|  |  |
| --- | --- |
| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27 September 2016 |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington |

|  |  |
| --- | --- |
| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 23 August 2016 |
| 12:30pm | New applications (see over for details) |
|  | i 16/CEN/125  ii 16/CEN/144  iii 16/CEN/130  iv 16/CEN/133  v 16/CEN/134  vi 16/CEN/135  vii 16/CEN/139  viii 16/CEN/140  ix 16/CEN/146  x 16/CEN/142  xi 16/CEN/143  xii 16/CEN/131 |
| 5:30pm | General business: |
| 5:50pm | Meeting ends |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 30/07/2015 | 30/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Apologies |
| Dr Melissa Cragg | Non-lay (observational studies) | 30/07/2015 | 30/07/2018 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |

## Welcome

The Chair opened the meeting at 12pm and welcomed Committee members, noting that apologies had been received from Dr Cordelia Thomas.

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 23 August 2016 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **16/CEN/125** |
|  | Title: | Women Spirituality and Mental Health |
|  | Principal Investigator: | Mr. Noel Tiano |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 September 2016 |

Mr Noel Tiano and Ms Kath Maclean were 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.

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

Summary of Study

1. The study involves women who are or who have been inpatients at Ratonga Rua O Porirua and have requested spiritual assistance during their time there. These women will take an intrinsic spirituality scaling test and those who have demonstrated positive religious coping will be interviewed or invited to focus groups. The aim of the research is to identify and develop practices that are helpful for clients so that these can be implemented more widely.

Summary of ethical issues (resolved)

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

1. The Committee asked about how the religious coping scale is scored. The Researchers explained that it is a scale between one and ten.
2. The Committee and Researchers agreed that individuals who had been flagged as having safety concerns would not be included in the research.
3. The Committee asked if participants could take part in both the focus groups and in an interview. The Researchers explained that this would depend on the study localities’ rules.
4. The Committee asked if one year is enough time to recruit a sufficient number of participants. The Researchers explained that yes, this is a sufficient amount of time.

Summary of ethical issues (outstanding)

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

1. The Committee enquired if undergoing the religious coping scale was standard of care at the facility. The Researchers explained that it is not. The Committee stated that therefore there needs to be informed consent sought for the administering of the questionnaire.
2. The Committee queried the use of anonymised data in the research and explained that the research does not have to use anonymised data. A coded transcript system would count as de-identified data. Please replace references to data being anonymous with references to data being de-identified.
3. The Committee asked about the choice to only include those women who have very high positive religious coping scores. Women with lower scores may benefit more from the service than those with high scores. The Researchers explained that they chose to exclude women who have negative religious coping experiences to prevent causing further trauma.
4. The Committee asked that, given the Researchers are aiming to develop a tool to inform best practice, please consider including all women who have not demonstrated negative religious coping in order to inform best practice and target those who could benefit more from the service in the future.
5. Please consider removing the intrinsic spirituality scale and talking to clinicians about individual’s eligibility as the method of screening for the study.
6. Please make sure that any health information gathered or stored in the study is stored in-line with New Zealand law.
7. Please provide information as to how safety concerns will be managed in this study. For example, how negative events occurring as a result of study participation will be managed.
8. Please explain how Māori cultural issues, such as whakamā, will be managed in this study.

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

1. Please clarify in the participant information sheet (PIS) that spirituality in this research is not of any specific type, for example theistic or non-theistic.
2. The committee had concerns about some participants being a captive population. Please make sure that it is clearly stated in the PIS that participation is voluntary.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please address how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Observational Studies* *para 4.3*).
* Please ensure that all health information is stored for a minimum period of 10 years (Health (Retention of Health Information) Regulations 1996).
* Please consider amending the studies’ protocol to include those who have demonstrated negative religious coping strategies. *(Ethical Guidelines for Observational Studies paras 5.5 – 5.12)*

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **16/CEN/144** |
|  | Title: | EG-01-1962-03: Comparison of EG-1962 to oral nimodipine in aSAH (NEWTON 2) |
|  | Principal Investigator: | Dr Edward Mee |
|  | Sponsor: | Edge Therapeutics, Inc. |
|  | Clock Start Date: | 15 September 2016 |

Dr Edward Mee and Ms Davina MacAllister were 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.

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

Summary of Study

1. The Committee noted the high quality of the application.
2. This study aims to compare intraventricular administration of the drug EG-1962 to standard of care oral nimodipine in patients who have been admitted with aneurysmal sub arachnoid haemorrhage (aSAH).

Summary of ethical issues (resolved)

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

1. The Committee queried how many study participants would be able to provide informed consent, at time of admission to hospital, to participate in this study. The Researchers explained that, given the nature of the condition, patients are considered confused by definition. Thus the majority of patients will not be able to provide informed consent at time of admission. In these situation consent is often sought from the family.
2. The noted that the consent form includes enduring power of attorney and that in New Zealand this is not legal for research participation. The Committee did note that the Researchers were aware of, and had noted in their application, their obligations under Right 7.4 of the Code of Health and Disability Services Consumers’ Rights.
3. The Committee enquired if all that is occurring in this study is a new administration of the study drug. The Researchers confirmed this.
4. The Committee asked if the new administration of the study drug could avoid some of the complications associated with the standard of care drug. The Researchers confirmed that this is true.
5. The committee asked if this method of administration had been trialled anywhere else. The Researchers explained that this method had been trialled in the United States of America and had shown positive outcomes with no safety concerns.
6. The Committee enquired about why participants will be randomised between standard care and the study administration. The Researchers explained that they needed to do this in order to develop a more rigorous evidence base.
7. The Committee noted that recommendations from the Belmont Report are not legally binding in New Zealand.
8. The Researchers confirmed that there will not be any retention of samples following the end of the study.

Summary of ethical issues (outstanding)

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

1. The Researchers and The Committee discussed the use of independent physician assent for the purposes of study inclusion. The Committee was happy to approve this as it is has been used in other similar studies conducted by the Researchers. Please seek independent legal advice confirming the legality of the consent methods associated with the study.

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

1. Please remove questions around participant’s drug, medicine, and alcohol intake from the Participant Information Sheet.
2. Please clearly state in the information sheet what withdrawal from the study means for study data already collected and if participants will be able to withdraw this.
3. Please add a past tense documents that will be given to patients who could not provide informed consent at time of admission.
4. Please provide evidence of or remove any references to a pregnancy release consent form.
5. Please amend references to samples being sent overseas from page nine of the information sheet.
6. Please fix any typographic errors such as those found on page six of the information sheet.

Decision

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

* Please provide a past tense participant information sheet and consent form.
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies para 6.22).*
* Please provide independent legal advice about the consent methods associated with the study.

This following information will be reviewed, and a final decision made on the application, by Dr Dean Quinn and Dr Angela Ballantyne.

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **16/CEN/130** |
|  | Title: | Zika virus and microcephaly |
|  | Principal Investigator: | Dr Gina O'Grady |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 September 2016 |

Dr Gina O’Grady was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates cases of microcephaly in New Zealand with the aim of identifying the underlying aetiologies. It will also seek to develop a guidelines for the investigation of congenital microcephaly.

Summary of ethical issues (resolved)

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

1. The Committee noted that recommendations made by the peer reviewer had been integrated into the study protocol.
2. The committee noted that the Researchers would be contacting GPs to tell them to contact parents in the event of children needing further care.

Summary of ethical issues (outstanding)

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

1. The Committee requests evidence of statistical review of the study as it is their understanding that the incidence of microcephaly is very low.
2. Please explain why seeking participant consent is not feasible.
3. Please explain the arrangements around the supervision of the summer student and what experience, if any, the summer student has of research.
4. Please provide evidence of Māori consultation. The Committee noted that any locality review that involves Māori consultation would be sufficient.

Decision

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

* Please provide evidence of statistical review of the study. *(Ethical Guidelines for Observational Studies para 5.12)*
* Please provide evidence of Māori consultation. (*Ethical Guidelines for Observational Studies paras 4.3 - 4.6)*
* Please provide information regarding the supervision arrangements of the summer student and their experience, if any, of research.
* This study, as presented in this application, involves accessing health information consent.
* The Committee noted that participants have a right to know that their health information is being used in research. Right 6(1)(d) of the HDC Code of Rights states:
  1. *Every consumer has the right to information that a reasonable consumer, in that consumer’s circumstances, would expect to receive, including … notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval.*

The Committee noted that they can approve access to identifiable health information without consent for research in certain circumstances. The Ethical Guidelines for Observational Studies states at Paragraph 6.43:

1. *Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:*
   * 1. *the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and*
     2. *there would be no disadvantage to the participants or their relatives or to any collectives involved; and*
     3. *the public interest in the study outweighs the public interest in privacy.*

To approve a study involving access to health information without consent the Committee must be satisfied that these requirements are met by the study concerned.

This following information will be reviewed, and a final decision made on the application, by Mrs Sandy Gill and Dr Patries Herst

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **16/CEN/133** |
|  | Title: | IMT study |
|  | Principal Investigator: | Dr Andrew Wood |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 September 2016 |

Dr Andrew Wood and Dr Sarah hunter were present by 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

1. The study hopes to include two New Zealand children in an Australian study investigating an extremely rare type of cancer known as ALK+ve. The Researchers explained that outcomes for this cancer are very poor and treatment is limited. The study aims to build knowledge about the cancer and its’ treatment.

Summary of ethical issues (resolved)

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

1. The Committee asked how many participants will be I this study. The Researchers explained that there are two potential participants, with another third who may or may not be able to be included.
2. The Committee noted that the peer review raises various issues with the study but these were addressed as part of the funding application process.
3. The Committee noted that the small sample size means there will be a limitation on the types of statistical analysis that can be performed. The Committee noted the planned genomic analysis will help offset this limitation.

Decision

This application was *approved* by consensus.

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **16/CEN/134** |
|  | Title: | Tear based breast cancer detection |
|  | Principal Investigator: | Dr. Dong-Xu Liu |
|  | Sponsor: | Ascendant Dx |
|  | Clock Start Date: | 15 September 2016 |

Co-investigator Dr Anna Dailey was present by 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

1. The study aims to test human tears for the presence of protein markers that may indicate breast cancer. Samples collected in New Zealand will be used to help gather stability data and protocol development of extraction of proteins from the Schirmer Strips used to collect the tears.

Summary of ethical issues (resolved)

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

1. The Committee queried who the study was open to in New Zealand. The Researcher explained that participation is open to anyone attending the Rialto event for Breast Cancer Awareness Month in November 2016. Registration for this event is online.
2. The Committee enquired about what will happen to the samples following collection. The Researcher explained that they will be transported back to the United States.
3. The Committee enquired about what tests will be performed on the samples once they reach the United States. The Researcher explained that the tests performed will look at the stability of proteins under different situations and in the presence of different protein buffers, inhibitors, or stabilisation agents. The Researcher explained that the study will be looking at how to remove proteins from the strips, how stable the proteins are, and how to enter them into the analysis device.
4. The Committee queried if samples would be retained for future unspecified research. The Researcher explained that would not be the case.
5. The Committee queried how many times tissue will be collected. The Researcher clarified that the tissue collection is linked to a one-time event.
6. The Committee asked about data collected to point of withdrawal. The Researcher explained that withdrawal of these data is possible.

Summary of ethical issues (outstanding)

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

1. The Committee noted a statement in the participant information sheet about the extraction of DNA from samples. The Researcher explained that this would not be performed on New Zealand samples as part of this study. The Committee suggest that the Researcher use the HDEC template participant information sheet to make sure information was New Zealand specific.
2. The Committee requested the removal of the requirement for all study withdrawal to be in writing.
3. Please provide evidence of Māori consultation. The Committee suggested the CI approach their home institution’s review panel.

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

1. The Committee asked how long the samples will be stored for. The Researcher explained that they will be stored for between three to five years. Please add this to the consent form and participant information sheet.
2. Please update the language in your information sheet and consent forms to be New Zealand specific.
3. The Committee asked what will happen to samples at the end of the time period. The Researcher explained that they will be destroyed. Please add this to the information sheet.
4. Please provide Māori consultation phone numbers and the Health and Disability Commissioner phone number in the information sheet.
5. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
6. The Committee requested that it be made very clear that all samples from New Zealand are being taken to help improve knowledge and techniques around extracting proteins from the strip and not for future unspecified research.
7. Please remove statements about legal representatives and the consent form being read to participants in their first language from the consent form.
8. Please remove all tick boxes from the consent form except for those choices that are truly optional.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (Ethical Guidelines for Observational Studies para 6.10)
* Please provide evidence of Māori consultation for this study and that recommendations have been taken into account. (*Ethical Guidelines for Observational Studies paras 4.3 - 4.6)*

This following information will be reviewed, and a final decision made on the application, by The Committee.

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **16/CEN/135** |
|  | Title: | MAPC-N |
|  | Principal Investigator: | Miss Lisa Kremer |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 September 2016 |

Miss Lisa Kremer, Dr Roland Broadbent, Dr David Reith, and Dr Natalie Medlicott were present by 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

1. The study investigates whether a reduced dose of phenylephrine and cyclopentolate in premature neonates will dilate their eyes sufficiently to allow for an examination of their retinas. Premature neonates are at risk of retinal detachment and the Researchers hypothesise a reduction in the amount of drugs administered would be sufficient to allow an examination.

Summary of ethical issues (resolved)

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

1. The Committee queried how many times the drops would be administered. The Researcher explained that the drops will be administered up to three times. The first two times will be either at the control amount, or study amount. Drops will only be administered if the eye does not sufficiently dilate. The third time will always be at the standard of care amount.
2. The Committee noted that dark irised neonates would potentially need an increased dose.
3. The Committee asked about the randomisation procedures in the study. The Researchers explained they will use 16 envelopes to determine which dose participants will receive.
4. The Committee asked if the Researchers had considered in-patient controls. The Researchers explained that they had, but that to do so would mean they would be unable to test for the secondary systemic outcomes of toxicity.
5. The Committee noted that the sample size may be too small to detect treatment failure. The Researchers explained that this is the equivalent of a backwards dose-finding study and that it needs to be performed in order to inform future research.
6. The Committee noted that the peer review was sufficient but lacking in detail.

Summary of ethical issues (outstanding)

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

1. The Committee considered the participant information sheet and consent forms to be too brief to provide informed consent. Please provide new participant information sheets and consent forms. The Committee suggested using the templates found on the Health and Disability Ethics Committees website.
2. The Committee noted that the Researchers were seeking parent group feedback on the consent forms and suggested the Researchers submit both the long and short forms to the group.

Decision

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

* Please provide suitable participant information sheet and consent forms. The Committee suggested that the Researcher use the templates found at: [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz)
* The Committee requested that both long and short information sheets and consent forms be submitted to parent groups for feedback.
* Please provide evidence of favourable peer review of the study protocol.

This following information will be reviewed, and a final decision made on the application, by Dr Patries Herst and Mrs Helen Walker

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **16/CEN/139** |
|  | Title: | Ovarian Tissue Bank |
|  | Principal Investigator: | Dr Sarah Hunter |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 September 2016 |

Dr Sarah Hunter, Dr Mark Winstanley, and Dr Mary Birdsall were present by 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

1. The application seeks to establish a tissue bank to store children’s ovarian if the course of treatment was going to impact their ability to have children later in life.

Summary of ethical issues (resolved)

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

1. The Committee asked about Māori consultation for the tissue bank. The Researchers explained that the feedback had included the importance on stressing that ovarian tissue is not the same as a viable embryo and thus is not an independent life. Feedback had also included that there should be the option for individuals to be buried with their tissue if they wanted.
2. The Committee enquired about storage costs of tissue after five years. The Researcher explained that if funding has not been secured by this time then families will have to pay storage costs. The Committee requested that this be included in the participant information sheet and consent form.

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

1. Please add information around the potential costs of storage of tissue to the participant information sheet.

Decision

This application was *approved with non-standard conditions* by consensus.

Non Standard conditions:

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **16/CEN/140** |
|  | Title: | The Intense Trial |
|  | Principal Investigator: | Dr Nada Signal |
|  | Sponsor: | AUT University |
|  | Clock Start Date: | 15 September 2016 |

Dr Nada Signal and Ms Bridget Dickson were present by 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

1. The Committee noted the quality of the application.
2. This Committee noted that this study has three parts. The first part of the study seeks to identify patients understanding of change and the barriers to their recovery. The second part of the study seeks to develop strategies around high dose, high intensity rehabilitation. The third part of the study seeks to test these strategies to determine efficacy and benefit for patients.

Summary of ethical issues (resolved)

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

1. The Committee queried how potential study participants will be identified. The Researchers explained that they will be using clinicians to identify potential participants on their behalf. The team involved with the identification is very experienced and the Researchers are confident in their ability to determine patient competency.
2. The committee noted that there would be follow up on traumatic brain injury patients and thanked the Researchers.

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

1. Please change fonts from italics to standard in the information sheets.
2. Please amend typographic errors in the footers of the information sheets.
3. Please clearly state in the title of the information sheets and consent forms if they are for staff or patients.

Decision

This application was *approved with non-standard conditions* by consensus.

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

|  |  |  |
| --- | --- | --- |
| **9** | **Ethics ref:** | **16/CEN/146** |
|  | Title: | BLIS nasal drops study |
|  | Principal Investigator: | Dr Tony Walls |
|  | Sponsor: | UOC |
|  | Clock Start Date: | 15 September 2016 |

Dr Tony Walls was present by 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

1. The study investigates the use of an oral formulation of the probiotic BLIS in those who waiting surgery for ventilation tube or grommet surgery.

Summary of ethical issues (resolved)

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

1. The Committee queried how old participants would be. The Researcher explained that they would be around five years of age with some perhaps in their first year of school.
2. The Committee asked about nasal swabs and collection of tissue. The Researcher explained that they are just looking at bacteria present in the nose, not at any human tissue or genetic information.
3. The Committee asked about how study outcomes will be assessed. The Researcher explained that a student will be phoning families after they are given the drops to check compliance. When the families come to the hospital for the procedure there will be the opportunity to discuss the study once again.
4. The Committee asked about exclusion criteria and if children already treated with BLIS will be excluded. The Researcher explained that they would not be excluded.
5. The Committee noted that the Researcher’s response to application questions about Māori participants and cultural issues was insufficient. The Committee reminded the Researcher to take care when dealing with issues such as whakamā and the tapu of the head.
6. The Committee was satisfied that peer review was suitably independent.

Summary of ethical issues (outstanding)

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

1. The Committee asked if there is a questionnaire involved in the phone call. The Researcher stated that there is not but that they may implement one. The Committee explained that if a questionnaire is developed and a scale used then they will need to review it.
2. The Committee noted that there is not an assent form for children of school age. Please provide an assent form for children of school age.

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

1. Please make it clear in the information sheet that swabs will be looking at the bacteria in the nose, not for the purposes of tissue collection.
2. Please make it clear that there will be two nasal swabs in the participant information sheet.
3. Please make sure that the participant information sheet states early on that participation is voluntary.
4. Please include Researcher and Māori support details in the participant information sheet.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide suitable information sheets and assent forms. This includes an information sheet and consent form for parents of participants unable to provide informed consent, an information sheet and consent form for participants able to provide their own informed consent (this includes all participants aged 16 years or older and may include some younger participants if they are deemed competent), an information sheet and assent form for children, and a very simple information sheet and assent form for young children that should very simply explain their participation in the study. Guidance on assent can be found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>
* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).

This following information will be reviewed, and a final decision made on the application, by Dr Dean Quinn and Mrs Sandy Gill

|  |  |  |
| --- | --- | --- |
| **10** | **Ethics ref:** | **16/CEN/142** |
|  | Title: | RECLAIM Hip System Subsidence Study |
|  | Principal Investigator: | Dr Paul Sharplin |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 September 2016 |

Dr Douglas Hancock 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.

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

Summary of Study

1. The study investigates why people’s hip replacements have failed and if this failure can be attributed to subsidence. If the failure can be attributed to subsidence then Researchers will examine if addressing subsidence makes a difference to patient wellbeing.

Summary of ethical issues (resolved)

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

1. The Committee noted that the replacement joint manufacturer is currently accused of surprising negative data about the long term viability of their replacement joints and asked if the company has any control of the data. The Researcher confirmed that the manufacturer has no control of study data.

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

1. Please clarify statements around data and who has access to the data in the information sheet.
2. Please statements about pregnancy and tissue samples from the consent form.
3. Please remove all tick boxes except for options that are truly optional in the consent form.
4. Please add Māori support details to the information sheet.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

This following information will be reviewed, and a final decision made on the application, by Mrs Helen Walker and Dr Melissa Cragg

|  |  |  |
| --- | --- | --- |
| **11** | **Ethics ref:** | **16/CEN/143** |
|  | Title: | Preventing progression from pre-diabetes to Type 2 diabetes in New Zealanders: The PROGRESS NZ Study |
|  | Principal Investigator: | Associate Professor Jeremy D Krebs |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 September 2016 |

Dr Patricia Whitfield 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.

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

Summary of Study

1. The study seeks to establish whether or not the two arms of a future study looking at type 2 diabetes prevention are feasible and tolerable to participants.
2. The Committee asked what procedures participants will undertake as part of the study. The Researcher explained that all participants will scanning to see if their body makeup is feasible. After scanning they will undergo a blood test to check blood sugars. Following these tests eligible participants will undergo a one month supervised gym program. After this month they will be put on a one month dietary plan. After this month participants will return to the lab for final testing and a chance to give feedback.

Summary of ethical issues (resolved)

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

1. The Committee queried what safety procedures are in place for patients during the overnight stay part of the study. The Researcher explained that they will have a single person monitoring participants for the whole time and that there are security staff on campus. They felt that 2 observers was unnecessary.
2. The Committee asked if participants can get out of the monitoring room. The Researcher confirmed they could.
3. The Committee asked if the 40 hour timeslot for the room is standard. The Researchers confirmed that it is for this type of research.
4. The Committee enquired about the study only being open to men. The Researcher explained that there are energy expenditure difference between genders, particularly relating to menstrual cycles in women. Thus in order to test the efficacy of the studies’ monitoring equipment with as little confounding variables as possible they have restricted the pilot study to men only. Future studies will be open to women as well.
5. The Committee suggested a flowchart or grid to explain what participation will involve exactly.

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

1. Add a flowchart or grid breakdown of study participation and the processes involved in participating to help participants understand what each step involves.

Decision

This application was *approved with non-standard conditions* by consensus.

Non Standard conditions:

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

|  |  |  |
| --- | --- | --- |
| **12** | **Ethics ref:** | **16/CEN/131** |
|  | Title: | ROLLIS Randomised Control Trial |
|  | Principal Investigator: | Dr Rebecca Hughes |
|  | Sponsor: |  |
|  | Clock Start Date: | 08 September 2016 |

Dr Rebecca Hughes, Ms Jenni Scarlet, Associate Professor Ian Campbell and Dr Diana Balog were present by 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

1. The study investigates the use of a radioactive seed instead of a standard of care device to help with surgical removal of breast lesions.
2. The Committee commended for their responses to the Secretariat’s request for further information for issues faced by Māori in relation to study participation.

Summary of ethical issues (resolved)

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

1. The Committee queried what exactly study participation would involve. The Researchers explained that participants will be randomised and will receive either standard of care, which is localisation dependent, or the radioactive seed. The seed implantation procedures are very similar to those received as part of standard care.
2. The Committee asked how participants will be selected. The Researchers explained that patients who are not pregnant or breastfeeding and who have non-palpable breast tumours that needs surgery will be included.
3. The Committee queried the Researchers answer in their application to data being made available for further research. The Researchers explained that they meant that they would be publishing their results.

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

1. Please make sure that information sheet states early on that study participation is voluntary.

Decision

This application was *approved* *with non-standard conditions* by consensus.

Non Standard Conditions:

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 25 October 2016, 12:00 PM |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington, 6011 |

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 5:50pm.