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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 26 July 2016 |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of [No previous meeting in database. A previous meeting must link to this as next meeting.] |
| 12:30pm | New applications (see over for details) |
|  | i 16/CEN/97  ii 16/CEN/82  iii 16/CEN/89  iv 16/CEN/88  v 16/CEN/91  vi 16/CEN/92  vii 16/CEN/95  viii 16/CEN/96  ix 16/CEN/72 |
| 4:15pm | Substantial amendments (see over for details) |
|  | i 15/CEN/47/AM02  ii 15/CEN/206/AM01  iii 15/CEN/19/AM04  iv 15/CEN/157/AM02  v 13/CEN/131/AM03 |
| 5:20pm | Meeting ends |

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| **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 | Present |
| 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 12:00pm and welcomed Committee members.

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 24 May 2016 were confirmed.New applications

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| 1 | **Ethics ref:** | **16/CEN/97** |
|  | Title: | HBV Switch Study |
|  | Principal Investigator: | Prof Ed Gane |
|  | Sponsor: | Gilead Sciences Pty Limited, Australia and New Zealand |
|  | Clock Start Date: | 14 July 2016 |

Dr Ed Gane 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 the efficacy and safety of two drugs against one another in patients with chronic hepatitis b or greater chronic kidney disease who have received a liver transplant
2. Two drugs are being tested: Tenofir Alafenomide (TAF) versus Tenofir Disoproxil Fumarate (TDF)
3. Patients will be assigned into one of two arms at a 1:1 ratio. The first arm receives 25mgs of TAF daily. The second arm continues on current regimen of TDF alone or TDF combined with other approved medicines.
4. The study will last 48 weeks. During the study participants will attend the clinic 9 times.
5. While attending the clinic patients will undergo tests. These include: assessment of adverse events, physical exams, vital signs, study drug adherence, concomitant medications, answering questionnaires, blood assays, and clinical laboratory tests.
6. Up to 5 DXA scans (x-rays) and 3 renal scans will be used to measure bone density and renal function to compare the effects of the drugs.
7. There will be the option to participate in further treatment at week 48 where all patients will be able to receive 25mg TAF daily for an additional 96 weeks.
8. Participants will be able to take part in optional sub studies.

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 the quality of the application.
2. The Committee noted the lack of a consent form for Future Unspecified Research. The Coordinating Investigator explained that this in contained within one of the other consent forms in the study.
3. The Committee asked about participant reimbursement. The Coordinating Investigator explained that they intend to reimburse up to 100 New Zealand Dollars for travel and parking expenses. If necessary they can pay more.

Summary of ethical issues (outstanding)

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

1. Please provide the PIS for pregnant women.
2. Please change the phrasing in the PIS regarding the placebo pill.
3. Please link the abbreviation of terms needed to be linked with the original term in the PIS.
4. Please consider a study events table in the PIS as information in the PIS about the study activities is very repetitive.
5. Please include in the PIS a statement about participants having a right to refuse to answer questions in the study questionnaire.
6. 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.”*

Decision

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (Ethical Guidelines for Intervention Studies para 5.30)
2. Evidence of changes made to PIS and CFs
3. A PIS for pregnant women.

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

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| **2** | **Ethics ref:** | **16/CEN/82** |
|  | Title: | CO2 monitoring in NICU: Agreement between two capnography devices and blood gas analyser |
|  | Principal Investigator: | Dr Maria Saito Benz |
|  | Sponsor: | Capital and Coast District Health Board |
|  | Clock Start Date: | 16 June 2016 |

Dr Maria Saito Benz 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 Angela Ballantyne and Dr Patries Herst declared a potential conflict of interest, and the Committee decided to allow them to continue and participate fully in the discussion and decision.

Summary of Study

1. The population of the study is ventilated newborns in the Neonatal Intensive Care Unit (NICU)
2. The study is a pilot study to assess the viability of a new blood gas analyser against the one currently used in standard practice. The aim of the study was to establish the accuracy of the new machine in detecting carbon dioxide (CO2) levels before it is used in future studies.
3. The primary issues with the machine used in standard care is that is cannot be used for research purposes easily, as data cannot be downloaded.
4. If the new machine proves viable then it will allow for future studies using the machine.

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 if the population would already be of pre-ventilated newborns in NICU or if any newborns would be ventilated as part of the study. The Coordinating Researchers explained that they would only approach parents of babies already ventilated as part of standard care. The participants will also already have an arterial line placed. Prior to any blood tests the alternate machine will be attached and the accuracy of the measurements will be recorded.
2. The Committee asked about the number of participants in this study. The Coordinating investigator explained that they aim to recruit about 20 babies and take between 40-120 paired measurements.
3. The Committee asked if the experimental device is used anywhere else in New Zealand. The Coordinating Investigator explained that it is not.
4. The Committee then asked if this meant that The Coordinating Investigator would be looking to replace the current machine. The Coordinating Investigator explained that this would only be done in future studies and the aim of this study is to assure the new machine’s reliability.
5. The Committee asked if the new machine only measures CO2 levels. The Coordinating Investigator confirmed this.
6. The Committee confirmed with The Coordinating Investigator that peer review comments had been responded to. The Coordinating Investigator confirmed that they had.
7. The committee asked how dealing with parents who may be emotionally distressed would be managed. The Coordinating Investigator explained that NICU staff are well trained and experienced with dealing with patient’s parents and parents will not be approached until they are acclimatised to the NICU environment.
8. The Committee enquired about future unspecified research use of the data as The Coordinating Investigator had indicated this in the application. The Coordinating Investigator explained that this was an error.
9. The Committee asked about tissue collection. The Coordinating Investigator explained that any tissue collection is part of standard care.

Summary of Ethical Issues (Outstanding)

1. The PIS opens with wording stating that there may be a benefit to the child from participation but later on contradicts this by saying that there is no benefit. The Coordinating investigator explained that the benefit mentioned is derived from being on a ventilator, not from participation. Please amend the PIS to resolve this ambiguity and clarify that nonparticipation would not result in babies requiring ventilation not being ventilated.
2. The Committee noted that the PIS erroneously stated that there was a legal requirement to keep study data for 16 years. The (Health (Retention of Health Information) Regulations 1996) state researchers are required to keep study data for a minimum of 10 years. Please change the data storage information in the PIS to reflect this.

Decision

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

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| **3** | **Ethics ref:** | **16/CEN/89** |
|  | Title: | Predictors and Relationships of Dental Health Status in two cohorts |
|  | Principal Investigator: | Associate Professor John Thompson |
|  | Sponsor: |  |
|  | Clock Start Date: | 07 July 2016 |

Dr John Thompson 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 is a data-linkage study. The researchers intend to examine how poor dental health status relates to other health outcomes by linking two previous studies: The ABC study and The Children of SCOPE study.
2. The specific aims of the study aim to look at how maternal, pregnancy, and early childhood factors are associated with poor dental health status. To look at how childhood body size relates to dental health status. To determine the relationship of dental health status and other outcomes in childhood including intelligence, behavioural problems, depression, and bullying.

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 The Coordinating Investigator to clarify the aims of the study. The Coordinating Investigator explained that there is opportunity for understanding how pregnancy-related factors such as gestational diabetes or hypotension and impact children’s dental health later in life. They also have data on diet and other factors through childhood. Other data included were outcome variables.
2. The Committee noted that the PIS erroneously stated that there was a legal requirement to keep study data for 16 years. The (Health (Retention of Health Information) Regulations 1996) state researchers are required to keep study data for a minimum of 10 years. 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 that “*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: *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.*
3. The Committee noted that given that there already are public initiatives regarding children’s dental health. Is the linkage hoping to examine on how pregnant women’s choices impact dental health? The Coordinating Investigator stated that they would do so if the data showed a correlation.
4. The Committee noted that genetic data had been collected as part of the two studies and there was no information around use of these data in the study. The Coordinating Investigator confirmed that they are not looking at genetic data and have no hypothesis relating to this.
5. The Committee noted the high percentage of Māori in the datasets and asked about the opportunity to look at how ethnicity and dental health status. The Coordinating Investigator confirmed that Māori health committee at Waitemata DHB have approved this. The Committee noted that it would have been prudent therefore to include statistics in The Coordinating Investigator’s response to question p.4.1. The Coordinating Investigator stated that whilst Māori dental health is listed as poorer there is not enough information on this issue. Data systems currently only record health status and aren’t used for research. DHBs now regularly report data to the Ministry of Health but this data is more akin to a clinical record and very little research has been done using this data.
6. The committee noted that as blood and tissue were collected then whakapapa could be an issue for Māori.
7. The Committee was sceptical of the Coordinating Investigator’s claims that correlations between diet (high sugar intake), diabetes and dental health were unknown. They were also sceptical about the third aim of the study and asked how these could impact dental outcomes. They noted the temptation to link large pools of data simply because they exist and that there are already extant programs targeting women’s and children’s dental health. The Coordinating Investigator noted that it is well known that sugar intake leads to decay. By linking the data they would be able to examine trend data around diet and dental health.
8. The committee was satisfied that the first two aims of the study meet all three criteria for use of health information without consent.

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 that the current peer review was provided by a researcher involved in the design of the data sets. Please provide evidence of more independent peer review.
2. Please provide evidence for how linking the datasets will help achieve the studies’ third aim and satisfy the Committee in respect of the Ethical Guidelines for Observational Studies and Right 6(1) of the HDC Code of Rights right 6(1)(d). Please provide this in the form of an amendment.

Decision

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

1. Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
2. The linking of data for the first two aims of the study was approved. Please provide an amendment for the third aim of the study that addresses the Committee’s concerns.

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

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| **4** | **Ethics ref:** | **16/CEN/88** |
|  | Title: | Breast arterial calcifications and cardiovascular disease in New Zealand |
|  | Principal Investigator: | Dr Lisa Johnston |
|  | Sponsor: | Volpara Solutions |
|  | Clock Start Date: | 07 July 2016 |

Dr Lisa Johnston, Miss Irene Ebyarimpa, and MS Lucy Barnes 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 aims to investigate the correlations between breast arterial calcifications and cardiovascular disease in women who have undergone arterial catheterisation or angiogram in Wellington Hospital Unit.
2. To check for correlation researchers will analyse mammogram data from the Volpara server for the presence of arterial calcifications and cross reference this with clinical notes from women who have been for cardiac evaluation or work up in the catheterisation laboratory.
3. The Committee noted that the above explanation means that this study is a cross-sectional design.
4. The Committee enquired as to the number of participants in this study. The researchers explained that they will be looking retrospectively at the routinely collected information of around 400 people.
5. The Committee enquired about the ages of participants, as mammogram data is generally for those who are over age 55. The Coordinating Investigator agreed and said that those who have other factors such as individuals with a family history or have had breast cancer will be included.
6. The Committee enquired about why the researchers chose to link coronary angiograms. The Coordinating Investigator explained that it is a more definite endpoint in terms of linking the results back to cardiovascular disease.

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 researchers intend to access health information without consent as part of this study. The Committee enquired about what data would be accessed and how the researchers would be accessing it. The Coordinating Investigator explained that they would be looking at mammogram information that is stored on a server used for calculations. This will be linked with cardiac information from the same patients. This will be done to check which patients have been to the catheter lab and have had mammograms. Following this they will go back and examine mammograms for arterial calcifications.
2. The Committee noted that Volpara is a commercial company and thus may have a private interest in the success of the study. The Committee also noted that the public is most sceptical of private companies using health information without consent for commercial interest.
3. The Committee enquired if obtaining consent for the study would undermine the scientific validity of the results. The Coordinating Investigator stated that it might do, but at this time they could not see how obtaining consent could impact validity.
4. The Committee enquired about those who have had calcifications but no cardiac event. The Researchers explained that this is a case-control study that would allow them to establish a threshold for calcification. The Committee noted that this would help to avoid false positives.
5. The Committee asked about the identifiability of population groups. The Coordinating Investigator explained that ethnicity would be recorded.

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 that obtaining participant consent would not be difficult and thus not obtaining consent does not satisfy The Ethical Guidelines for Observational Studies Paragraph 6.43 b(a
2. The Committee noted that there would be no reason not to provide a consent form at the time of patients having a mammogram.

Decision

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

1. 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: *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.*
2. Health and Disability Ethics Committees 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:
3. *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:*
4. *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*
5. *there would be no disadvantage to the participants or their relatives or to any collectives involved; and*
6. *the public interest in the study outweighs the public interest in privacy.*
7. To approve a study involving access to health information without consent a committee must be satisfied that these requirements are met by the study concerned.
8. The Committee welcomes the Researchers to resubmit this application with provision to obtain informed consent for all participants.

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| **5** | **Ethics ref:** | **16/CEN/91** |
|  | Title: | MegBio - Prospective Study |
|  | Principal Investigator: | Dr Maggie Kalev |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 14 July 2016 |

Dr Maggie Kalev 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. This study investigates factors in human bone marrow that drive cancer growth, in particular looking at cells known as megakaryocytes and calcium signalling. The main aim is to identify mechanisms that lead to megakaryocytic cancers and identify targets for new treatments.

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 study would be funded by external grants.
2. The Committee noted that all members of the research team are competent and experienced.
3. The Committee noted that extensive consultation had been undertaken, including Māori consultation.
4. The Committee noted that study data will be de-identified however there is a potential to identify participants in case a rare genetic defect is discovered. The Coordinating Investigator confirmed that this is the case and that a master list will be kept. The purpose of the master list is to allow for double checking or in the case of scenarios such as the above. When researchers are interacting with the data it will be de-identified.
5. The Committee was satisfied with provisions for Māori cultural issues, such as Whakapapa, with tissue collection would be managed.
6. The Committee enquired about future unspecified use of tissue. The Coordinating Investigator stated there would be no future research as it is unlikely that there will be enough tissue left over

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 that there was no consent form for participants with Downs syndrome who are over 16. Legally, Children with Downs syndrome over 16 must consent for themselves. Parents can only consent for children under 16. The Committee stated that if participants who are over the age of 16 cannot give informed consent then they cannot be enrolled in the study. Please either consent participants with Downs syndrome who are over 16 years or do not enrol them if they are unable to provide consent. The Committee noted that any participants who are aged 16 years or older and cannot provide their own informed consent cannot be included in this study as proxy consent (including by their parents) is not acceptable for research in New Zealand. To include adult participants unable to The Committee noted that any participants who are aged 16 years or older and cannot provide their own informed consent cannot be included in this study as proxy consent (including by their parents) is not acceptable for research in New Zealand. To include adult participants unable to consent would require the study to meet Right 7(4) of the HDC Code of Rights and the Committee is not satisfied that this requirement has been met in this case. Consent would require the study to meet Right 7(4) of the HDC Code of Rights and the Committee is not satisfied that this requirement has been met in this case.

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

1. The Committee noted that there were was a single consent box for consenting to three different aspects of the study. Please separate these out so participants can consent to each individually.
2. Please ensure there is no vague language in participant information sheets or consent forms. Participants need to fully understand what they are consenting to.
3. Please indicate what age groups each information sheet and consent form is for. For younger groups consider adding in pictures to aid in getting assent.
4. Please provide a consent form for participants over the age of 16 who have downs syndrome.

Decision

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

1. Please make the required changes to the participant information sheets and consent forms.
2. Please confirm that any participants included in this study aged 16 years or older will be able to provide their own informed consent and that if they cannot they will not be enrolled in the study.

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

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| **6** | **Ethics ref:** | **16/CEN/92** |
|  | Title: | MegBio - Retrospective Study |
|  | Principal Investigator: | Dr Maggie Kalev |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 14 July 2016 |

Dr Maggie Kalev 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. This study investigates factors in human bone marrow that drive cancer growth, in particular looking at cells known as megakaryocytes and calcium signalling. The main aim is to identify mechanisms that lead to megakaryocytic cancers and identify targets for new treatments.
2. This study aims to test the analytical protocols to be used in 16/CEN/91 in order to guide that study’s methodology.

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 there is a possibility that some of the donors of tissue samples being used in this study may still be alive. They enquired as to if the researchers would be seeking consent from these individuals. The Coordinating Investigator stated that in that case they would and would enrol these patients into 16/CEN/91. They have not yet investigated the status of tissue donors as they wanted to wait for ethics approval.
2. The Committee asked why researchers are not going back to seek consent from families of deceased individuals. The Coordinating Investigator stated that to do so may cause uncertainty in families about who gets to decide to provide consent. Further they had consulted with consumer representatives and discussed that the process can be traumatic for families. The practical difficulties of tracing families who may have moved was also discussed. Given the population size the difficulty could be prohibitive. The researchers had considered only asking Māori families but had reservations about targeting families in this way. The Committee shared these reservations.
3. The Committee noted that the applications states the research is not being conducted for financial gain. The Coordinating Investigator confirmed this.
4. The Committee enquired about the use of tissue samples where, following the experimental testing, the sample would be used up. This would mean that there would be nothing left for families or individuals wanting to use the tissue for testing relating to their own health. The Coordinating Investigator stated in cases where testing would foreseeably use up remaining tissue then those samples would not be used.
5. The Committee noted that the application included a letter for the family of deceased patients, however the researchers have confirmed that they will not be approaching these families and the letter ill not be used.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **16/CEN/95** |
|  | Title: | Study of airway microbiome |
|  | Principal Investigator: | Dr Naveen Pillarisetti |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 July 2016 |

Dr Naveen Pillarisetti 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 airway microbiomes of children with chronic or acute respiratory diseases. There are possible multifactorial causes of this, one of which is bacteria in the airway.
2. They are studying the bacteria of the children’s’ airways, these children are being intubated as part of standard care. Samples will be taken from the tip of the nose and from the lower airway. These samples will be taken at time of intubation and extubation.

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 there were two consent forms for the study. The Coordinating Investigator explained that this was an administrative error.
2. The Committee enquired about statistics for Māori and Pasifika children. The Coordinating Investigator explained that these groups are overrepresented in respiratory disease statistics.
3. The Committee asked about questions raised as part of the peer review process. The Coordinating Investigator explained that the concerns of the reviewers had been addressed and their recommendations incorporated to increase study validity.
4. The Committee asked about age-matched controls. The Coordinating Investigator explained that while there are a large number of bronchial cases admitted to hospital they are mostly very young. Getting age matched controls for such a young population is difficult, thus the control population will be older. The Committee was concerned that this might undermine the validity of the study, however the Coordinating Investigator explained that as this is an exploratory study they are aiming to indicate for future research.

Summary of ethical issues (outstanding)

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

1. Please remove yes/no boxes from the consent form for any statement that is not truly optional. Truly optional statements are those that a participant could select no for and still participate in the study.

Decision

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

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| **8** | **Ethics ref:** | **16/CEN/96** |
|  | Title: | HARMONI Toric Trial |
|  | Principal Investigator: | Dr Dean Corbett |
|  | Sponsor: | ClarVista Medical |
|  | Clock Start Date: | 14 July 2016 |

Dr Corbett 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 seeks to demonstrate the safety and performance of the HARMONI Modular Toric intraocular cataract lens.
2. Key objectives are: to refine the lens constant of the lens. To evaluate the refractive outcomes, including astigmatism correction, in primary cataract surgery. To evaluate the axial and rotational stability of the lens.

Summary of ethical issues (resolved)

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

1. The Committee enquired about the wording of the ACC section in the participant information sheet. The Committee noted that earnings-related compensation is not covered by the sponsor. The Coordinating Investigator explained that this was not the case and that the sponsor will provide cover. The Coordinating Investigator resolved to change the information sheet to reflect this.
2. The Committee asked about why breastfeeding or pregnant women would be excluded and if there is any particular risk to these groups. The Coordinating Investigator explained that this is a standard exclusion provided by the study sponsor. The Committee noted that this may be considered discriminatory. The Coordinating Investigator resolved to discuss removing this exclusion with the study sponsor.

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 the lack of adequate Māori consultation and review for the study. The Committee noted that the touching of the head is an issue of tapu for Māori. The Coordinating Investigator explained that eye clinic staff are trained in managing this and cultural sensitivity will be maintained throughout. The Committee was unsatisfied with the response given the importance of the tapu of the head. Please address how cultural issues that may arise for Māori participants in the study will be managed (Ethical Guidelines for Intervention Studies para 4.7).
2. The Committee noted that scientific review of the study may not be sufficiently independent. The Committee noted that the reviewer has a pre-existing relationship with the sponsor as a consultant. The Coordinating Investigator explained that they also have an independent review form from a clinical management committee.
3. The committee asked if withdrawing from the study would mean that participants would have to have the product removed from their eye. The Committee noted that if patients withdraw from the study then their data cannot be used. The Coordinating Investigator explained that the lens would only be removed from the eye if it was in the medical best interest of the participant. If participants withdraw then they have the option of having the lens removed but this is not required.

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

1. The Committee noted that information regarding withdrawal from the study and what it means for participants is vague. Please amend the information sheet to clearly state that withdrawal from the study means that participant’s data will not be used and that withdrawal from the study does not mean participants will have to have the lens removed unless it is in their medical best interests.

Decision

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

1. Please provide evidence of favourable independent peer review of the study protocol (Ethical Guidelines for Intervention Studies Appendix 1).
2. Please address how cultural issues that may arise for Māori participants in the study will be managed (Ethical Guidelines for Intervention Studies para 4.7).
3. 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).

This following information will be reviewed, and a final decision made on the application, by Dr Melissa Cragg and Dr Cordelia Thomas.

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| **9** | **Ethics ref:** | **16/CEN/72** |
|  | Title: | Project EVERYCHILD |
|  | Principal Investigator: | Dr Mark Winstanley |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 02 June 2016 |

Dr Lochie Teague 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 maintain a cancer registry for infants, children, adolescents, and young adults with cancer. It will use these data to help determine eligibility or stratification for COG therapeutic clinical trials. To develop a biorepository through the collection of specimens from children with cancer at COG institutions. With consent to allow families to be contacted in the future to consider participating in non-therapeutic and prevention research studies involving the child or their parents.
2. The Committee clarified with the researcher that the registry discussed in this application would be separate to the New Zealand National Cancer Registry.
3. The Committee noted that this will be a very significant project, given the aims of the study. The Coordinating Investigator noted that studies examining each disease had been ongoing but that over time these would be closed and replaced by a registry of all patients, rather than segregating them by disease. Only those registered under the old system will be eligible for being registered under this new system.

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 there was a main study and several optional studies
2. The Committee noted that there was a double up of consent forms. The Coordinating Investigator explained that this is in order to prevent confusion on behalf of the Children’s Oncology Group.
3. The Committee asked about the Certificate of Confidentiality that will be given to parents. The Coordinating Investigator explained that the provisions in this certificate relate to America. The Committee asked that this be made clear and that abbreviations of names of United States Government departments in the certificate be expanded.
4. The Committee enquired about the collection of ethnicity data and how it will be analysed. The Coordinating Investigator explained that ethnicity data is collected for the purposes of entry into the New Zealand-based children’s cancer registry. The Coordinating Investigator explained that they had placed priority on Māori and had placed Māori at the top of the ethnicity list to make sure this information is properly recorded due to United States-centric ethnicity options on the form.
5. The Committee enquired about who enters data into the registry. The Coordinating Investigator explained that Starship Hospital’s Oncology department will enter data for all NZ patients except those from Wellington or the South Island. Those data will be entered by Christchurch Hospital staff.

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

1. The Committee noted that the consent form titles could be confusing. For example “study 1” should be replaced with “main study” The Committee noted that there is a “second” study for re-consenting patients is confusing. Please change the titles so as to clearly communicate the purpose of each form and the study.

Decision

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

## Substantial amendments

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| --- | --- | --- |
| **1** | **Ethics ref:** | **15/CEN/47/AM02** |
|  | Title: | Risk factors for multi-drug resistant bacterial in |
|  | Principal Investigator: | Dr Jacqueline Benschop |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 July 2016 |

Dr Jacqueline Benschop was present by teleconference for discussion of this amendment.

Potential conflicts of interest

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

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

Summary of Amendment

1. The amendment seeks to address various issues surrounding the recruitment of participants for the control group, the storage of samples, and the accessing of patient information.
2. To aid recruitment the researchers intend to call potential participants and remind them to return their consent forms. As part of this call they will take verbal consent. However this will not cover the optional consent aspects of the study.
3. To store anonymised bacterial isolates in a freezer for genomic analysis.
4. To have access to non-identifying patient information relating to the bacterial isolates, such as age or gender.

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 genomic analysis is not to be performed on human DNA but bacterial. DNA.

Summary of ethical issues (outstanding)

1. The Committee approved the use of phone calls to follow up on individuals who have not responded. The Committee approved a single call, that reaches potential participants, to follow up on consent. The Committee felt that any more than this could be perceived by individuals as harassment. Please only call participants once to follow up on consent.

Decision

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

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| **2** | **Ethics ref:** | **15/CEN/157/AM02** |
|  | Title: | COG AALL1231: Phase III Randomised Trial of Bortez |
|  | Principal Investigator: | Dr Siobhan Cross |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 14 July 2016 |

Potential conflicts of interest

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

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

Summary of Amendment

1. The amendment looks to correct the number of days that pegaspargase is administered during delayed intensification.
2. The amendment also covered minor administrative changes and emphasises the supportive care guidelines for invasive fungal infections.

Decision

This amendment was *approved* by consensus.

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| **3** | **Ethics ref:** | **15/CEN/19/AM04** |
|  | Title: | IntReALL SR 2010 |
|  | Principal Investigator: | Dr Siobhan Cross |
|  | Sponsor: | Robyn Strong |
|  | Clock Start Date: | 14 July 2016 |

Potential conflicts of interest

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

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

Summary of Amendment

1. This amendment entails the receipt of new information to the study’s Investigational Medicinal Product Dossier and additional administrative changes.

Decision

This amendment was *approved* by consensus.

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| **4** | **Ethics ref:** | **15/CEN/206/AM01** |
|  | Title: | Segmentation Towards Enabling Pathways (STEP) |
|  | Principal Investigator: | Professor Matthew Parsons |
|  | Sponsor: | Mr Damian Edwards |
|  | Clock Start Date: | 14 July 2016 |

Mr Damien Edwards indicated that he was not able to attend for the discussion of this amendment.

Potential conflicts of interest

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

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

Summary of Amendment

1. This amendment requested additional routinely collected data held by three DHBs, Waitemata, Waikato, and Canterbury.
2. These data will be matched within the Statistics New Zealand Integrated Data Infrastructure. After matching data will be anonymised and non-identifiable.

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 there is a danger of targeting patient populations for research projects when data linking. The Committee also noted that there is potential for identifying individuals. The Committee was satisfied that there were no additional risks posed by this amendment.

Decision

This application was *approved* by consensus.

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| **5** | **Ethics ref:** | **13/CEN/131/AM03** |
|  | Title: | R3ACT CTL Study |
|  | Principal Investigator: | Dr Nyree Cole |
|  | Sponsor: | Professor David Gottlieb |
|  | Clock Start Date: | 14 July 2016 |

Potential conflicts of interest

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

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

Decision

This progress report was *approved* by consensus.

## 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:** | 23 August 2016, 12pm |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington |

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 5:20pm.