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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 11 June 2019 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 11:00am | Welcome |
|  | Confirmation of minutes of meeting of 14 May 2019 |
|  | New applications (see over for details) |
| 11:30 – 11:55  11:55 – 12:20  12:20 – 12:45  12:45 – 1:10  1:10 – 1:35  1:35 – 2:00  2:00 – 2:25  2:25 – 2:50  2:50 – 3:15  3:15 – 3:40  3:40 – 4:05 | i 19/STH/68  ii 19/STH/101  iii 19/STH/100  iv 19/STH/102  v 19/STH/104  vi 19/STH/107  vii 19/STH/108  viii 19/STH/110  ix 19/STH/111  xi 19/STH/113  xii 19/STH/114 |
|  | General business:  Noting section of agenda |
| 4:05 | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 27/10/2015 | 27/10/2018 | Present |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Assc Prof Nicola Swain | Non-lay (observational studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 | Present |
| Ms Sandy Gill (co-opted) | Lay (consumer/community perspectives) | 30/07/15 | 30/07/2018 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Paul Chin | Non-lay (intervention studies) | 27/10/2018 | 27/10/2021 | Present |
| Professor Jean Hay-Smith | Non-lay (health/disability service provision) | 31/10/2018 | 31/10/2021 | Present |

## Welcome

The Chair opened the meeting at 11:30 and welcomed Committee members.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Sandy Gill confirmed her eligibility, and was co-opted by the Chair as a member of the Committee for the duration of the meeting.

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 14 May 2019 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **19/STH/68** |
|  | Title: | Micronutrients and traumatic brain injury: case studies |
|  | Principal Investigator: | Prof Julia Rucklidge |
|  | Sponsor: | N/A |
|  | Clock Start Date: | 28 March 2019 |

Professor Julia Rucklidge was present in person for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application, and no potential conflicts of interest related to this application were declared by any member.

Summary of Study

The aim of this study is to determine whether a micronutrient formula called DEN (Daily Essential Micronutrients) can support a population of children with traumatic brain injury in managing resulting cognitive and behavioural problems. This pilot feasibility study will review a series of individual case studies to investigate the effects of micronutrients on emotional dysregulation in children with TBI recruited through ACC.

This discussion centred on the Researchers’ response to the Committee’s prior provisional approval of this 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 observed that the revised participant information sheet still leads the parents of participants to believe that this is an efficacy study, rather than a feasibility study. Parents and children may mistakenly enrol their children due to the belief that there is a therapeutic benefit – for a lay readership efficacy and effectiveness should be considered interchangeable, and words such as ‘change’, ‘feasibility’, ‘viability’, and ‘tolerability’ should be used in their place. The Committee advised that is must be clearly stated that this is a hypothesis-generating study only, and that results cannot be taken as a demonstration of efficacy or effectiveness of the micronutrient tablet. It would be acceptable to say that the safety of the micronutrients is also being investigated, but not the efficacy of the drug. (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
2. The Committee noted that study advertisements must be amended to reflect that this is a feasibility study, in line with the protocol (*Ethical Guidelines for Intervention Studies* paragraph 6.22).

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

1. Please amend the title, which still refers to a ‘case study’, to match the feasibility study title in research protocol.
2. Please provide a consent form for the teachers who will be completing the questionnaires.
3. Please include in the side-effect profile those of the previous micronutrient formulation, as it is closely related to the product used in the current study. Please also include frequencies, given in the form of percentages, if this information is available.
4. Please add to the child assent form that teachers will performing assessments on the children. Please also remove the images from the assent form. The form’s language should be tailored to the target age group and proof-read for grammatical and formatting errors – terms such as “emotion” and “capsules” may not be appropriate for some 6-13 year olds.
5. Please include Māori support contact numbers, and note that the HDC does not provide this service.
6. Please be clear about the difference between consent to future unspecified research and consent to be contacted about future research.
7. Please ensure that both page numbers and page number references are correct.
8. Please provide a lay explanation of phrases such as “recruitment of our sample”, child’s emotional dysregulation”, and “phlebotomist”.
9. Please provide a contact number for the crisis resolution team.
10. The consent form should read “I request a Karakia at the disposal of my *child’s* blood samples”.
11. Please see the HDEC template for further guidance.

Decision

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

* Sufficient changes had not been made, in line with the conditions of this application’s provisional approval, in order to secure fully informed parental consent. Please update the patient information sheet and consent forms, and the study advertisements, taking into account the Committee’s comments. (*Ethical Guidelines for Intervention Studies* paragraph 6.22).

Notes

The Committee was happy for the Researchers to send amended study documents to Dr Nicola Swain for comments prior to resubmission.

The Committee advised that in future applications for similar studies whakamā should be raised as a potential cultural issue for Māori.

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| **2** | **Ethics ref:** | **19/STH/101** |
|  | Title: | ZiPP-LTE |
|  | Principal Investigator: | Dr Anne Horne |
|  | Sponsor: | European Commission |
|  | Clock Start Date: | 30 May 2019 |

No member of the research team 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, and no potential conflicts of interest related to this application were declared by any member.

Summary of Study

The proposed study is a 5 year follow-up of participants who took part in both the interventional and observational arms of the ZiPP study, to evaluate the proportion who develop new Paget's disease of bone lesions.

Summary of outstanding ethical issues

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

1. Regarding study data being shared with off-site collaborators, the Committee asked for clarification of the identifiability of data being sent overseas; for example, whether NHI numbers will be sent. The data management plan in general was said to be in need of clarifying. (*Ethical Guidelines for Observational Studies* paragraph 8.2).

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

1. Please ensure that participants are informed that they have previously been prescribed zoledronate.
2. *If* it is mandatory that NHI numbers are collected and shared with University of Edinburgh staff, please make it explicit that these are highly identifiable, and outline the risks of data harm associated with this.
3. Please make clear, in lay language, what genetic and genomic analysis will be conducted, where samples will be sent, and whether this is mandatory for inclusion in the study. The document should make clearer in general what is optional and what is not for participants.
4. Please move the table of study processes under the “What will happen if I take part” heading, preceding the text.
5. Please amend the following passage: “We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very small chance (approximately 0.01%) of this happening to you.” This is unnecessary and potentially distressing.
6. Please include Māori contact numbers at the end of the PIS.

Decision

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

* Please amend the patient information and consent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observational Studies* paragraph 6.10).
* Please clarify the data management plan as requested by the Committee (*Ethical Guidelines for Observational Studies* paragraph 8.2).

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Sandy Gill and Dr Devonie Waaka.

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| **3** | **Ethics ref:** | **19/STH/100** |
|  | Title: | Manaaki |
|  | Principal Investigator: | Ms Gayle Humphrey |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 30 May 2019 |

Gayle Humphrey and Stephanie Eric were present via teleconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application, and no potential conflicts of interest related to this application were declared by any member.

Summary of Study

This study will develop and examine the feasibility of an evidence-based cognitive behavioural therapy – a mobile phone application intervention – aimed at reducing problems and harm from gambling, in people at risk of developing or currently experiencing problem gambling and gambling-related harms.

Summary of resolved ethical issues

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

1. The Committee queried whether audio recordings taken of participants will be transcribed. The Researchers clarified that only notes would be taken from these recordings for the purpose of validation, and that access will be limited to the investigators.
2. The Committee asked whether there was a safety plan in case of the intervention triggering other psychological issues in the participant group. The Researchers answered that any incidental psychological reactions/findings will be directed towards the gambling counselling services who have cared for and are familiar with the person.
3. The Committee noted that three groups of participant will be delineated in this study – Māori, Pasifika, and young adult – and queried whether participants will be screened based on ethnicity. The Researchers responded that they will not exclude people in the youth cohort based on ethnicity. The other groups will accommodate the ethnicities predicted to be most strongly represented.
4. The Committee noted that the current cultural consultation being undertaken is sufficient for the present study, but wished to make clear that any study involving Māori participants *requires* consultation with Māori, which was not acknowledged in the application form. The Committee also advised that use of the title ‘Manaaki’ ought to be included in this consultation, and that whakamā may be a salient issue for Māori – it was therefore problematic for the application form to state that no cultural issues were foreseen for this 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 requested that any public-facing recruitment material to be used by service providers and community groups be provided for review (*Ethical Guidelines for Intervention Studies* paragraph 6.2).
2. The Committee asked that more detailed peer review be provided in line with the HDEC template (*Ethical Guidelines for Intervention Studies* paragraph 5.11). This may clarify methodological issues. For example, as few as a total of around 18 participants may be involved in this study (as opposed to 50 stated) – it is unclear if the validity of the results will be undermined, if this is the case.

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

1. Please amend to state that recordings will be ‘audio’ rather than ‘digital’.
2. Please add Pasifika contact numbers alongside those for Māori. These contact people must also be independent of the study.
3. Please make clear to participants that if they withdraw from the study all information provided up to that point will be retained for use in the research.
4. Please emphasise the confidentiality required of participants in relation to other members of the focus groups.
5. Please reword the focus group meetings to read as ‘sessions’ or ‘discussions’, to differentiate from the three focus groups that will be recruited.
6. Please secure consent for the use of de-identified quotations, and make clear in the body of the PIS that these may be used.

Decision

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

* Please amend the patient information and consent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
* Please provide evidence of peer review (*Ethical Guidelines for Intervention Studies* paragraph 5.11)
* Please submit all public-facing recruitment material *(Ethical Guidelines for Intervention Studies* paragraph 6.2).

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Raewyn Idoine and A/Prof Mira Harrison-Woolrych.

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| **4** | **Ethics ref:** | **19/STH/102** |
|  | Title: | The PRESERVE Aotearoa pilot study (Prevent delirium through Eating and drinking, Sleep, Exercise, Reorientation, Vision and hearing, and Enabling family) |
|  | Principal Investigator: | Dr Aileen Collier |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 30 May 2019 |

Dr Aileen Collier was present via teleconference 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

This is a single-arm feasibility study which aims to determine if a multi-component non-pharmacological delirium prevention intervention is feasible and acceptable for Māori and non-Māori with advanced cancer and receiving palliative care in two New Zealand hospices. The results will inform a future phase III (efficacy) trial of the intervention.

Summary of resolved ethical issues

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

1. The Committee queried what medical oversight would be in place to manage the risk of patients needing treatment for delirium not receiving it. The Researcher emphasised that this is a delirium prevention study, not a study on an intervention for delirium. It was stated that a system will be in place, as part of routine hospice care, to diagnose and treat delirium.
2. The Committee queried whether the repeat of measurements every eight hours would involve participants, or simply the nursing staff and volunteers. The Researchers confirmed that this will only involve staff.

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 required confirmation of a confidentiality agreement with any third party who will be transcribing interview recordings (*Ethical Guidelines for Intervention Studies* paragraph 5.40).
2. The Committee asked for clarification over what data is being sent overseas, to whom, the location, and the level of identifiability of these data (*Ethical Guidelines for Intervention Studies* paragraph 7.2).
3. The Committee asked for justification of why five Māori specifically are being sought for inclusion, whether this number referred to the hospice participants or also included their whanau, and clarification of whether a Māori health issue is under investigation (*Ethical Guidelines for Intervention Studies* paragraph 5.4).

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

1. Please re-write the PIS so that it is shorter, simpler, and suitable for a lay readership. For example, the introduction and intervention list should be shortened, and neither is it necessary to include a photograph of the research team. Please also proof-read for errors.
2. Please remove ‘video’ from the description of interview recordings.
3. Please do not use an acronym in the title of the PIS.
4. Please remove information relating to the randomised controlled trial.
5. Please add the length of time that will be taken to complete questionnaires.
6. In the case of data being sent overseas, please secure consent from participants.
7. Please make clear to participants that all identifiers will be removed from interview transcriptions.
8. Please provide more information on what the intervention involves. The intervention should have its own section (including how long it will take, who is conducting it, how it differs from standard care, and so on) and also be included in risks and benefits.
9. Please include page numbers.

Decision

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

* Please amend the patient information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
* Please provide a response to the Committee’s queries around the study’s confidentiality and data management (*Ethical Guidelines for Intervention Studies* paragraph 5.40 & 7.2).
* Please address the Committee’s query around the sample size of Māori within this study (*Ethical Guidelines for Intervention Studies* paragraph 5.4).

After receipt of the information requested by the Committee, a final decision on the application will be made via the HDEC full-review pathway.

Notes

The Committee commented that it was disappointed with the quality of the application.

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| **5** | **Ethics ref:** | **19/STH/104** |
|  | Title: | HRcSCC |
|  | Principal Investigator: | Mr Richard C W Martin |
|  | Sponsor: | N/A |
|  | Clock Start Date: | 30 May 2019 |

No member of the research team 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

The primary aim of this study is to evaluate molecular markers in primary cutaneous Squamous Cell Carcinoma that predict metastatic nodal spread – that is, potential molecular and genetic markers which may predict metastatic risk. In particular, this will involve investigating DNA methylation differences between metastatic and non-metastatic cSCC in pathology samples collected during routine surgery.

Summary of outstanding ethical issues

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

The Committee stated that it was unable to approve the use of human tissue samples without consent as an argument had not been forwarded pursuant to the HRC guidelines on the *Collection and use of human materials*. (*Ethical Guidelines for Observational Studies* paragraph 1.9). The Committee noted that this issue had also been raised by the study’s peer reviewer.

1. The Committee advised that Māori consultation is required for this study (*Ethical Guidelines for Observational Studies* paragraph 4.4).

Decision

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

* Please provide justification for the use of human tissue without consent as above (*Ethical Guidelines for Observational Studies* paragraph 1.9).
* Please consult with Māori on potential cultural issues arising in this study (*Ethical Guidelines for Observational Studies* paragraph 4.4).

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| **6** | **Ethics ref:** | **19/STH/107** |
|  | Title: | Olfactory mucosa in Parkinson's disease |
|  | Principal Investigator: | Dr Tary Yin |
|  | Sponsor: | N/A |
|  | Clock Start Date: | 30 May 2019 |

Dr Tary Yin was present via teleconference 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

The purpose of this randomised placebo-controlled study is to compare the efficacy of intranasal administration of twice-daily doses of 186mg and 372mg of OPN-375 (fluticasone propionate), a new medication, with placebo in subjects with chronic sinusitis without nasal polyps.

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 the Researchers that genetic analysis raises cultural issues for Māori due to the perceived collective ownership of tissue and its link to whakapapa, and that this should have been addressed in the Māori responsiveness section of the application form.
2. The Committee commended the clarity of the patient information sheet and stated that it had been written in suitable lay-language. It does however omit some important information which is outlined below.

Summary of outstanding ethical issues

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

1. The Committee asked that it be stated in writing that biopsies will be performed by a licensed medical professional (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
2. The Committee recommended adding anticoagulant use and clotting disorders as exclusion criteria, as this will minimise risk in a non-therapeutic study (*Ethical Guidelines for Intervention Studies* paragraph 5.4).
3. The Committee stated that a safety plan should be added to the protocol for any incidental psychological findings emerging from the questionnaires (*Ethical Guidelines for Intervention Studies* paragraph 5.4).
4. The Committee requested that a statistics plan be added to the protocol (*Ethical Guidelines for Intervention Studies* paragraph 5.41).

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

1. Please notify participants that genetic analysis will be conducted on tissue samples, and that incidental findings will be communicated if serious.
2. Please discuss how incidental nasal pathology will be managed.
3. As this study will be collecting a unique tissue set, the Committee strongly suggested securing consent for bio-banking for future unspecified research. The HDEC template for future unspecified research can be used for this purpose.
4. Please indicate how biopsies will be taken, such as whether both nostrils will be accessed or just one, and who will be performing them. The “What will my participation involve?” section on page 2 should be expanded in general, including what medication will be applied to the nostril.
5. Please state what will happen following the study to data and donated tissue. Please also explain how people can withdraw from the study, and that data collected up to the point of withdrawal will be retained for analysis.
6. Please include a Māori tissue statement, using the HDEC-approved wording (see HDEC template).
7. Please include in the risks and benefits section that there may be no individual therapeutic benefit from participation in this study. Also include any risk related to bleeding.
8. Please add that tissue will be sent overseas.
9. Please remove tick boxes for elements of the study which are not truly optional.

Decision

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

* Please amend the participant information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
* Please clearly state that biopsies will be performed by a licensed medical professional, and add a statistics plan to the protocol (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
* Please add anticoagulant use and clotting disorders as exclusion criteria, and develop a safety plan for any incidental psychological findings emerging from the questionnaires (*Ethical Guidelines for Intervention* Studies paragraph 5.4).

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Sandy Gill and Dr Sarah Gunningham.

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| **7** | **Ethics ref:** | **19/STH/108** |
|  | Title: | PETAL Study: Preventing recurrent acute lower respiratory infections study |
|  | Principal Investigator: | A/P Catherine Byrnes |
|  | Sponsor: | Menzies School of Health Research |
|  | Clock Start Date: | 30 May 2019 |

A/Prof Catherine Byrnes was present via teleconference 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

This international, multi-centre, randomised controlled trial aims to determine whether the weekly use of azithromycin for 12-months (compared to placebo) reduces recurrent acute lower respiratory infections and future bronchiectasis among Māori and Pasifika children. The impact of azithromycin on safety, antibiotic resistance, upper airway bacteria, and cost-effectiveness will also be determined.

Summary of resolved ethical issues

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

1. The Committee queried how incidental findings, for example from the ECGs, which aren’t standard of care, will be managed. The Researcher responded that anything detected on the ECG would be referred to the cardiology dysrhythmia clinic. Similarly, other abnormal results will be handled by the clinical care team with follow-up by the Researchers.
2. The Committee noted that a peer reviewer had commented on the feasibility of the study timeline, where no time had apparently been allowed for analysis. The Researcher answered that the recruitment window should be smaller than that allowed for in the protocol, which would provide sufficient time for 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 advised that it should be the clinical care team who approaches parents about their child’s potential participation. A research nurse can observe patients on the ward and remind clinicians about the study, so long as no health information is accessed without consent for screening purposes. (*Ethical Guidelines for Intervention Studies* paragraph 6.2).
2. The Committee stated that despite this study targeting Māori and Pasifika children it should not have ethnicity as an inclusion or exclusion criterion, and the research team should instead consider framing the study in terms of “high risk” (*Ethical Guidelines for Intervention Studies* paragraphs 5.26 & 5.41).

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

1. Please remove the acronym from the layperson study title, and simplify it.
2. Please re-read the document for typos.
3. Please amend the description of ‘placebo’, as “pretend medication” may not be age appropriate.
4. Please expand the risk section, and give specific advice about taking other antibiotics in addition to azithromycin while on this study.
5. Please include information on previous studies which is relevant to this participant population.
6. Please reword the term “clinical assessment” on page 2 to “physical examination”.
7. Please include a section on withdrawing from the study, which describes what will happen to already collected tissue and data. For example, state that if tissue has been analysed then this data will not be able to be withdrawn.
8. When explaining the study initially, please make it clear that participants will be provided medication for 12 months, and then followed-up for a further 12 months.
9. Please include HDC contact details.
10. Please remove tick boxes for elements of the study which are not truly optional.

Decision

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

* Please amend the patient information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
* Please ensure that patient recruitment is in line with the Committee’s suggestions (*Ethical Guidelines for Intervention Studies* paragraph 6.2).
* Please take into account the Committee’s *suggestion* that ethnicity not be included in the study’s title and its inclusion and exclusion criteria. The Committee is also willing to consider a justification, made as a response to this provisional approval, of the existing focus on ethnicity. (*Ethical Guidelines for Intervention Studies* paragraphs (5.26 & 5.41).

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Raewyn Idoine and Dr Devonie Waaka.

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| **8** | **Ethics ref:** | **19/STH/110** |
|  | Title: | Q122-2001: A study assessing the safety and effectiveness of Q-122 for treating hot flushes, in women who have, or have had, breast cancer. |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | Organisation: INC Research New Zealand Limited (a |
|  | Clock Start Date: | 30 May 2019 |

Dr Chris Wynne was present via teleconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application. Dr Devonie Waaka declared a conflict of interest for this application.

Summary of Study

This study will assess the safety and effectiveness of Q-122, a new medicine being developed for the treatment of vasomotor symptoms in women who have, or who have had, breast cancer.

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 that a number of documents uploaded for review were unnecessary (for example, electronic and paper versions of the same questionnaire; and multiple participant identification / safety cards), and asked that document submission was more considered in the future.

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 clarification on whether non-post-menopausal and non-surgically sterile women are being excluded due to the nature of the study, or due to the reproductive risks to an exposed foetus. The Committee stated that it must be very clear in the protocol and PIS (see point 4) why women are being excluded. (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
2. The Committee stated that it is appropriate for participants in this non-therapeutic study to be compensated for their time (*Ethical Guidelines for Intervention Studies* paragraph 6.34).

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

1. Please amend the explanation of why participants may be excluded from the study following the initial week of placebo, so that it include the following: “If at the end of the first week of treatment you are found to have had a significant reduction of hot flushes, you will not be able to continue on to the trial”. This explanation is more honest with participants while still maintaining the blind.
2. If the study will pose risks to the foetus if pregnancy occurs, please ensure that information and advice on this is included in the reproductive risks section. The pregnancy exclusion should also be added to section four: “Who can take part?”
3. Please include secure consent for data being sent overseas on the consent form.

Decision

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

* Please amend the patient information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
* Please clarify the reason for excluding non-post-menopausal and non-surgically sterile women (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
* Please ensure that participants are compensated (*Ethical Guidelines for Intervention Studies* paragraph 6.34).

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Sandy Gill and A/Prof Mira Harrison-Woolrych.

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| **9** | **Ethics ref:** | **19/STH/111** |
|  | Title: | REOPEN 2 STUDY. A study of intranasal OPN-375 in participants with chronic sinusitis without nasal polyps |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: | Covance New Zealand Limited |
|  | Clock Start Date: | 30 May 2019 |

Dr Dean Quinn was present via teleconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application, and no potential conflicts of interest related to this application were declared by any member.

Summary of Study

The purpose of this randomised placebo-controlled study is to compare the efficacy of intranasal administration of twice-daily doses of 186mg and 372mg of OPN-375 (fluticasone propionate), a new medication, with placebo in subjects with chronic sinusitis without nasal polyps.

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 clarification of whether the study device, if found to be effective, would be made available to participants after the conclusion of the study (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
2. The Committee asked for confirmation that study questionnaires will be analysed promptly, and that a safety plan is in place to deal with incidental psychological findings (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
3. The Committee queried whether participants will be excluded from the study following the single blind run-in, and what these exclusion criteria are (if any) (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
4. The Committee noted that no independent data monitoring committee was in place, and queried what is in place to ensure adequate monitoring of safety signals in its absence. It was observed that it may be difficult for individual sites to detect these given the small participant numbers at each site. (*Ethical Guidelines for Intervention Studies* paragraph 6.38).
5. The Committee asked that the degree of identifiability of participant data being sent to the sponsor were more clearly explained. For example, whether this is identifiable, re-identifiable, or non-identifiable. (*Ethical Guidelines for Intervention Studies* paragraph 7.2).
6. The Committee asked for clarification of whether safety screening blood samples would be sent to three separate international laboratories as outlined in the protocol (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
7. The Committee requested that it be a study requirement that participants’ GPs are informed of participation (*Ethical Guidelines for Intervention Studies* paragraph 5.4).
8. The Committee believed it was appropriate to provide participants remuneration in addition to the covering of expenses (*Ethical Guidelines for Intervention Studies* paragraph 6.34).
9. The Committee observed that the application form omitted questions related to ionising radiation which is beyond standard of care. The Committee therefore requested that the following questions be answered (*Standard Operating Procedures for Health and Disability Ethics Committees* paragraph 42.4):

* Please briefly describe the form(s) in which ionising radiation not needed for normal clinical management will be administered.
* Please provide the name(s) of the person(s) licensed under the Radiation Protection Act 1965 under whose supervision ionising radiation will be administered to participants in your study.
* Has a medical physics expert verified that accurate effective doses have been calculated for this ionising radiation?

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

1. Please amend the sentence on page one of the information sheet, which states that “patients with chronic sinusitis currently have limited medical options for treatment” and that there is no approved treatment for sinusitis. This is potentially confusing for participants who may not understand off-label use. Please reword appropriately, making it clear to participants that other treatment options are available, and commonly used in New Zealand, despite not being approved for this purpose.
2. Please add frequencies to the list of side-effects. Please also review the adverse events section for repetition.
3. Please add the level of identifiability of data going to sponsor once this is clarified. Please clearly differentiate between identifiable source data and records being reviewed for audit purposes, and coded data being used for research purposes.
4. Please replace the unknown risk section with the HDEC template.
5. Please make it clear that participants in the placebo arm will not receive any benefit, and that symptoms may increase due to other medications being withdrawn during participation.
6. Please amend the statement that participants will be monitored “very closely”, as there will be only monthly visits.
7. Please tailor the consent forms to the information sheets, including all relevant information such as data being sent overseas.
8. Please amend the footer, as it is currently six lines long and blends into the text.

Decision

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

* Please amend the patient information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
* Please address the Committee’s queries and requests, and update the protocol accordingly (*Ethical Guidelines for Intervention Studies* paragraphs 5.4, 5.41, 6.34, 6.38, & 7.2).
* Please answer the questions regarding ionising radiation (*Standard Operating Procedures for Health and Disability Ethics Committees* paragraph 42.4):

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Raewyn Idoine and Dr Paul Chin.

Notes

The Committee advised that it is not appropriate or necessary to outline that Māori have the same rights as non-Māori in the Māori responsiveness section.

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| **10** | **Ethics ref:** | **19/STH/113** |
|  | Title: | MRI identification of bio-markers of ocular aging |
|  | Principal Investigator: | Professor Paul J Donaldson |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 30 May 2019 |

Prof Paul Donaldson, Alyssa Lie, and Renita Martis were present via teleconference 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

This study aims to identify the role of the crystalline lens in maintaining microcirculation and antioxidant homeostasis in the eye to prevent the onset of age-related eye disease. In order to do so, MRI will be used to investigate the changes of the lens water transport system in vivo with age and in presbyopia and cataract.

Summary of resolved ethical issues

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

1. The Committee wished to record that a previous study which involved MRI tests on healthy participants was within HDEC’s scope but only received University of Auckland Human Ethics Committee approval.
2. The Committee queried whether an optometrist will be performing this surgery. The Researchers clarified that it will be ophthalmologists who will be collecting the tissue samples.
3. The Committee queried whether human tissue will be sent overseas in this study. The Researchers stated that this will not be the case.
4. The Committee whether all participants, including the control group, will receive free eye exams. The Researchers confirmed that all participants will receive these.

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 health information usually must be retained for 10 years, and advised the research team to look into their data retention responsibilities (*Ethical Guidelines for Observational Studies* paragraph 1.9).
2. The Committee stated that participants must be informed of any incidental findings and that it is also the research team’s responsibility to ensure clinical follow-up. The Committee required that participants’ GPs therefore be informed of the study. (*Ethical Guidelines for Observational Studies* paragraph 9.1).
3. The Committee advised that formal Māori consultation must be undertaken for this study (*Ethical Guidelines for Observational Studies* paragraph 4.4).

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

1. Please simplify the study introduction into lay language.
2. Please make clear on page 3 that tissue collection is mandatory in this study, and give an indication of long participation in the study will be for each group and what this involves.
3. Please rewrite the future unspecified use of tissue document for a lay readership, as it is currently very technical. Please also include information on genetic testing, and that this is a possible future use of the participants’ tissue – this should also be on the consent form. It should be stated where tissue will be stored and that it may be sent overseas, and the paragraph on where the future use will *conducted* should be removed.
4. Please provide a lay explanation of what “de-linking” information involves.
5. Please add information on what will happen if participants choose not to consent to the storage of their tissue for future unspecified research.
6. Please provide a yes/no option for the removal of identifiers from tissue samples.
7. Please add Māori contact numbers to the future use of tissue PISCF.
8. Please remove the pregnancy clause on the main consent form.
9. Please remove the statement that MRIs are “completely safe”.
10. Please include what parts of the body the MRI will capture. For example, whether parts of the brain are included.
11. Please advise participants that if they withdraw from the study any data collected up to the point of withdrawal will be kept for analysis, though no further data will be collected. Remove the statement on the one month window of withdrawal.

Decision

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

* Please ascertain the study’s data retention responsibilities (*Ethical Guidelines for Observational Studies* paragraph 1.9).
* Please ensure that participants are informed of any incidental findings and that they receive clinical follow-up. Participants’ GPs must be informed of the study. (*Ethical Guidelines for Observational Studies* paragraph 9.1).
* Please ensure that Māori consultation is undertaken for this study (*Ethical Guidelines for Observational Studies* paragraph 4.4).

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Sandy Gill and Dr Devonie Waaka.

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| **11** | **Ethics ref:** | **19/STH/114** |
|  | Title: | Microdrop Administration of Phenylephrine and Cyclopentolate Eye Drops in Neonates |
|  | Principal Investigator: | Miss Lisa Kremer |
|  | Sponsor: | N/A |
|  | Clock Start Date: | 31 May 2019 |

No member of the research team 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

This study aims to determine whether low dose versus very low dose pupil dilating eye microdrops are effective in a neonatal population, and if the eye drops are associated with a low risk of harm.

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 *suggests* amending the study design so that the blind is broken only in the event of an SAE which requires seeing which dose the participant was assigned to (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
2. The requested that data be stored in a re-identifiable form only, and not with NHI numbers attached (*Ethical Guidelines for Intervention Studies* paragraph 7.2).

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

1. Please add Māori contact numbers (note that the HDC does not provide Māori support).
2. Please amend the statement “If you agree your baby can be part of the study they will receive either a low dose or lower dose” to say “…low dose or very low dose”.
3. Please amend the PIS on page 3 to state that upon withdrawal the baby’s data up to that point will remain in the study, as this is currently inconsistent with the consent form.
4. Please amend to state that reducing the dose *may* reduce the side-effect profile.

Decision

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

* Please amend the patient information sheet and consent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
* Please consider amending the study design as suggested by the Committee (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
* Please store study data in a re-identifiable form only (*Ethical Guidelines for Intervention Studies* paragraph 7.2).

## 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, namely:

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| --- | --- |
| **Meeting date:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |
| **Meeting venue:** | 9 July 2019 |

* Dr Devonie Waaka gave her apologies for this meeting, but noted that she could attend via teleconference if required for the Committee meet quorum.

1. **Problem with Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

The meeting closed at 4pm.