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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 22 September 2015 |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 25 August 2015 |
| 12:30pm | New applications (see over for details) |
| 12:30-12:55pm  12:55-1:20pm  1:20-1:45pm  1:45-2:10pm  2:10-2:35pm  2:25-2:50pm  2:50-3:15pm  3:15-3:40pm  3:40-4:05pm  4:05-4:30pm  4:30-4:55pm  4:55-5:20pm | i 15/CEN/135 Helen / Devonie  ii 15/CEN/122 Nicola / Peter  iii 15/CEN/124 Sandy / Cordelia  iv 15/CEN/125 Peter / Mali  v 15/CEN/129 Nicola / Helen  vi 15/CEN/132 Peter / Sandy  vii 15/CEN/133 Cordelia / Devonie  viii 15/CEN/134 Nicola / Mali  ix 15/CEN/123 Helen / Sarah  x 15/CEN/136 Sandy / Sarah  xi 15/CEN/142 Nicola / Cordelia  xii 15/CEN/143 Helen / Mali |
| 5:20pm | Substantial amendments (see over for details) |
| 5:20-5:35pm | i 15/CEN/64/AM01 Helen |
| 5:35-5:50pm | General business |
| 5:55pm | 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 |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 01/07/2015 | 01/07/2018 | Apologies |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Apologies |
| Dr Dean Quinn | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Apologies |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |
| Dr Nicola Swain | Non-lay (observational study) | Co-opt | Co-opt | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | 01/07/2015 | 01/07/2018 | Apologies |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Maliaga Erick | Lay (Consumer/community perspective) | Co-opt | Co-opt | Present |
| Dr Devonie Waaka | Non-lay member in the design and conduct of intervention studies | Co-opt | Co-opt | Present |
| Dr Sarah Gunningham | Non-lay member in the design and conduct of intervention studies | Co-opt | Co-opt | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Dr Angela Ballantyne, Dr Patries Herst, Dr Melissa Cragg, and Dr Dean Quinn.

The Chair noted that fewer than five appointed members of the Committee were present, and that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Mrs Maliaga Erick, Dr Nicola Swain, Dr Devonie Waaka, and Dr Sarah Gunningham confirmed their eligibility, and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 25 August 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/CEN/135** |
|  | Title: | Older people in retirement villages: unidentified need & intervention research |
|  | Principal Investigator: | Professor Martin Connolly |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 10 September 2015 |

Professor Martin Connolly 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 follows previous research that looked into reducing hospitalisation of patients in residential rest homes.
2. The Researcher explained that a previous census of hospitalisation in the elderly found that individuals in rest homes had a greater rate of hospitalisation than those living in retirement villages, who had a greater rate of hospitalisation than elderly living in the community.
3. The Researcher explained that the goal was to reduce hospitalisation of the elderly, not only individuals in residential care and they believed that they had the best chance to make a difference by focusing on individuals in retirement villages.
4. There is a lack of research of people living in retirement villages in New Zealand and this fostered a lack of understanding of this population group. It is hoped that further research would aid in improving health outcomes for the elderly New Zealand.
5. The Researcher explained that this study has a number of phases and that the first phase is a recruitment phase where they will approach approximately half of the 60-65 retirement villages in the Auckland DHB and Waitemata DHB regions. From these 30-35 retirement villages that are recruited approximately 100 participants will be randomly selected from these retirement villages.
6. Once the participants are recruited the researchers propose to supply either them or their legal representative, for participants who are unable to provide informed consent, with a questionnaire and a consent form to allow the researchers to access their NHI number and health information.
7. These participants will be followed for 3 to 6 years depending on the funding available (Phase 2).
8. Participants, or their representative, will be approached annually and asked to complete a questionnaire.
9. The researchers will also follow participants’ routinely collected health information through their NHI throughout the study.
10. A subset of the recruited participants who are identified as being at risk at the beginning of the study will be randomised into a further phase of the study, which will run at the same time as the main study. Participants for this phase of the study will be randomised to an active or control group where the active group will receive an intervention aimed at reducing their presentations to hospital emergency departments and admittance to residential aged care.
11. The Researcher explained that entering a retirement village entailed a large financial cost and that one of the primary reasons individuals entered rest homes was for security as it increased their perception of current and future security. The Researcher explained that many elderly believed entering a retirement village helped to ensure that when their health deteriorated they would be able to move into the rest home attached to the retirement village, however this was not necessarily the case.

Summary of ethical issues (resolved)

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

1. The Researcher noted that a potential ethical issue is the continued collection of data from participants who, although able to consent at the time of recruitment, lose the ability to provide informed consent over the course of the study. The Committee agreed that this may be a potential issue, however, explained that it is acceptable if they have obtained prospective consent from these participants while they are capable of providing it.
2. The Committee questioned if interpreters will be provided if needed. The Researcher explained that funding from Aging Well and the DHB was sourced and that they will fund interpreters for this 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 Committee stated that it is unacceptable to have someone else consent on behalf of potential participants unable to provide their own informed consent.
2. The Committee noted that the HDC Code of Health and Disability Services Consumers' Rights Regulation 1996 applies to all health research and that a representative is unable to consent for someone on their behalf.
3. The researcher explained that they intended to have the family or representative provide assent for the participant rather than consent and that it was important to include participants who are unable to consent for themselves as the study is focused on improving outcomes this group of people and excluding them would not be representative of the people who live in these facilities.
4. The Committee suggested the possibility of excluding any individuals unable to consent for themselves, however the researcher explained that this would not be representative of the population in these facilities and would jeopardise the results of the study.
5. The Committee explained that if an individual cannot consent for themselves it must be shown that participating is in the best interest of the individual pursuant to Right 7(4) of the Code.
6. Right 7.4 of the HDC Code of Rights states that “Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where –
   * a) It is in the best interests of the consumer; and
   * b) Reasonable steps have been taken to ascertain the views of the consumer; and
   * c) Either, -
     + i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
     + ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.”
7. Further, the Committee noted that Right 9 ensures that these rights extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.
8. The Researcher questioned if this meant that it was impossible to conduct research on individuals who cannot provide informed consent.
9. The Committee clarified that it is possible (under Right 7.4) if it can be shown that participation is in the best interest of the consumer and they take into account the views of other suitable persons or believe that the consumer would wish to consent if they were able to. In these cases the consent can be provided by the clinician for this individual to participate in the research.
10. The Committee explained that they did not believe that this study meets the best interest measure and, therefore, could not include participants who are unable to consent for themselves.
11. The Researcher agreed that it may be difficult to see how Phases 1 and 2 are in the best interest of the participant, however Phase 3 has a beneficial intervention and therefore would be in the best interest of the participant.
12. The Committee noted that Phase 3 is randomised and therefore not all participants would get the beneficial intervention.
13. The Committee questioned if participating in the study would be directly beneficial to each individual participant. The Researcher explained that they believe it would be, for all phases of the study. Although they confirmed that individual results would not be fed back into the retirement village to influence each individual participant’s health care, they felt that increased understanding of the circumstances of elderly consumers living in retirement villages would help to provide the best possible care for all individuals.
14. The Committee suggested that the Researcher seek independent legal advice regarding this as the only way to approve a study with non-consenting participants was under Right 7.4 and this would require the Researchers to satisfy the Ethics Committee that participation in the study is in the best interest of the individuals, as well as consulting with suitable persons interested in the individual’s welfare.
15. The Researcher explained that they would seek legal advice as although they cannot imagine participating in the study to increase the risk of harm to participants they also do not believe that they can ensure each participant will get a benefit from participating in the study.
16. The Researcher questioned if the University or DHB legal team would be acceptable to provide this legal advice due to the potential for bias. The Committee explained that this was unlikely to be a problem as a lawyer must abstain if they have a conflict of interest and the advice must stand up if challenged.
17. The Committee suggested that when seeking legal advice the researchers may wish to consider the possibility of auditing the de-identified information from participants unable to consent once the data collection is complete, however, they will need legal advice regarding the possibility of obtaining the NHI numbers of participants unable to consent in order to make this possible.

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

1. The Committee requested that the Participant Information Sheet was made more user-friendly, they suggested that the language could be edited to better facilitate the informed consent process.
2. Please explain in the Information Sheet the randomisation process for participants included in Phase 3 of the study.
3. Please edit the contact details in the Participant Information Sheet to include Māori support details, the HDC number, and the correct Ethics Contact Details.
4. In the Participant Information Sheet it states that if participants would like to complain about the study they can speak to a member of the research team. The Committee requests that an independent contact number is included.
5. The Committee notes that the information sheet refers to all nurses as female and they ask that this is modified to a gender neutral pronoun.

Decision

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

1. Please obtain independent legal advice regarding the possibility of including participants unable to provide informed consent, or modify the study protocol to exclude participants unable to consent for themselves.

This following information will be reviewed, and a final decision made on the application, by the whole committee, including the Co-opted members attending this meeting.

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| **2** | **Ethics ref:** | **15/CEN/122** |
|  | Title: | The effect of alcohol consumption on injury presentations at Auckland City Hospital Adult Emergency Department. |
|  | Principal Investigator: | Dr Bridget Kool |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 September 2015 |

Dr Bridget Kool and Dr Peter Jones 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 how alcohol consumption impacts the kinds of injuries people present to the Emergency Department with.
2. The Committee noted that a similar study had been done before on a smaller scale.
3. The Researcher explained that the previous study had considered 160 people and this study intended to recruit 500 participants.
4. The Researcher explained that although there had been the previous study this study involved a new research team.
5. The Researcher explained that they would recruit consecutive people presenting to the Emergency Department with injuries less than 6 hours old, and that they would keep recruiting until they had 500 participants.
6. Participants would undergo a breath alcohol test and complete a questionnaire regarding their alcohol consumption and the nature of the injury sustained. Participant’s NHI numbers would also be recorded to allow the researchers to follow the outcomes of their injury.

Summary of ethical issues (resolved)

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

1. The Committee questioned the training that would be given to research assistants as the questionnaires include questions regarding patterns of alcohol use and may identify risky drinking behaviours. The Researcher explained that the Professor who originally developed this study and was involved in the previous study would provide the training to the research assistants. If risky drinking behaviour is identified the participant will be asked if they are comfortable with this information being shared with the clinical team, this information will only be shared if the participant consents to this or an acceptable reason to break confidentiality is identified.
2. The Committee questioned if tourists would be included in the study as they would not have an NHI number and their inclusion may pose a language barrier. The researchers explained that although they had not considered this specifically they did not anticipate it being an issue. However, an interpreter would not be available at all times due to funding restrictions and this may impact on their ability to recruit some participants if they are unable to obtain informed consent.
3. The Committee questioned if the research assistants would be available 24/7. The Researcher explained that they would be in pairs into rostered 8 hour shifts that covered the full 24 hour period.
4. The Committee questioned the availability of a private area for participants to complete the questionnaire. The Researcher explained that participants would have a curtained area available and, if necessary, a private room could be used to complete the questionnaire.
5. The Committee questioned the statement on the Participant Information Sheet that the results would be confidential. They were concerned that if the police requested the results of the breath alcohol test, for example when investigating an assault case, if this may be provided to them. The Researchers explained that although the police are able to request information from the hospital the information collected for this study would not be placed on the participants medical records and, therefore, would not be available to police.
6. The committee questioned the status of the Māori Consultation for this study. The Researchers confirmed that they had consulted with the Auckland DHB Māori Research Team, who had reviewed and approved the study. They also explained that they had attempted to recruit Māori researchers and would try to include Māori research assistants, but did not yet know if this would be possible. They intend to approach the local Iwi and have a representative on the study’s oversight committee.
7. The Committee queried how it would be determined whether a patients was too intoxicated or in too much pain to consent to be included in the study. The Researcher explained that the research assistants who would conduct the interviews and consent process would work closely with clinicians and triage nurses who are experienced with intoxicated patients in the emergency department and would be able to judge individuals’ ability to 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 questioned what would happen to individuals who were unable to provide consent, due to their level of intoxication or pain. The researcher explained that the research assistant would return to these patients later when they were able to consent, although it would need to still be in a relatively short time frame as patients whose injuries occurred more than 6 hours prior to the questionnaire would be excluded from the study.
2. The Researcher also explained that in cases where the injured person would be unable to consent for various reasons they would approach their family or friends in the Emergency Department with them and attempt to obtain their views.
3. The Committee noted that this was acceptable if the family or friend was then considered the participant and answered a questionnaire on their own views on what happened, but that they could not consent or complete the questionnaire on the injured person’s behalf.
4. However, the Researcher and the Committee noted that this may cause difficulties regarding the breath alcohol test and obtaining the NHI number of the injured patient as the questionnaire alone would not provide all of the necessary information as a relative may not have a full picture of the situation and could only respond regarding their views on the injury.
5. The Committee noted that although participants unable to consent must be excluded from the study it would be possible to obtain delayed consent from the participants, once their level of pain or intoxication reduces and they are able to consent. This would allow the researchers to obtain the patient’s information within the required timeframes but only use this information if consent could be obtained from the participant once they were able to provide it. The Committee notes that if the researchers wish to pursue this option they would need to provide appropriate information and consent forms for this situation.
6. The Committee noted that some individuals would be unable to provide informed consent at any point, such as some individuals with mental illness, and that these patients must be excluded.

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

1. Please be clear in the Participant Information Sheet that the data collected and the consent forms would be kept for 10 years.
2. Please clarify in the Information Sheet that information collected is partially de-identified, not anonymous, as a subject number will be allocated to all information before it leaves the hospital and this will be linked with the participant’s NHI.
3. Please modify the ACC statement in the Participant Information Sheet. The Committee suggests 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* by consensus, subject to the following information being received.

1. Please provide appropriate consent forms for the various consent processes that will be available.  
   1. For participants who are able to consent at the time of the Breath Alcohol test being administered.
   2. For participants who will be asked to consent retrospectively as they were unable to provide informed consent at the time of recruitment.
   3. For family and friends who will be invited to share their views on the circumstances of the injured person’s injury being obtained.

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

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| **3** | **Ethics ref:** | **15/CEN/124** |
|  | Title: | Problem Solving Therapy with Young Stroke Survivors |
|  | Principal Investigator: | Ms Charlotte Wainwright |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 10 September 2015 |

Ms Charlotte Wainwright and Dr Simon Bennett 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 will investigate the effectiveness of problem solving therapy for young stroke survivors.
2. There are two parts to the study, Part 1 involves an online questionnaire being sent to participants by email. Part 2 may involve a different participant group who will participate in the intervention aspect of the study.
3. The Committee noted that it was clear from their application that they had done a lot of cultural consultation, but that the potential impact of whakamā was not discussed and that this would benefit future applications.
4. An information pack will be sent to potential participants by the hospital and if they are interested in participating they will be invited to approach the researcher. The Committee noted that this was a good way to recruit.
5. The Committee noted that it was good to see such a high level of support and supervision available to the researcher.

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 literacy comprehension issues would be managed. The Researcher explained that as participants would be recruited through referrals from their regular practitioner, who will know their level of competence, this should not be a substantial issue. However, the participants will be able to contact the research team by phone to discuss any questions they may have.
2. The Committee questioned the inclusion criteria that participants needed to have had a stroke in the past 6 months to 2 years. The Researcher explained that they did not want to include individuals who were in the early stages of stroke recovery, but they also did not want participants who were in later stages of their stroke recovery. The Committee requested that this was made clear in the Participant Information Sheet.
3. The Committee questioned what happens if participants do not attend all of the sessions in Part 2. The Researcher explained that the majority of the skills are taught in the first two sessions and that the rest of the sessions are to review and practice the skills. All participants will be included in the results, but how many sessions they attended would be factored into the results.
4. The Committee questioned the arrangements for compensation for travel costs. The Researcher explained that taxi chits were included as part of the funding application. The Committee requested that this was made clear in the Participant Information Sheet.
5. The Committee noted the possibility of participants to show signs of depression, anxiety, or other mental health issues, and asked how this would be handled by the research team. The Researcher clarified that if necessary this information would be shared with appropriate people. The Committee noted that this was good, but they requested that this was made clear to participants.
6. The Committee questioned the rate of strokes in Māori. The researcher explained that they do have increased rate of strokes and, therefore, this study has to potential to contribute positively to the health outcomes of Māori.

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

1. Add information to the Participant Information Sheet regarding what participants need to do in the study, include clearly explaining how long participation takes.
2. Please add a warning to the start of the questionnaire that some of the questions may be distressing and include contact details at the end regarding who participants can contact if they were distressed by the questions.
3. Please ensure the ACC statement on the Participant Information Sheet is accurate. The Committee suggests 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.”*
4. Ensure it is clear in the information that some information may be shared if participants’ answers raise concerns about their mental health status.
5. Include information about compensation for travel costs in Participant Information Sheet.
6. Explain the Inclusion and Exclusion criteria to participants.

Decision

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

1. Minor changes to Participant Information Sheet.

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| **4** | **Ethics ref:** | **15/CEN/125** |
|  | Title: | Venous Ulcer study |
|  | Principal Investigator: | Mr Janaka Kesara Wickremesekera |
|  | Sponsor: | CCDHB |
|  | Clock Start Date: | 10 September 2015 |

Mrs Marina Dzhelali and a co-investigator 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 investigates the potential benefits of a newly developed dressing to treat Venus Ulcers.
2. The current standard of care involves patients being see by their GP and then referred to a specialist if the GP is unable to treat the Venus Ulcer. However, there is no effective standard treatment available and patients are treated with an ointment.
3. Participants in this study will be randomised to an active and a control group. The Active group will receive the experimental dressing and the standard ointment used, whereas the control group will only get the standard ointment.
4. Participants will not need to travel to the hospital more regularly to participate in the study as they will be seen by a nurse in their home.
5. Any patients with an infection, or who develop an infection during the study, will be excluded as standard treatment in this case is different.
6. The researcher explains that this dressing could theoretically be used to treat other conditions such as burns, however, it has the greatest potential benefits in this area as there is no current established best standard 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 queried if participation in this study increased the risks to participants or if there was a risk that this dressing would be inferior to standard care. The researchers explained that the dressing contained a natural compound that has been used on humans regularly without signs of harmful effects.
2. The Committee questioned if interpreters would be available to participants. The researchers explained that, due to the high number of Pacifica participants they expect to recruit, interpreters would be available. The Committee requested this was made clear in the Participant Information Sheet.
3. The Committee questioned if the treatment will be available to participants after the end of the study. The researcher explained that it will not as if they still need the treatment after the end of the study it does not work for that participant, and if it does work for them they will no longer require it after the study ends.

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

1. Please correct the study start date in the Participant Information Sheet.
2. Please ensure it is clear that if participants require antibiotics during the study they will with withdrawn as different dressings are used to treat infections.
3. Ensure it is clear that there may be risks involved as it is not known if this treatment is better than standard care.
4. The Committee requests that the Participant Information Sheet is rewritten to ensure it includes appropriate lay terms and accurate grammar.

Decision

This application was *approved* by consensus with non-standard conditions to be checked by the Secretariat.

1. Please make minor changes to the Participant Information Sheet as outlined above.

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| **5** | **Ethics ref:** | **15/CEN/129** |
|  | Title: | Drama Therapy and Dementia |
|  | Principal Investigator: | Miss Sophie Buchanan |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 10 September 2015 |

Miss Sophie Buchanan 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 will recruit participants from 3 rest homes who will initially be approached by rest home staff. If they are interested a researcher will be able to go through the consent process with them.
2. Participants will be randomised to one of 3 groups, Drama Therapy, Conversational Therapy, and a waiting list control group.
3. Participants on the waiting list will be able to participate in one of the two active therapy types, determined by which one shows the best outcomes for participants in this study. After the study, the participants who are randomised to the other therapy group will also be able to participate in the therapy that is determined to be best by the study.
   1. For example, if the Drama Therapy proves to be superior to the Conversational Therapy (as the researchers hypothesise it will) then both the waiting list control group and the group that received the Conversational Therapy will be able to participate in Drama Therapy after the study ends.
4. Both the Conversational Therapy and the Drama Therapy are conducted by the same therapist.
5. The Committee notes that in the application the question regarding the potential benefit to Māori was not answered fully. In future please include statistics regarding the prevalence of the condition in Māori.

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 who would be assessing the competency of potential participants as it would need to be someone appropriately qualified. The researcher confirmed that the rest home had assured them that someone would be able to assess competency, however, they stated that they would confirm this. The Committee suggested that it may be appropriate for the Rest Home GP to assess competency.
2. The Committee questioned the number of participants who would be recruited and asked the researchers to confirm if only information from these 3 rest homes would be included. The researcher confirmed that it would only be from these 3 rest homes and that there would be approximately 45 participants as each group had a maximum of 15 participants.
3. The Committee questioned what would happen if a participant revealed that they were at risk, for example from depression. The researcher explained that the participant will be spoken to about this and offered options for information and support. The Committee requested that it was added to the Participant Information Sheet the process if a participant is found to be at risk.
4. The Committee asked what would happen if a participant initially consented to be included in the study but forgot about this before the treatment started. The Researcher explained that this was relatively common and that from the experience of the therapist conducting the treatment participants started to remember from the third or fourth session. However, they explained that if participants seemed to be disorientated or unwilling at the time of treatment they could withdraw at any time.
5. The Committee noted that as they would be asked to complete a questionnaire or survey therapists and rest home staff are participants in this study too, and, therefore, they require consent forms and information sheets.
6. The Committee queried whether the study would only include participants who are able to consent for themselves. The researchers explained that they would like to include participants who cannot consent for themselves by having a family member consent on their behalf. The Committee explained that it was not appropriate to have someone else consent on another adult’s behalf, and that it would only be possible to include participants unable to consent if it was deemed that participation is in their best interests.
7. The Committee asked if it would be possible to only include participants who can consent for themselves. The researcher confirmed that this would be acceptable.
8. The Committee continued the ethical review process on the grounds that participants who are unable to consent for themselves would not be included in the study.

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

1. The Committee notes that health information must be kept for 10 years and states that this must be included in the Participant Information Sheet.
2. Please only include tick boxes on the Consent Form for aspects of the study that are truly optional.
3. The Committee notes a biased statement at the beginning of the Participant Information Sheet regarding fun and friendship and suggests that the researchers may wish to remove this as they cannot guarantee this result for participants.
4. Please add to the Participant Information Sheet that if a participant falls or is injured in the study they will receive standard care in the rest home as participation does not require them to leave the rest home.
5. Please add a Māori support contact number to the Participant Information Sheet.

Decision

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

1. Please make changes to Participant Information Sheet as detailed above.
2. Please create a brief Participant Information Sheet and Consent Form for the therapists and rest home staff who will be participants in this study.
3. Please amend Consent Forms and Protocol to reflect that only individuals competent to provide their own informed consent will be included in the study.

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

Dr Nicola Swain and Mrs Helen Walker.

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| **6** | **Ethics ref:** | **15/CEN/132** |
|  | Title: | Comparing the satiety and blood glucose effects of formulated beverages in adults |
|  | Principal Investigator: | Ms Irene H.H. Ho |
|  | Sponsor: | The New Zealand Institute for Plant & Food Researc |
|  | Clock Start Date: | 10 September 2015 |

Ms Irene Ho and Dr Lee Huffman 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 (resolved)

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

1. The Committee queried how the researchers intend to recruit participants. The researchers explained that they intend to advertise at Plant and Food and Massey University in Palmerston North.
2. The Committee noted that there is a relatively large time commitment to participate in this study and questioned the appropriateness of the $30 voucher compensation. The Researchers explained that although participants would need to be at the study site from 8:30am-12:45pm for 3 days they expected the majority of the participants to be Plant and Food employees who would already be at work for this time and could bring work with them to complete at the study site.
3. The Committee questioned the start date given in the application form. The Researcher explained that this was an administrative error and they expect the study to begin in November 2015.
4. The Committee questioned if this is a commercially sponsored study as the results may benefit a company and there may be significant commercial gain. The Researchers explained that although the product being tested belongs to a company (NZ Extracts) this company is not involved in the study and are not providing any funding. The product has been purchased by Plant and Food for this study and Plant and Food does not stand to achieve any financial gain from this study.
5. The Committee questioned why, if Plant and Food will not stand to benefit commercially from this study, the application indicated that there would be restrictions on publication of study results. The Researcher explained that the results would need to be approved by Plant and Food before publication, as per their usual protocols. The Researchers stated that the intention is to publish the results. The Committee noted that the study will be registered on a Clinical Trials Registry and at a minimum the results would be put on there, however, they requested that in future the researchers are more careful when completing the application form to reduce confusion over issues like this.

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 questioned why participants cannot be told what the potential ingredients in the beverage are, as they expect this to be included in the Participant Information Sheet. The Researcher explained that due to media coverage of the ingredient they are concerned that this could bias the results. The Committee explained that even with the potential for bias participants must be told the information that a reasonable person would expect to receive (Right 6 of the Code), and they believe this includes the potential ingredients in the beverages.
2. The Committee asked for the status of the Māori consultation for this study. The Researcher answered that they were not seeking Māori consultation. The Committee stated that as obesity is a health issue for Māori they must seek Māori consultation and noted that this may be a requirement for their locality assessment.
3. The Committee asked why the researchers believed that they did not need to seek Māori consultation. The Researchers explained that the advice they had received from others was to this effect. The Committee noted that the application form is specific regarding when Māori consultation must be obtained and requests that the researchers consider this more carefully in future.
4. The Committee questioned the statement in the application that data would be identifiable to allow for outlying participants to be excluded from future trials. The Researchers explained that they wanted to make this identifiable data available to recruit for future research. The Committee questioned how many people would have access to this identifiable information. The Researchers responded that at least 7 people, the current research team, would have access. The Committee requests that two people are named and nominated to have access to the identifiable information.

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

1. Add Māori support contact numbers to Participant Information Sheet.

Decision

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

1. Please address the outstanding ethical concerns raised by the committee outlined above, including two named individuals who will have access to identifiable information.
2. Please add the Māori support contact number to the Participant Information Sheet.

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

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| **7** | **Ethics ref:** | **15/CEN/133** |
|  | Title: | A Study of APD334 in Patients with Moderately to Severely Active UlcerativeColitis. |
|  | Principal Investigator: | Prof Richard Gearry |
|  | Sponsor: | Covance New Zealand Limited |
|  | Clock Start Date: | 10 September 2015 |

Neelima Jagtap 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 involves participants being randomised to 3 study arms. One group will receive 1mg of the study drug, another arm will receive 2mg, and one arm will receive a placebo.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether participant in the placebo arm still received standard care. The Researcher confirmed that this was the case.
2. The Committee asked if all participants would be in Christchurch as the application states that chest x-rays would be done in Christchurch. The Researcher explained that originally there was only one site and this has now been expanded to include Auckland also.
3. The Committee questioned the prevalence of this condition in Māori. The Researcher explained that Ulcerative Colitis has a low incidence in Māori and, therefore, they are unlikely to recruit Māori participants.
4. The Committee notes that participants must have had an inadequate response to standard treatment to be included in the study. The Committee questions why this is not included in the Participant Information Sheet. The Researcher explains that this is part of the pre-screening process, completed by the participant’s clinicians, and that only individuals who have had an inadequate response to standard treatment will be recruited and see the Participant Information Sheet.

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 queried whether APD334 exposure was associated with any increased surgical risk, and whether there was any preferred ‘stand-down’ period between last dose of APD334 and surgery. The Committee noted that this is the case for several other biologics used in the treatment of UC. If there is a potential risk this should be made clear in the Information Sheet.
2. The Committee queried whether clinicians and participants would be able to find out after the study whether they were randomised to the active or placebo arms of the trial, as this may affect eligibility for other clinical trials or potentially the timing of surgical treatment for UC (see above). If not, this should be clearly stated in the Information Sheet.
3. The Committee noted that as participants will be referred to the study by their clinician who is also the Coordinating Investigator, Prof Richard Gearry, there is the potential for a conflict of interest. They question how this conflict of interest will be managed and suggest that although the initial approach to gauge interest in the study could be made by Prof Gearry or another clinician, it may be more appropriate, if the individual is interested, to have someone separate in the research team complete the informed consent process with the participant.
4. The Committee questioned which forms are optional as there seemed to be mention of both optional genetic tests and a future unspecified use of tissue form. The Researcher explained that both the genetic tests and the future unspecified use of tissue are optional. The Committee requested that these information sheets and consent forms are made more distinct, for example currently the genetic testing form currently has information about the study drug and this makes them appear less distinct.
5. The Committee questioned why specific monitoring for progressive multifocal leukoencephalopathy (PML) was undertaken regularly during the study but was not mentioned as a potential risk in the Risks section of the ICF.. They noted that PML is a serious viral disorder that frequently results in severe disability or death. The Committee notes that if the disorder is considered enough of a potential risk to monitor specifically during the study, it must be thoroughly covered in the Participant Information Sheet.
6. The Committee noted that the researchers state that samples will be destroyed at the end of the study. As genetics samples and samples for Future Unspecified Research are being collected, the Committee questions whether the application is correct and asked if the researchers will be setting up or using a tissue bank for these samples once the study is completed.
7. The Committee noted that the birth control section of the Participant Information Sheet refers to spermicide, which is not easily available in New Zealand. They request that the researchers either remove this from the information sheet or clarify who will be responsible for providing this.

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

1. Add more detailed and lay information about the expected side effect on participant’s blood that returned to normal after the study to the Participant Information Sheet.
2. The Participant Information Sheet states that HIV will be notifiable but the Committee notes that Tuberculosis is also a notifiable disease and this needs to be clearly stated in the information sheet.
3. Please moderate the language in the Participant Information Sheet to be less forceful and directive.
4. Please state in the participant information that their GP will be notified if they choose to participate in the study.
5. Page 13 of the Participant Information Sheet states that the study may be stopped in the commercial interest of the sponsor, however this is not acceptable and needs to be removed.
6. Please include more details regarding what happens to participants’ tissue samples during and after the study.
7. The Committee queried the lack of a Māori tissue statement in both Participant Information Sheets. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/Whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*

Decision

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

1. Please address the outstanding ethical concerns noted in in points 6-11 above.
2. Please modify the Participant Information Sheet in accordance with points 12-18 above.

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

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| **8** | **Ethics ref:** | **15/CEN/134** |
|  | Title: | Acceptance and Commitment Therapy (ACT) for Alcohol and Drug Populations |
|  | Principal Investigator: | Miss Rachel Cotter |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 10 September 2015 |

Miss Rachel Cotter and Dr Simon Bennett 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 30 participants with previously diagnosed alcohol and drug disorders, plus two control groups.
2. All 30 active participants will attend 10 sessions. Upon completion of these sessions participants will receive a $20 voucher as compensation, they will receive a further $20 voucher at the follow up appointment. This method of compensation is designed to minimise attrition, although some attrition is still expected.
3. The Committee noted that this is a high quality application and a good study.
4. The Committee noted that the information regarding Māori consultation is good, however, more detailed information regarding the rates of alcohol and drug disorders in Māori would be beneficial in any future applications. Please also include information and statistics regarding other population groups in future.
5. The Committee also noted that there are likely to be whakamā and Whānau pressures faced by participants and that this information would be useful in any future applications.
6. The Committee noted that they were pleased to see a good level of support from the Coordinating Investigator’s supervisor.

Summary of ethical issues (resolved)

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

1. The Committee mentioned that the researchers are likely to get different results from using group sessions, opposed to individual sessions. The Researcher agreed and noted that they are aware of the potential impact of this feature of their study.
2. The Committee noted that the researchers are unable to ensure confidentiality as the participants will be involved in group sessions and they cannot ensure the other participants will not share any information. The Committee suggested that this needs to be clear to participants.
3. The Committee questioned when the questionnaire would be given to participants. The Researcher explained that it would be completed at 3 different points, prior to the sessions, during the treatment period, and at the follow up interview. The Committee noted that this needs to be made clearer in the Participant Information Sheet.
4. The Committee asked what would happen if participants mention suicide or criminal behaviour in the sessions. The Researcher explained that there were already protocols in place to manage these possibilities at the AOD facility. The Committee requested it is made clearer in the Participant Information what may be shared. The Researcher agreed and also noted that the co-facilitator is a qualified clinical psychologies and they would be able to make the decision to break confidentiality if necessary.

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 the researcher to clarify the control group for the study. The Researcher explained that the control group would consist of an anxiety group in Wellington and a CBT group in Palmerston North who would continue to receive treatment as usual, they would have similar measures recorded and these would be compared to the active treatment group. The Committee noted that informed consent must be obtained from these participants to use their data for the purposes of this study, they note that consent forms and information sheets would need to be developed for this purpose.
2. The Committee noted the possibility of auditing the information from the control groups rather than pursuing a regular consent process, however, the information would be anonymised before being provided to the researchers. The Committee noted that it would be preferable to seek informed consent from the control group instead if possible.

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

1. Add further information to Participant Information Sheet regarding what participation involves, this information is currently only in the Consent Form.
2. The Committee notes that the Participant Information Sheet comes across as bias towards the study as it refers to how beneficial the treatment is. The Committee requests that this is rephrased for clarity and accurateness as the researchers cannot guarantee the benefits from participation.
3. Please add page numbers to the Participant Information Sheet.
4. Please rephrase ‘reimbursement’ as it makes it appear that participants are being paid for their participation.
5. The Participant Information Sheet refers to a table of what is involved in participation, however, there is not a table included, please add this.
6. The Committee notes that the Participant Information Sheet states that participants cannot come to the sessions intoxicated, they suggest that the researchers also mean to include ‘under the influence of drugs’ in this statement.

Decision

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

1. Please provide further details regarding the consent process for the control groups.
2. Please make minor changes to the Participant Information Sheet and Consent Form.

This following information will be reviewed, and a final decision made on the application, by Dr Nicola Swain.

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| **9** | **Ethics ref:** | **15/CEN/123** |
|  | Title: | WO29519: Idasanutlin in relapsed/refractory AML |
|  | Principal Investigator: | Dr Steven Gibbons |
|  | Sponsor: | Roche products (New Zealand) limited |
|  | Clock Start Date: | 03 September 2015 |

Dr Steven Gibbons and Ms Helen McDermott 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 ability of experimental drug in combination with standard treatment compared with standard treatment alone to control leukaemia.
2. The Committee noted that participants have few options remaining at the time of recruitment and this is reflected in the inclusion criteria for the study.
3. The Researcher noted that one subgroup of leukaemia patients is excluded from the trial as the treatment strategies for that group is different.
4. The Committee noted for future reference that when completing the application please include any statistics regarding the prevalence of the condition in Māori and other ethnic or cultural groups. The Researcher stated that in this particular case they are not aware of any greater incidence in Māori, the Committee requested that this is included in future applications also.

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 researchers to confirm whether tissue samples would be sent overseas or made available for future studies. The Researcher states that yes, tissue samples for future use will be stored in a registered tissue bank. The Committee requests that this is clear in the Participant Information Sheet.
2. The Committee asked the researchers if the study meets the equipoise standard with each arm of the study being equally balanced in terms of risks and benefits. The Researchers explained that the study arms may be unequal as it is unknown if any benefit will be obtained from the study drug. Due to the nature of the study and the position of the participants the Committee agreed that is acceptable.
3. The Committee questioned the status of the Māori consultation. The Researchers answered that it has been submitted for Māori consultation.

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 Participant Information Sheet states that participants must withdraw in writing. They note that, although written withdrawal is acceptable, if a person verbally withdraws that is legally binding. The Researchers agreed to follow this up with the study sponsor.

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

1. Please modify the language of the pregnant partner consent form to improve clarity as it is for a lay audience.
2. Please adjust the Participant Medication Diary to reflect that the study drug is to be taken twice daily, currently there is only space to include once daily information.
3. Please explain all acronyms the first time they are mentioned in each document.

Decision

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

1. Please adjust the Participant Information Sheet and Consent Forms as per the comments above.

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

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| **10** | **Ethics ref:** | **15/CEN/136** |
|  | Title: | Epidemiology of Trichomoniasis in the Auckland and Northland Communities |
|  | Principal Investigator: | Dr Arlo Upton |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 September 2015 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (outstanding)

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

1. The Committee questioned why participants would not give informed consent to their participation in the study.
2. The Committee stated that under Right 6(1) (d) of the HDC Code of Rights every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including notification of any proposed participation in teaching or research.
3. The Committee further noted that not only did the researchers propose to preform tests on individuals’ samples without their consent, they also proposed to access their identifiable health information, including their NHI number, to determine their deprivation score, without consent.

Decision

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

1. Informed consent would not be obtained from participants.

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| **11** | **Ethics ref:** | **15/CEN/142** |
|  | Title: | Diabetes in Pregnancy effects on subsequent generations |
|  | Principal Investigator: | Dr Rosemary Hall |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 September 2015 |

Dr Rosemary Hall 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 Committee noted that this was a great study and had received HRC funding.
2. The study is a feasibility study to determine how many participants can reasonably be contacted and recruited.
3. The Researchers aim to contact as many of the 1080 women who went to a diabetes clinic between 1981 and 2002 as possible.
4. They hope to recruit approximately 3000 participants for the full study, comprised of as many of the original 1080 women as possible, their children, and hopefully grandchildren.
5. However, the women attending the clinic did not consent to being contacted in the future.
6. The researchers intend to use the information collected at the clinic to link the patients to their NHI number to allow them to be contacted through a recent address.
7. A confidential letter will be sent to the most current address available through NHI linking, alternatively they propose to contact people by phone or email if appropriate.
8. The original patients from this clinic will be asked to participate in the study and also to invite their children and grandchildren to participate as the study hopes to consider the impacts of gestational diabetes across generations.
9. Part of the feasibility aspect of this study is to determine how many children and grandchildren are available to participate, as many may have moved internationally.
10. The Researcher noted that it will likely take a long time to contact these 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 noted that to approve health information being accessed without consent for the purposes of recruiting participants for research the Committee must be convinced that this is the best or only option to recruit participants, and that this was balanced against the potential risks and benefits from participation in the study.
2. The Committee suggested the possibility of recruiting participants by advertisement rather than directly contacting individuals without their consent. The Researcher stated that although this may be possible it would be difficult to contact the right people this way and may not allow them to recruit sufficient participants.
3. The Committee noted that the risks involved with contacting these individuals is relatively low.
4. The Researcher stated that they intend to use the NHI numbers to confirm potential participants are still alive before attempting to contact them to reduce the risk of distressing their relatives.
5. The Committee noted that gestational diabetes has a high risk of foetal death and this should also be considered a sensitive area. The Researcher agreed and stated that although they wish to reduce the risk of distressing the people contacted they are unable to know in advance if this outcome was experienced by the women they are planning to contact.
6. The Committee noted that the Participant Information Sheet contains a broad statement regarding participants bringing their children to study visits, they are concerned that it will not be clear to participants what is expected. The Researcher stated that their intention is to discuss this on the phone with any participants to clarify this as they have left it deliberately general as they would like participants to bring their children and grandchildren if possible, but it is not required.
7. The Committee noted that information on the baby’s biological father is going to be included and they questioned why these fathers would not be provided with consent forms or information sheets if they will also be participants. The Researcher responded that only general, non-identifiable, information on the father will be collected such as his health status at the time and therefore he is not a participant.
8. The Committee noted that the storage of human tissue form does not include information for children. The Researcher explained that the blood tests is optional and not a requirement to participate.
9. The Committee questioned the protocols for storing tissue for future unspecified research. The Researcher explained that they intend to store these samples de-identified in a tissue bank that is being set up at the University, however, if this tissue bank is not set up they will not be storing any samples for future use.

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 requested the researchers provide a sample letter and script for the phone call intended to be used to contact the potential participants. Please also include a protocol for contacting these people.
2. The Committee questioned the recruitment of a control group as they do not seem to be included in the Participant Information Sheet. The Researcher explained that a control group will be recruited from a database of women who were treated by a GP during the same time and did not have diabetes. The Committee raised concerns that it is more difficult to justify accessing the health information of these individuals for the purposes of recruitment. The Committee suggests that it may be more appropriate for potential control group participants to be approached by their GP, who has access to their health information, and given information to contact the researchers if they are interested. The Committee requested that further information is provided regarding how the researchers intend to approach and recruit the control group, this must include appropriate Participant Information Sheets and Consent Forms for these participants.

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

1. Please develop age appropriate consent and information sheets for children. The Committee suggests that these are split into forms for 7-12 year olds and forms for 13-16 year olds.
2. The parental consent form for children 0-14 should be adjusted to include children 0-16.
3. Please provide appropriate Participant Information Sheets and Consent Forms for the control group.
4. The Consent form does not require a table for interpreter options, a statement regarding the availability of an interpreter is more common.
5. Please remove the tick boxes from the consent form for all statements that aren’t truly optional.
6. Please make it clearer that all participants, including children, can withdraw from the study at any time.
7. Please adjust the ACC paragraph.

Decision

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

1. Please adjust the Participant Information Sheets and Consent Forms as detailed above.
2. Please address the Committees outstanding ethical concerns.

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

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| **12** | **Ethics ref:** | **15/CEN/143** |
|  | Title: | Human tissue bank of surgical cancers |
|  | Principal Investigator: | Associate Professor Peter Larsen |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 September 2015 |

Associate Professor Peter Larsen 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 application is to set up a surgical cancer tissue bank at the University of Otago.

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 the Governance Arrangements for the tissue bank. The Researcher explained that tissue would only be made available within their department to studies approved by a HDEC, use of tissue from the tissue bank would also need to be approved by Associate Professor Peter Larsen and two surgeons.
2. The Committee questioned the appropriateness of a paper log for use of tissue from the bank. The Researcher explained that this would replicate the information stored in an electronic database.
3. The Committee questioned who would be responsible for the tissue stored in the bank. The Researcher explained that the Lab Manager would be responsible for any use of tissue from the tissue bank.
4. The Committee asked how requests for samples to be withdrawn from the tissue bank would be managed. The Researcher explained that he would be responsible for this. The Committee requests that this is included in the formal governance arrangements for the tissue bank.

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

1. Please consider rewording ‘we are after your permission’ to ‘we are seeking your permission’ in the Information Sheet.
2. Please consider rewording ‘you have been nominated’ to ‘you have been invited’ in the Information Sheet as ‘nominated’ implies that the participant was nominated by someone else.
3. The Committee questioned if participants will understand the terms RNA and DNA in the Information Sheet, they understand that the full terms may be more confusing but suggest adding the word ‘genetic’ if possible.

Decision

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

1. The Committee requests that the practical governance arrangements are detailed in the Governance Protocol. The Committee suggested that contacting Helen Morrin, the Curator of the Cancer Society Tissue Bank, may be useful when developing this document further.

## Substantial amendments

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| **1** | **Ethics ref:** | **15/CEN/64/AM01** |
|  | Title: | Ki67 and Mitotic count in endocrine sensitive earl |
|  | Principal Investigator: | Dr Sarah Barton |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 August 2015 |

Dr Sarah Barton 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 application.

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

Summary of Study

1. This application is for a substantial amendment to an approved study.
2. The Researchers intend to expand the study to include tissue from patients who have not consented to their tissue being used for unspecified future research.
3. The Researchers also need to access these individuals’ health information without consent to determine if they had a second malignancy for the exclusion criteria of the study.
4. Originally this study was approved with access to tissue and health information from patients who had consented to their tissue being available for unspecified future use.
5. The Study involves retrospectively conducing 2 extra tests on tissue samples taken from breast cancer 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 why the researchers now wanted to expand their study to use tissue from patients who did not consent. The Researcher explained that they have currently identified 120 samples that they are able to use however they require more samples for their study.
2. The Committee noted that the survival rate for these patients is quite high and if they attempted to obtain consent they would not be likely to be contacting patients who had since died.
3. The Researcher explained that consent to future research was not explicitly include in consent forms before 2002 and that it may be difficult to contact patients who had tissue removed prior to this time. The Committee stated that they could use the patient’s NHI number to look up their most recent contact details. The Researcher responded that given their timeframes it would be difficult to contact the patients needed, and due to how closely related the tests are to what was already conducted for standard care they believe that most patients would have no problem with their tissue being used for this research purpose.
4. The Committee questioned how similar the tests conducted for the study are to those conducted on the tissue already. The Researcher explained that these tests are very closely related and may already be done in some cases as standard care.
5. The Committee questioned if the patients who did not consent to their tissue being used for research know it is stored. The Researchers explained that they will be aware it is stored as it may need to be used for future tests to benefit their treatment.
6. The Committee stated that under the HDC Code of Rights, right 7.10, No body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved, or used otherwise than (a) with the informed consent of the consumer; or (b) For the purposes of research that has received the approval of an ethics committee. As informed consent has not been obtained from patients for their tissue to be used in this way for the Committee to approve this amendment they must be convinced that there is sufficient reason to warrant HDEC approval of the use of this tissue without consent.
7. The Committee states that as the tests being performed on tissue in this study are very closely related to the tests already conducted on it as part of standard care, and that this study has the potential to provide valuable evidence to an important body of research, it is acceptable for this tissue to be used under Right 7.10.b.

Decision

This application 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:** | 27 October 2015, 08:00 AM |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 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 5.30pm.