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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 24 June 2014 |
| **Meeting venue:** | Terrace Conference Centre, 114 The Terrace, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.10pm | Confirmation of minutes of meeting of 27 May 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/CEN/89  ii 14/CEN/88  iii 14/CEN/90  iv 14/CEN/91  v 14/CEN/92  vi 14/CEN/94  vii 14/CEN/96  viii 14/CEN/97  ix 14/CEN/100  x 14/CEN/99 |
| 4.40pm | General business:   * Noting section of agenda |
| 5.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2014 | Present |
| Mrs Gael Donoghue | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2014 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |
| Dr Kay de Vries | Non-lay (observational studies) | 19/05/2014 | 19/05/2017 | Present |

## Welcome

The Chair opened the meeting at 12.15pm and welcomed Committee members, noting that no apologies had been received.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

The Chair noted that at the recent Chairs’ day there had been discussions about consistency among Committees. Several areas were identified to improve consistency and a list of these will be sent to members as a separate document.

## Confirmation of previous minutes

The minutes of the meeting of 27 May 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/CEN/89** |
|  | Title: | A Two Part, Phase I/IIa Assessment of Citramel |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | Breathe Easy Ltd |
|  | Clock Start Date: | 05 June 2014 |

Ms Andrea Miller and Ms Michelle Lockhart 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 ethical issues

The Committee discussed the following points.

* The Committee noted this was a well written application.
* The Committee noted that this is a two part study of a new inhalation drug for Cystic Fibrosis (CF) patients. The first part will be a first in human study of five healthy participants. Part 2 will be a crossover study of 25 participants with CF.
* The Committee asked whether a report of Part 1 would be sent to the Committee before starting Part 2. Ms Lockhart explained that a report would be sent to the DSMB and agreed to send it to the Committee as well.
* The Committee noted that this was a two part study and in future two separate applications should be submitted.
* Ms Lochkhart agreed to send the SCOTT approval to the HDEC Secretariat when it is received.
* The Committee noted that the sputum and blood samples will be sent to Breathe Easy for analysis and asked where the laboratory was located. Ms Lockhart advised that they were not yet sure of this.
* The Committee advised that for future applications, P.4.1 requires statistics for the prevalence of CF in Māori. If this is not known, then this should be noted. F.1.2 is a similar question but is asking this not just for Māori but for other groups such as Pacific people and Asians.
* The Committee advised that there have been several recent cases where an insurance company has refused cover to participants when something has gone wrong on a trial. The Committee recommended that the researchers check with their insurance broker that if something does go wrong during the trial that participants are covered for at least the ACC equivalent
* The Committee asked whether formal consultation with Māori had occurred. Ms Lockhart advised that this was being organised by CCST.
* The Committee requested the following changes to the PIS and consent form:
  + Please remove the reference to placebo under the baseline visit section (page 3 of the PIS for healthy participants).
  + Please amend reference from Southern Health and Disability Ethics Committee to Central Health and Disability Ethics Committee on both PIS.
  + Please ensure that people are given the option of receiving results in lay terms and include this on both PIS.
  + Please include nursing mothers and smokers as exclusion criteria in both PIS.
  + Please include Māori cultural support contact details on both PIS.

Decision

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

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

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| **2** | **Ethics ref:** | **14/CEN/88** |
|  | Title: | DPM-CF-303 |
|  | Principal Investigator: | Prof. John Kolbe |
|  | Sponsor: | Pharmaxis |
|  | Clock Start Date: | 12 June 2014 |

Professor John Kolbe 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 ethical issues

The Committee discussed the following points.

* The Committee noted that this was a generally well put together application with a few obvious errors that should have been picked up on review prior to submission.
* The Committee asked for the researchers understanding of why this study was being done in New Zealand. Professor Kolbe advised that the drug is available in New Zealand on compassionate grounds and is potentially indicated for both Cystic Fibrosis (CF) and non-CF bronchiectasis. He thought that the EU and FDA felt that there was insufficient evidence to support funding of this drug, particularly given that it is drug powder that requires inhalation of a number of capsules. The EU and FDA have asked for more studies to demonstrate the efficacy of the drug in CF. Professor Kolbe explained that he was asked to take part in this trial as he had been involved in Phase II and Phase III trials for non-CF bronchiectasis
* Professor Kolbe advised that it may be difficult to recruit many people for this trial as participants are not able to take nebulised hypertonic saline during the trial.
* The Committee noted that several questions on the application had been answered incorrectly (D – will your study involve human participants, G – will your study involve the use or disclosure of health information). This means that the Committee does not get all of the information required as some of the drop down boxes will not appear when completing the application.
* The Committee noted that R.2.3.1 on whether the study will involve the use of surveys or questionnaires was not answered. Professor Kolbe advised that he thought the CF quality of life questionnaire would be used.
* The Committee advised that for P.4.1 they are looking for statistics on the prevalence of CF for Māori and what the benefit for this population group would be. Professor Kolbe read out the response he had sent to Auckland and Waitemata DHB and the Committee noted that a summary of this would have been appropriate to include in the answer to P.4.1.
* The Committee advised that for F.1.2 the answer given to Auckland and Waitemata DHB would have been useful.
* The Committee requested the following changes to the PIS and consent form:
  + Please correct typos, for example number of participants.
  + Please remove the consent form for trial DPM-CF-204 as this relates to another trial (pages 13 and 14 of the PIS).

Decision

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

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

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| **3** | **Ethics ref:** | **14/CEN/90** |
|  | Title: | AQX-1125-202/ FLAGSHIP Study |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: | Clinical Network Services |
|  | Clock Start Date: | 12 June 2014 |

Dr Dean Quinn 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.

Dr Dean Quinn declared a conflict of interest as he is a Committee member and Principal Investigator for the study. Dr Quinn was present in his capacity as a researcher to answer the Committee’s questions, but did not participate in the Committee’s decision making in relation to this application.

Summary of ethical issues

The Committee discussed the following points.

* Dr Quinn explained that this was a study of a new drug aimed at inhibiting the inflammatory pathways in patients with COPD. Potential participants would either come to the study site within three days of an exacerbation of their COPD or have been hospitalised for their COPD.
* The Committee asked how potential participants would be approached. Dr Quinn advised that this would depend on the site. He noted that his site does not anticipate seeing people who had been hospitalised. Potential participants taken from his site’s database would be contacted by phone and would be sent a PIS in advance alerting them that they may be eligible for the trial when they get an exacerbation of COPD.
* Please clarify whether meals will be reimbursed.
* Dr Quinn advised that the answer to B.4.5 (will any human tissue collected but not used be made available for use in future research) should have been ‘no’.
* The Committee queried the answer to R.2.4.1 which stated that documents data will be either identified or potentially identifiable. Dr Quinn advised that patient records would be identifiable and the data potentially identifiable.
* The Committee noted that for future applications the reference to the Treaty should be removed in answer to P.4.1.
* The Committee commended the inclusion of over the counter medications in the treatment and medications that participants need to tell their study doctor that they are taking.
* The Committee acknowledged that the PIS is clear and easy to understand.
* The Committee requested the following changes to the PIS and consent form:
  + Please add the word “whanau“ after “you might want to talk about it with a relative, friend” (page 1 of the PIS).
  + Please add “and New Zealand” after “This means that it is not an approved treatment for COPD in Australia” (page 2 of the PIS).
  + Please clarify why participants are not allowed to take Roflumilast and Theophyline during the study (page 4 of the PIS).
  + Please ensure that the compensation clause (page 9 of the PIS) is made relevant for a New Zealand audience.
  + Please review the exclusion criteria and include any that would not be obvious from a participant’s medical records in the PIS.
  + Please ensure that the paragraph on privacy is made relevant to a New Zealand audience (para 4, page 9 of the PIS).
  + Please add “it would be helpful if you could this but this is your choice” after “final examination” (para 3, point 6, page 5 of the PIS)
  + Please state that this study has been approved by the Central Health and Disability Ethics Committee (page 10 of the PIS).
  + Please include in the consent form that tissue will be sent overseas for testing.

Decision

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

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

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| **4** | **Ethics ref:** | **14/CEN/91** |
|  | Title: | Diamond COPD Study |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: | GSK New Zealand Pty Ltd |
|  | Clock Start Date: | 12 June 2014 |

Dr Dean Quinn 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.

Dr Dean Quinn declared a conflict of interest as he is a Committee member and Principal Investigator for the study. Dr Quinn was present in his capacity as a researcher to answer the Committee’s questions, but did not participate in the Committee’s decision making in relation to this application.

Summary of ethical issues

The Committee discussed the following points.

* The Committee commended a well set out and straightforward application.
* The Committee queried whether there were any co-investigators for the study. Dr Quinn advised that there were but they were not sure of the sites and the investigators when the application was completed.
* The Committee commended the answers to P.4.1 and F1.2 in the application.
* The Committee requested the following changes to the PIS and consent form:
  + Please add “optional” to the title of the PIS for genetics research.
  + Please review the exclusion criteria and include any that would not be obvious from a participant’s medical records in the PIS.
  + Please change “Multi-region Ethics Committee” to “Central Health and Disability Ethics Committee” on both PIS.
  + Please include that participants must be proficient in English to take part in this study as this is listed as an ethical issue in the application.

Decision

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

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

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| **5** | **Ethics ref:** | **14/CEN/92** |
|  | Title: | Infant TBI Genetics study |
|  | Principal Investigator: | Dr Kelly Jones |
|  | Sponsor: | National Institute of Stroke and Applied Neuroscience |
|  | Clock Start Date: | 12 June 2014 |

Dr Kelly Jones 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 ethical issues

The Committee discussed the following points.

* Dr Jones explained that this study is looking at the genetic contribution to recovery from a TBI and is a follow on from the BIONIC study which took a saliva sample from all participants. This latest study is looking at the youngest group of participants from the BIONIC study.
* The Committee acknowledged that the PIS was clear and that cultural issues had been acknowledged.
* The Committee noted that some of the parents may have lower levels of literacy and asked whether someone would take the parents through the PIS or they would read it by themselves. Dr Jones advised that parents of potential participants would be contacted by phone and if they agreed would be sent a PIS to read by themselves. The researchers would contact the parents the following week to answer any questions they may have. If the researchers think that people do not understand any aspects of the study, they will ask them to repeat it back.
* The Committee felt that the PIS for children would be difficult for six to eight year olds to understand and recommended the use of a diagram, cartoons and age appropriate language.
* The Committee noted that for future applications statistics (if any) on the rates of TBI in Māori should have been identified (P.4.1) and for other ethnic groups, such as Pacific people and Asians (F.1.2).
* The Committee noted that consultation with Māori still needs to take place even though the processes are the same as a previous study (P.4.3.1).
* The Committee asked for clarification on what “your records” referred to on page 3 of the PIS for parents. Dr Jones explained that this was not medical records but study documentation, for example contact details and notes on any discussions with participants.
* The Committee noted that anyone residing outside Hamilton or Waikato would be excluded from this study. Unless the researchers can be certain that PIS will not be sent to anyone who has moved outside the area, this should be included in the PIS.
* The Committee requested the following changes to the PIS and consent form:
  + Please change “would be eligible for compensation from ACC” to “may be eligible for compensation from ACC” (page 3 of the PIS).
  + Please add this study has received ethical approval from the Central Health and Disability Ethics Committee.
  + Please include an option in the future unspecified research consent form for participants to withdraw their consent when they have reached the age of consent.
  + Please remove the reference to receiving ethical approval on 14th October 2013 (page 4 of the PIS for parents).

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Observational Studies, para 6.10).*

The response from the researcher will be reviewed, and a final decision made on the application, by Mrs Sandy Gill and Dr Kay de Vries.

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| **6** | **Ethics ref:** | **14/CEN/94** |
|  | Title: | A Study of Adalimumab in Paediatric Subjects with Moderate to Severe Ulcerative Colitis.- M11-290 |
|  | Principal Investigator: | Prof Andrew Day |
|  | Sponsor: | Clinipace Worldwide |
|  | Clock Start Date: | 12 June 2014 |

No researchers were 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 ethical issues

The Committee discussed the following points.

* The Committee acknowledged that while the PIS was long, it included relevant information and noted that the serious side effects of Adalimumab were thoroughly outlined in the PIS.
* The Committee noted that 28,000 participants had been treated in clinical trials with the study drug.
* The Committee noted that the study drug had not been approved in New Zealand for use in children (but was approved in the UK for children 6-17 years old) and were concerned that it would be used on children as young as four, particularly given that a child’s immune system is not developed until around seven years of age.
* The Committee noted that the study drug had been used in 2 to 17 year olds for the treatment of idiopathic arthritis.
* The Committee noted that the European Medicines Agency review contained a lot of detail on the dosage for participants.
* The Committee advised that there have been several recent cases where an insurance company has refused to cover participants when something has gone wrong on a trial. The Committee recommended that the researchers check with their insurance provider that if something does go wrong during the trial that participants are covered for at least the ACC equivalent.
* Please clarify the reference “your child’s personal health information” on page 25 of the PIS. Is this study data?
* The Committee commended the inclusion of over the counter medications in the treatment and medications that participants need to tell their study doctor that they are taking.
* The Committee noted that for R.1.13 the researcher answered no as to if any radiation exposure but participants would receive chest and wrist x-rays as part of the study
* The Committee advised that for future applications P.4.1 and F.2.1 are looking for statistics on the prevalence of ulcerative colitis on Māori (P.4.1) and other ethnic groups (F.2.1).
* The Committee requested the following changes to the PIS and consent form:
  + Given the length of the PIS, please include a flow chart at the beginning identifying where to find each section of the PIS.
  + Please amend “If a medical emergency should occur, please contact your child’s study doctor” to “please call 111” (page 22 of the PIS).
  + Please review the exclusion criteria and include any that would not be obvious from a participant’s medical records in the PIS.
  + Please provide age appropriate PIS and assent forms for 6 to 12 year olds and 13 to 15 year olds.
  + Please review wording in the PIS and ensure that the wording is applicable to the participant involved in that PIS.
  + Please include that this has received ethical approval from the Central Health and Disability Ethics Committee.
  + Please include Māori cultural support contact details.
  + Please add the word “optional” to title of the sub-study of genetic and non-genetic biomarkers.

Decision

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

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

The response from the researcher will be reviewed, and a final decision made on the application, by the Committee.

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| **7** | **Ethics ref:** | **14/CEN/96** |
|  | Title: | Total hip joint arthoplasty skin sealing with steristrips vs. skin glue |
|  | Principal Investigator: | Dr Liam Dunbar |
|  | Sponsor: | Hutt Valley DHB |
|  | Clock Start Date: | 12 June 2014 |

No researchers were 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 ethical issues

The Committee discussed the following points.

* The Committee noted that this was a study to compare the effects of steristrips vs skin glue on wound sealing for total hip joint replacements. Both methods are currently extensively used.
* The Committee noted that for future applications F.1.2 is looking for statistics (if any) on the prevalence of hip replacements in other ethnic groups, for example Pacific people and Asians and how this study may contribute to reducing any inequalities.
* The Committee requested the following changes to the PIS and consent form:
  + Please include a footer on the PIS with a version number and page numbers.
  + Please include that this study has received ethical approval from the Central Health and Disability Ethics Committee.
  + Please include a known skin allergy as an exclusion criteria in the PIS.
  + Please change “would be eligible for compensation from ACC” to “may be eligible for compensation from ACC”.

Decision

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

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

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| **8** | **Ethics ref:** | **14/CEN/97** |
|  | Title: | The STRENGTH trial |
|  | Principal Investigator: | Professor Richard Troughton |
|  | Sponsor: | Clinical Research Organisation |
|  | Clock Start Date: | 12 June 2014 |

No researchers were 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 ethical issues

The Committee discussed the following points.

* The Committee noted that this was a study of the effect of Epanova vs corn oil for the treatment of high triglycerides.
* The Committee noted that due to the large number of participants, there may be some literacy issues with understanding the PIS/CF. The Committee found the description of the visits in the PIS confusing and repetitive and recommended the inclusion of a flow chart to explain how study progresses and a table with a list of what happens at each visit.
* Please confirm where the central laboratory for testing blood and urine samples is located.
* Please confirm whether it is just the genetic samples going to Boston and what will happen to the other samples.
* The Committee asked that the study results be made available to participants in lay language. This needs to be included in the PIS.
* The Committee advised that for future applications F.1.2 is looking at how this study will help other ethnic groups, for example Pacific peoples and Asians.
* The Committee requested the following changes to the PIS and consent form:
  + Please amend “type of fat found” to “type of fat found in your blood” (page 1 of both PIS).
  + Please add the name of the New Zealand sponsor (page 3 of the PIS).
  + Please amend “no tissue samples being taken” to “no other tissue samples being taken” as blood and tissue samples are also being taken.
  + Please amend typo “right to refused” (para 4, page 14 of the PIS).
  + Please review the exclusion criteria and include any that would not be obvious from a participant’s medical records in the PIS.
  + Please include the italicised paragraph on Māori cultural beliefs on tissue (page 4 of the covering letter) in the optional PIS.
  + Please amend Southern Health and Disability Ethics Committee to Central Health and Disability Ethics Committee.
  + Please include Māori cultural support contact details.
  + Please include a statement on participation in the study being confidential in the optional PIS.

Decision

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

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

The response from the researcher will be reviewed, and a final decision made on the application, by Dr Patries Herst and Dr Cordelia Thomas.

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| **9** | **Ethics ref:** | **14/CEN/100** |
|  | Title: | The Experience of Diabulimia in People with Type I Diabetes |
|  | Principal Investigator: | Ms Lisa Hoyle |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 June 2014 |

Ms Lisa Hoyle 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 ethical issues

The Committee discussed the following points.

* The researcher explained that there were a wide range of people with diabulimia ranging from those who do it occasionally to those who have to be hospitalised.
* The Committee queried whether all participants had mental health issues. Ms Hoyle explained that one of the issues identified from the literature is that it is seen as more of a behavioural issue than a mental health issue. Ms Hoyle agreed that all participants would have mental health issues but these ranged in severity.
* The Committee advised that they would like to see the interview questions, given the background of the people being interviewed. Ms Hoyle explained that a statistician had recommended starting with some basic questions but these would change as the study progresses if the questions are not providing the researcher with the information required. Ms Hoyle agreed to send the Committee the first set of questions that might be asked.
* The Committee asked whether the researchers would ask questions on how the diabulimia started or if they would be concentrating on the behavioural issues. Ms Hoyle advised that this would be a combination of both and would look at whether people had eating issues before they were diagnosed with diabetes or if they had discovered by accident that they could lose weight by skipping insulin.
* The Committee asked what support would be in place if a risk to a participant was identified. Ms Hoyle explained that participants would first be referred to a community mental health team, then to the regional mental health team who would decide if inpatient care was appropriate. The Committee asked what would happen if a person did not want to be referred on. Ms Hoyle advised that if she had identified a safety issue, she would have to refer them regardless of whether they had given permission.
* The Committee noted that referrals to mental health teams can take time and asked what would happen if it was an immediate risk. Ms Hoyle advised that in an emergency, she would call Crisis which is part of the community mental health service and if they were not available she would call the police. She noted that if the surveys were done at the Superclinic, she would have immediate access to doctors and nurses but she would call Crisis for interviews done in participant’s homes. Ms Hoyle advised that she was trained in doing risk assessments and would feel comfortable doing these. She would also be able to call her supervisor if this was required.
* The Committee asked how the researcher would ensure her personal safety when she was conducting interviews in participant’s homes. Ms Hoyle advised that she would carry her cell phone and her co-investigator would have the address of where she was going. The Committee recommended considering whether two people attend interviews.
* The Committee asked whether there will there be Kaumatua or cultural support on call. Ms Hoyle advised that her co-investigator Caran Barratt-Boyes and Eva Morunga, a Māori health psychologist will be available. She noted that she will have access to Māori and Pacific support through the DHB but was not sure if they would always be available by phone.
* The Committee noted that the PIS does not tell the participant that if they disclose information that the researcher views as risky, then the researcher may have to refer them. Ms Hoyle explained that this would hopefully be with the participant’s consent but she was obligated to refer even without consent.
* The Committee asked if participants would review the interview transcripts. Ms Hoyle agreed that this would be useful as participants could clarify their answers. This will need to be added to the PIS as it will change the length of time that the study will take participants.
* The Committee noted that vulnerable participants had not been identified in the application (question O). Ms Hoyle advised that this was in error.
* The Committee asked for clarification on the answer P.4.2 on whether whanau would be present during the interview. Ms Hoyle advised that whanau will not be present if the participant does not want them there, even if the whanau want to be involved.
* The Committee requested the following changes to the PIS and consent form:
  + Please change “would be eligible for compensation from ACC” to “may be eligible for compensation from ACC”.
  + Please include in the PIS that this study has received ethical approval from the Central Health and Disability Ethics Committee.
  + Please include PTSD and schizophrenia as exclusion criteria in the PIS.
  + Please give the participants the option of whether they want their GP to be informed.
  + Please include that if a participant may need to be referred to mental health services if they disclose information that the researcher deems risky.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Observational Studies, para 6.10).*
* Please provide a document outlining safety procedures for researcher and participants *(Ethical Guidelines for Observational Studies, para 9.1).*
* Please provide a list of the first set of questions that will be asked *(Ethical Guidelines for Observational Studies, para 6.10).*

This following information will be reviewed, and a final decision made on the application, by Mrs Sandy Gill and Dr Kay de Vries.

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| **10** | **Ethics ref:** | **14/CEN/99** |
|  | Title: | RELIEF II Study |
|  | Principal Investigator: | Assoc Prof Peter Gilling |
|  | Sponsor: | GT UROLOGICAL, LLC |
|  | Clock Start Date: | 12 June 2014 |

No researchers were 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 ethical issues

The Committee discussed the following points.

* The Committee asked for clarification on how the patients on the waiting list would be approached as there may be the risk of inducement given that patients are waiting to be treated.
* The Committee asked for suggestions on how Māori could be more engaged to enable greater rates of participation (P.4.3.1)
* The Committee noted that for future applications P.4.1 is looking for statistics (if any) on the rates of urinary stress incontinence in Māori, while F.1.2 is looking for statistics for other ethnic groups.
* Please provide evidence of insurance.
* The Committee requested the following changes to the PIS and consent form:
  + For consistency, please amend references from “pressure compensator” to “pressure mechanism” in the picture on page 2 of the PIS.
  + Please quantify the small risk of bleeding (page 8 of the PIS).
  + Please review the exclusion criteria and include any that would not be obvious from a participant’s medical records in the PIS.
  + Please amend reference from “presenting to your nearest Accident and Emergency department” to “call 111” (page 9 of the PIS).

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide evidence of insurance *(Ethical Guidelines for Intervention Studies, para 8.4).*

## 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:** | 22 July 2014, 12:00 PM |
| **Meeting venue:** | Deloitte House, MEDSAFE, Level 6, 10 Brandon Street, Wellington, 6011 |

No members tendered apologies for this meeting.

Dr Cordelia Thomas, Dr Kay de Vries and Mrs Helen Walker tendered their apologies for the August meeting.

Mrs Helen Walker and Mr Paul Barnett tendered their apologies for the September meeting.

The meeting closed at 4.04pm.