasifika services and Lifeline which was mentioned in the Protocol but was not outlined for participants.

**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 Mr Jonathan Darby and Dr Andrea Forde.

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| **8** | **Ethics ref:** | **2022 FULL 12266** |
|  | Title: | A Study of SZN-043 in Healthy Volunteers and Patients with Liver Cirrhosis |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Novotech |
|  | Clock Start Date: | 03 March 2022 |

Professor Edward Gane, Sharmin Bala, Julia O’Sullivan and Amanda Liang 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. A Phase 1 trial to characterise the safety and tolerability of single ascending doses of SZN-043 in healthy volunteers, a Novel Bispecific Fusion Protein Targeting ASGR1 and ZNRF3/RNF43.

Summary of resolved ethical issues

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

1. The Committee asked about managing compliance with the standardized meal. The Researcher explained the meal is given during the unit and prepared by a third party and includes a vegetarian option.
2. The Committee asked about treatment following the withdrawal of participants. The Researcher confirmed this and explained the participant is already under care from their physician if they do withdraw from this treatment they will continue to be treated as normally by their specialist/physician.
3. The Researcher explained the background to the HepQuant Shunt and its reason for use; the Researcher stated that this is in commercial use, and that it is low risk and provides relevant data for the study.

Summary of outstanding ethical issues

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

1. Please upload the Investigator’s Brochure.
2. Please clarify indication for drug administration by IV or infusion as it is related to volume of drug administration.
3. The Committee noted the following issues with the application form:
   1. C16 is not answered.
   2. D21: no smoking allowed for the whole duration of the study not just the inpatient stay. This is not clear in the advertising or participant information sheet.

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

1. Please include prohibition on smoking for entire study period; this has not been stated in the "You must not..." list.
2. Please clarify what is meant by the statement that the liquid ‘contains a label with no radioactive potential.’
3. Please revise to explain that it is a site requirement of NZCR that those coming onto site are double vaccinated and if appropriate following discussion with the Sponsor, alter the reference to receiving a booster.
4. Please amend the dosing regimen table.
5. Please provide the frequency and time points of blood withdrawal in PK and PD determination.
6. Please specify the test/s to be analysed in different laboratories overseas. Overseas samples all need to be retained for 10 years for study purposes, these go to different sites for analysis, and not all are explained.
7. Please ensure there is reference to all notifiable diseases that are being tested for.

**Decision**

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

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

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

## General business

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

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| --- | --- |
| **Meeting date:** | 19 April 2022 |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting.

* Dr Karen Bartholomew

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 5.00pm