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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 21 June 2016 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 17 May 2016 |
| 12:10pm | New applications (see over for details) |
| 12:10-12:30  12:30-12:55  12:55-1:20  1:20-1:45  2:10-2:35  2:35-3:00  3:00-3:25  3:25-3:50  3:50-4:15 | i 16/STH/92  ii 16/STH/73  iii 16/STH/75  iv 16/STH/77  v 16/STH/80  vi 16/STH/81  vii 16/STH/84  viii 16/STH/85  ix 16/STH/88 |
| 4:15pm | Substantial Amendments   * MEC/07/11/150/AM07 * MEC/07/01/006/AM04 |
| 4:30pm | General business:   * Noting section |
| 5:00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 27/10/2015 | 27/10/2018 | Present |
| Mrs Angelika Frank-Alexander | Lay (consumer/community perspectives) | 27/10/2015 | 27/10/2018 | Present |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Nicola Swain | Non-lay (observational studies) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Mathew Zacharias | Non-lay (health/disability service provision) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Devonie Eglinton | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Fiona McCrimmon | Lay (the law) | 27/10/2015 | 27/10/2018 | Present |

# Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Dr Nicola Swain and Dr Mathew Zacharias.

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 17 May 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/STH/92** |
|  | Title: | The Cancer Society Tissue Bank (CSTB) |
|  | Principal Investigator: | Ms Helen Morrin |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 June 2016 |

Ms Helen Morrin 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 Sarah Gunningham declared a potential conflict of interest, and the Committee decided to allow her to fully participate in the consideration of this application.

Summary of Study

1. The Committee thanked the Researcher for the high quality of this application.
2. The Cancer Society Tissue Bank has been running since 1996 and tissue contained in this tissue bank was obtained with consent for Future Unspecified Research.
3. The tissue bank is open to applications for the use of this tissue from around New Zealand, all applications are considered by the governance board.
4. The Committee commended the tissue bank and noted that their systems and processes are on the leading edge and other tissue banks could learn from their example.

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 an inaccuracy in the version date on the Participant Information Sheet. The Committee noted that this should be changed before they are given to new participants, but this change does not need to be submitted to HDEC.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **16/STH/73** |
|  | Title: | SODIUM-HFSODIUM-HF Trial |
|  | Principal Investigator: | Professor Richard Troughton |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 June 2016 |

Professor Richard Troughton 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 whether reduced salt intake is beneficial for patients with heart failure.
2. It is believed that low sodium intake may prevent fluid retention, however there is no clear evidence that this is the case.
3. This is a large Canadian based study with some study sites in New Zealand.
4. The Committee commended the high quality of the evidence of scientific review provided with the application.

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 the low sodium diet is associated with potential increased costs for participants. The Researcher stated that it should be cost neutral as although it involves eating less processed foods it mainly focuses on using less salt in cooking and at the table.
2. The Committee questioned whether there were any risks associated with a very low sodium diet long term. The Researcher stated that it was possible participants would become sodium deficient and experience mild hypotension. The Committee noted that the PIS states that there are no known side effects and requested this is amended to clarify the risk of becoming sodium deficient and becoming mildly hypotensive, it would be suitable to say that although this is possible it has not been reported but the possibility needs to be included.

Summary of ethical issues (outstanding)

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

1. This study includes tissue being stored for Future Unspecified Research, the Committee questioned whether participants’ samples would retain a link to their identity to allow them to withdraw their tissue from continued storage, even if they initially consented to this aspect of the study. The Researchers stated that they would confirm this.
2. The Committee questioned whether tissue samples are being sent overseas for the study or the Future Unspecified Use of Tissue aspect of the project. The Researcher explained that New Zealand is the central lab for the study and therefore samples analysed as part of this study will be sent to New Zealand from overseas sites and New Zealand samples will not leave the country.
3. The Researchers were unable to confirm where samples retained for future unspecified use would be stored within New Zealand or overseas. The Committee stated that this must be clear to participants and if the samples will be stored in New Zealand they must be stored in a HDEC registered Tissue Bank.
4. The Committee questioned why it is optional for the participant’s GP to be informed of their participation in the research and any significant results as knowledge of their participation could have an impact on the care prescribed by the GP. The Researcher stated that in their experience most participants agree to have their GP informed of study participation. The Committee stated their preference that all participants’ GPs are informed of their study participation and requested that this is made compulsory.

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

1. The Committee stated that studies that include optional Future Unspecified Use of Tissue must include a separate information sheet and consent form for this. Please see the end of the HDEC template PISCF for guidance on this.
2. Please ensure it is clear in the information sheet and consent form that it is compulsory for the participant’s GP to be informed of their participation in the study and any significant results.
3. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. 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/whanau 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*.”
4. Please clarify where samples stored for future research will be stored in the Future Unspecified Research Participant Information Sheet.
5. Please state in the PIS the risk of becoming sodium deficient and developing mild hypotension.

Decision

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

1. 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).
2. Please respond to outstanding ethical concerns, including where tissue would be kept for Future Unspecified Research. The Committee noted that tissue cannot be stored in New Zealand beyond the end of the study unless it is stored in a HDEC registered Tissue Bank.

This following information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine and Assc Prof Mira Harrison-Woolrych.

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| **3** | **Ethics ref:** | **16/STH/75** |
|  | Title: | Skin cancer in chronic lymphocytic leukaemia patients |
|  | Principal Investigator: | Dr Sean A MacPherson |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 June 2016 |

Dr Sean A MacPherson 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. This study involves investigating the characteristics of Skin cancer in chronic lymphocytic leukaemia patients.
2. Patients with leukaemia have an increased risk of secondary malignancies.
3. In a previous project the Researchers retrospectively considered 300 patients with lymphocytic leukaemia and identified a significantly increased risk of secondary malignancies, including an interesting higher risk of skin cancer. The Researchers identified 30 patients who developed skin cancer and want to further consider these patients and the characteristics of their disease.
4. There are a range of possible reasons for this including that these patients have a suppressed immune system from their disease and their treatment, the increased radiation damage in New Zealand, and a possible link with HPV which may be due to participant’s lessened ability to fight the virus.
5. This study will involve a range of characteristics being considered including whether ultraviolet damage and/or HPV can be detected.
6. The patients proposed to be included in this study had tissue stored for diagnostic and treatment purposes, these samples were not provided with consent for research.
7. The lymphocytic leukaemia patients will be compared with kidney transplant patients who have an increased risk on skin cancer.
8. The Committee noted that this is an interesting study with the potential to produce important results.
9. The Committee commended the respectful nature of the cover letter emailed to the secretariat.

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 the patients whose samples will be used in this study are still alive. The Researcher explained that these samples have been collected starting in 1998 and many of these patients will be deceased.
2. The Committee questioned whether it would be practical or reasonable to collect new tissue samples, with consent, from new patients going forward, rather than using these samples that do not have consent for research. The Researcher explained that looking back over the past 18 years they were only able to identify 30 patients who fitted their inclusion criteria of having a secondary malignancy (specifically skin cancer), out of 300 patients with lymphocytic leukaemia. They feel that this sample size is reasonable to obtain generalizable results, and to prospectively collect a similar sample size could be expected to take a very long time.
3. The Committee noted that the tissue samples that this study proposes to use were collected for treatment and diagnosis and are leftover from this process, no indication would have been given to these patients that their samples could be used for research. Further, the Committee noted that these samples are identifiable.
4. The Committee questioned whether the researchers could access the samples and health information from these patients with all identifying information removed. They suggested that the agency which holds this information could link it to the samples with a study number and then provide this de-identified tissue and data to the researchers. The Researcher stated that although this is not their preference this would be acceptable as long as they obtained complete medical information about the participants as they are considering a wide range of possible factors contributing to increased skin cancer in lymphocytic leukaemia patients. The Researcher noted that as part of a previous study they have already identified the 30 patients whose data and tissue they wish to access for this project, and although they could be partially de-identified a link would need to remain to the identity of the patient in case additional information needed to be accessed, however this link could be held by the agency that provides the information rather than by the research team themselves.
5. The Committee stated that when the data and samples are provided to the research team they must not include identifiable information and that participants must not be identifiable in any publication of the results.
6. The Committee noted that the use of these samples is quite related to the reason they were collected as the research project is directly considering the characteristics of their disease, however, it is still secondary use as the data and tissue were collected for diagnosis and treatment, not research.
7. The Committee noted that contacting deceased participant’s families to obtain consent may be very distressing and stated their preference that this not occur.

Decision

This application was *approved* by vote, with 5 for and 1 against, and Dr Fiona McCrimmon dissenting.

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| **4** | **Ethics ref:** | **16/STH/77** |
|  | Title: | Effect of probiotic BLIS M18 on the post-radiotherapy oral microbiome. |
|  | Principal Investigator: | Associate Professor Richard Douglas |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 09 June 2016 |

Dr Kim Gear, Anna Vesty, and Kristi Biswas were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee noted that although the application included a provision for storage of tissue for Future Unspecified Research that following an email exchange with the secretariat the researchers confirmed that they would not be pursuing this and the Committee considered this application with no storage of tissue beyond the end of this study.
2. This study aims to investigate the manifestation of oral decay in patients treated with radiation and determine whether a probiotic lozenge reduces oral decay in this patient group.

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 whether following 50 patients (25 control and 25 in study arm) for 1 year will produce sufficient evidence to statistically verify or substantiate the study results. The Researcher stated that there is significant variation between patients, including between those who can afford to attend regular dentist visits and use high fluoride toothpaste, this study will involve providing all participants with regular dentist visits and high fluoride toothpaste to remove some variables. The Researcher explained that very high rates of decay can be seen in these patients in a short period of time and one year will be sufficient to see significant decay, the Researcher further stated that if the results from a 1 year period were not sufficient they could extend the study as necessary.
2. The Committee questioned whether power calculations have been conducted on the study methodology to determine if statistically significant results can be produced with the limited population group. The Researcher stated that they have not done any power calculations, but there are only limited patients who meet the inclusion criteria and they are unlikely to be able to recruit more participants in a reasonable timeframe. The Committee noted that, although they understand that it may be impractical to recruit more participants, they must be assured that the study will produce results with statistical significance and that the study has scientific merit in order to justify recruiting participants for the study.
3. The Committee questioned the primary outcome measures for the study. The Researcher explained that they will be looking at the levels of dental disease to see if there is a reduction in decay. The Committee noted that the protocol should contain specific details about the primary outcome measures, including how they will be measured and quantified.
4. The Committee noted that the lack of power calculation and detail about outcome measures should have been picked up by a thorough scientific peer review and stated that they require further evidence of peer review, specifically focusing on the suitability of the outcome measures, a power analysis, and the potential statistical significance of the study results with the population size and timeframes.
5. The Committee noted that due to the current lack of information on outcome measures included in the protocol, and the small sample size, this appeared to be a feasibility study.
6. The Committee noted that the protocol needs to be significantly more fleshed out to ensure that all study tests, measures, and procedures are fully detailed in the protocol. For example, all tests that will be conducted on blood and saliva samples must be detailed in the study protocol, and how the primary outcomes will be measured and quantified must also be fully explained in the protocol.

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

1. The Committee noted that PIS currently makes it appear that the probiotic is far better for participants, however there is not enough evidence to back this claim yet and obtaining more evidence is the purpose of this study. The Committee stated that they expect that participants who read this information sheet and end up being in the control group are likely to want to purchase the lozenges as it appears that they will have significant benefit from their use. The Researcher stated that any participants who are in the control group and use the lozenges will be detected in the testing of their mouth microbes and withdrawn from the study.
2. The Committee stated that the PIS should be reworded to not overstate the expected benefit from the lozenges to reduce the number of people self-treating with lozenges and to ensure accuracy. Rephrasing the PIS in this way should also ensure that it is clear that both study arms are in equipoise.
3. The Committee requested that the PIS is altered to ensure it states how frequently study visits occur, where they are to be held, how long they last.

Decision

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

1. The PIS provided was not suitable for the proposed research project (Ethical Guidelines for Intervention Studies para 6.22).
2. Please provide evidence of favourable independent peer review of the study protocol, including statistical analysis, the suitability of the primary measures, and a power analysis (Ethical Guidelines for Intervention Studies Appendix 1). This is required to assure the committee of the scientific merit of the study, the suitability of the study design and methods, and the feasibility of the research.
3. The Committee noted that scientific soundness is ethically important, projects without scientific merit needlessly expose participants to risk and misuse their time, and waste resources (Ethical Guidelines for Intervention Studies para 5.5). The Current proposal does not assure the committee of the scientific soundness of the project.
4. Please amend the study protocol to ensure that all study procedures are fully documented (Ethical Guidelines for Intervention Studies section 5).

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| **5** | **Ethics ref:** | **16/STH/80** |
|  | Title: | vTv Therapeutics-TTP488-301/ STEADFAST |
|  | Principal Investigator: | Dr Nigel.L Gilchrist |
|  | Sponsor: | inVentiv Health Clinical |
|  | Clock Start Date: | 09 June 2016 |

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

Potential conflicts of interest

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

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

Summary of Study

1. The Committee noted that this is an intervention study in patients with mild Alzheimer’s disease. Some of these patients will not be able to provide informed consent to their participation in the study. The application included the facility to obtain proxy consent, however, prior to the meeting this was discussed with the Researchers by email as proxy consent is not legally acceptable in New Zealand. Prior to the email, in an email exchange with the Secretariat the Researchers clarified that they would remove the option of proxy consent for New Zealand participants but still intended to recruit participants unable to consent under the best interests provisions of Right 7 (4) of the HDC Code of Rights.
2. The Committee noted that this study has received ethical approval in America.

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 regarded the email from the Researchers stating their view that participation in the study is in the best interest of each individual participant. The Committee disagreed with this assessment, based on the information available to them, and stated that the benefits of the study drug from the Phase 2 trials has been overstated to make a best interest’s claim.
2. The Committee further noted that it appeared that some of the earlier trials found detrimental results in patients with moderate or severe Alzheimer’s disease and although participant’s recruited to the study may have only mild Alzheimer’s disease that this may progress to moderate during the course of the study. The Committee requested further information about this including whether participants would be regularly monitored and withdrawn from the study if their Alzheimer’s disease progressed.
3. The Committee stated that they are not convinced that participation in this study is in the best interest of each individual participant and are unable to approve this study being conducted in participants unable to provide informed consent as it does not appear to meet the best interest’s test of Right 7 (4).
4. The Committee stated that it is not possible for HDECs to approve an application unless it is consistent with New Zealand law, including the right not to be subjected to medical or scientific experimentation without that person's consent (section 10 of the New Zealand Bill of Rights Act 1990). Research involving participants who are not competent to consent is inconsistent with the Bill of Rights unless it is undertaken in accordance with Right 7 (4) of the of the Code of Health and Disability Services Consumers’ Rights. In addition to requirements regarding ascertaining the views of the consumer and other suitable persons (forms consistent with this aspect are currently included in this application), Right 7(4) of the Code requires that any health services provided without the informed consent of the consumer must be in the best interests of the consumer. This means that there must be some benefit, or potential benefit, to the participant beyond what they would receive if they were not participating in the research.
5. The Committee noted that some participants may be able to provide informed consent as they only have mild Alzheimer’s disease and continued their consideration of this study based on only participants able to provide informed consent being included.
6. The Committee stated that they do not have sufficient evidence that the potential benefits from this study outweigh the potential harms from the study.

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

1. The Committee voiced disappointment at the inappropriate nature of the PIS for the study population group and were not convinced that participants would be able to follow the document.
2. The Committee suggested a complete re-write of the PIS as a number of areas in the PIS needed to be redone. For example;
   * the 6 line study title should be replaced with a very short lay title,
   * a large amount of repeated information should be removed,
   * the tone needs to be revised to ensure it appears that participants are being invited to the study rather than commanded,
   * the risk section must be revised to make the risks of the study drug clearer,
   * the density and highly clinical language in the PIS must be removed or revised,
   * more information on risks such as falls should be provided as it is unclear why the study drug may increase this risk,
   * the compensation statement is not ACC equivalent and must be revised,
   * please clarify who will pay for study visits,
   * statements such as ‘you will not be punished’ should be replaced with more tone appropriate statements,
   * all references to non-consenting participants must be removed,
   * the overly legal language in the PIS must be revised to make it more in line with New Zealand standards as the PIS exists to inform participants about what is involved in the study rather than to protect the study sponsor,
   * and, information on possible drug interactions must be included.
3. Please revise the advertising material for this study to ensure the potential benefits are not over stated. For example, the statement that participants can be involved in an important study of a drug that may be effective at slowing the progression of Alzheimer’s disease should be revised to reflect that they could participate in a study on an experimental drug for Alzheimer’s disease.
4. The Committee noted that the PIS listed some serious possible side effects that participants may already have that could be worsened by the study drug. The Committee stated that it was essential that participant’s carers are involved in the decision to enrol participants as they must care for the participants and bring them to study visits, and this could be made more difficult is participants are experiencing more severe side effects.

Decision

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

1. The PIS provided was not suitable for the study participant group (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. The Committee does not feel that the study meets the equipoise standard as insufficient evidence has been provided that the potential risks of the study are outweighed by the potential benefits (Ethical Guidelines for Intervention Studies para 5.18).
3. Participants are entitled to provide informed consent to their participation in a research project (Ethical Guidelines for Intervention Studies para 6.8). Participation by participants unable to provide informed consent must be done in line with Right 7(4) of the HDC Code of Rights. The Committee were unable to approve this study for non-consenting participants as they were not convinced that this study met the best interest test of Right 7(4).

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| **6** | **Ethics ref:** | **16/STH/81** |
|  | Title: | Beta-Blockers in COPD: Feasibility Study |
|  | Principal Investigator: | Associate Professor Robert Hancox |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 June 2016 |

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

Potential conflicts of interest

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

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

Summary of Study

1. This is an open label feasibility study investigating the use of beta blockers in patients with COPD.
2. Although patients with COPD have increased rates of heart disease they often do not receive beta blockers due to concerns about possible risks. However, a previous study suggested that these concerns are unfounded with the use of certain beta blockers in patients with COPD.
3. The Committee noted that this is a well-designed study and should produce valuable results.
4. Overall the Committee were satisfied with the good quality of the study documents, including the PIS.

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 whether participants need to stay at the study location for 4 hours post the initial dosing to look for allergic reactions. Please clarify the reason that 4 hours is stated as currently this seems to be an arbitrary time frame.

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

1. The Committee noted that although the application form included detailed information on the risk of adverse reactions this is not included in the PIS. Please add this information to the PIS, the Committee suggests listing the information in bullet points with expected rates of occurrence and any other relevant information.
2. Please clarify in the PIS that participants must stay at the study site for 4 hours post dosing.
3. Please clarify in the PIS whether participants will start on the study medication at their first assessment visit.
4. Please clarify in the PIS whether study visits are at an outpatient facility or a research clinic.
5. Please add subheadings to the section ‘What will my participation involve’ to help ensure clarity.
6. The Committee questioned whether there are any known risks of the study drug for women who are pregnant or become pregnant while in the study. Please state in the PIS any known risks of fetal exposure, including whether there is only a low risk. The Committee suggested that if the risks are low enough a statement recommending the participants speak to their study doctor if participants are of child bearing potential they should speak to their study doctor about contraception requirements.
7. Please consider moving information on the study funding to the ‘who pays for the study’ section of the PIS, rather than including it in the ‘purpose of the study’ section.
8. Please clarify in the PIS that participants may experience no benefit.
9. Please clarify in the PIS that if participants want to stop taking the study drug they need to speak to their GP or study doctor as they need to reduce their dose over time to avoid adverse withdrawal effects.
10. Please clarify how much will be reimbursed in terms of reasonable expenses for attending study visits.
11. Please ensure that all health information is stored for a minimum period of 10 years (Health (Retention of Health Information) Regulations 1996).

Decision

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

1. 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).
2. Please respond to the Committee’s outstanding ethical concern detailed above.

This following information will be reviewed, and a final decision made on the application, by Assc Prof Mira Harrison-Woolrych and Dr Fiona McCrimmon.

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| **7** | **Ethics ref:** | **16/STH/84** |
|  | Title: | Establishment of a spinal cord injury registry in New Zealand |
|  | Principal Investigator: | Mr Balraj Singhal |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 June 2016 |

Jo Nunnerley 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. Currently limited data is available about spinal cord injury and clinicians and researchers have been pushing for a registry to help add to knowledge in this area.
2. As part of a pilot process the researchers investigated a range of registries to determine the best design for their context.
3. The researchers proposed an opt out registry as they believed this offered the best practical solution in terms of increased compliance and less clinician time invested.
4. The researchers intend to collect a minimum data set on all patients with spinal cord injury in New Zealand. In addition, they will interview patients to collect additional information. In order to participate in the registry participants will need to actively engage in the interview process, the researchers consider this to be part of the opt out process, if they do not participate in the interview the researchers will take this as indication of the participant not wanting to be included in the registry.
5. This registry is funded by ACC and the Ministry of Health.

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 why this registry couldn’t just involve accessing retrospective records. The Researcher explained that although they would obtain routinely collected health information they would also interview participants to obtain important information that is not routinely collected.
2. The Committee questioned why written informed consent cannot be obtained from participants, considering that all participants will engage directly with researchers when they are interviewed. The Researchers said that apart from some participants who may be unable to indicate their consent in writing, due to physical limitations from their injury – rather than reduced capacity to understand the study – that participants could provide informed consent if it was preferred by the Committee.
3. The Committee questioned whether any additional information would be added to the registry after the initial information is recorded. The Researcher explained that participants would be followed up at 1, 2, and 5 years, and although this is medically standard practice it is not always followed diligently as patients may move or become difficult to locate and not be followed up appropriately.

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 that the recruitment protocol for participants is modified to obtain active informed consent from participants. Where possible, participants should indicate their consent in writing, however, if the participant had the capacity to agree to participation in the study but was unable to record this in writing it would be acceptable to record this in an alternative way on the consent form.

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

1. Please an amended participant information sheet and consent form, which includes facilities for participants to indicate their own consent where possible and for researchers to record where participants have indicated a willingness to consent but are unable to provide written consent.

Decision

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee.

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| **8** | **Ethics ref:** | **16/STH/85** |
|  | Title: | MicroRNAs and subclinical atherosclerosis |
|  | Principal Investigator: | Dr Nikki Earle |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 09 June 2016 |

Dr Nikki Earle 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 Committee commended the high quality of the PIS, noting that it is well written and easy to understand.

Summary of ethical issues (resolved)

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

1. The Committee agreed it was suitable to not state in the PIS that there are 3 groups participants could be found to be in, in terms of their risk of heart disease, as this may unnecessarily alarm participants.
2. The Committee questioned whether tissue was being stored for Future Unspecified Use. The Researcher explained that although tissue may be stored up to 15 years it is only being stored for use in this study. The Committee agreed that this does not count as future unspecified research.

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

1. Please add a lay title to the PIS, the Committee suggests ‘Blood Markers for Early Stages of Heart Disease’.

Decision

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee.

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| **9** | **Ethics ref:** | **16/STH/88** |
|  | Title: | CMLD Register |
|  | Principal Investigator: | Mr Richard C W Martin |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 June 2016 |

Mr Richard C W Martin 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 registry previously obtained HDEC approval, however this approval lapsed due to lack of personnel.
2. This registry aims to retrospectively collect information from 2005 – present, and to continue collecting information from patients going forward.
3. The Researchers expect approximately 20-25 eligible patients to be identified annually, meaning that retrospective data from the past 10 years is expected to be from 200-250 patients.
4. This application proposes that this registry would operate on an opt-out basis and all eligible patient’s data would be included in the registry, unless they explicitly opted out. The Committee noted that they consider this to be non-consent, although opt-out is a preferable version of non-consent as it offers participants the possibility of deciding to not have their data included.
5. The Researcher noted that they have had another, similar, registry approved by the HDECs.

Summary of ethical issues (resolved)

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

1. The Committee requested more information about the governance arrangements for this registry, including who is on the governance committee and how they will determine if applications to use the registry data are acceptable. The Researcher explained the membership of the governance committee and explained that all research applications to use data from the registry, internal and external, would be considered by the governance committee.
2. The Committee questioned why the researchers do not just set up one skin cancer registry. The Researcher stated that they had considered this option but it was not suitable at this stage.
3. The Committee questioned whether information on the medicines being used by participants would be included in the registry. The Researcher explained that currently no medicines are widely used, however, they would include this information where available.

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 research is intended to be covered by this application as this appears to be an application for a registry to be set up, however, the application also included some specific research questions. The Committee requested clarification of whether these are covered by this application, or if these will be from separate studies that will apply for HDEC approval as needed.
2. The Committee noted that the use of Health Information is regulated by the Health Information Privacy Code (HIPC) and this code requires researchers who wish to use health records without the individual’s authorisation to obtain the approval of an ethics committee. Applications to an ethics committee for the use of health information without consent should justify the reasons (scientific, practical, or ethical) for not obtaining consent. The potential benefits of the research should also be explained to the ethics committee and may be weighed against the loss of privacy.
3. The Committee also referenced paragraph 6.43 of the Ethical Guidelines for Observational Studies states that access to identifiable 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.
4. HDECs can only approve health research in line with these guidelines. In this instance, to approve access to patients’ health information without their consent the Committee must be convinced that the justifications for not obtaining consent (scientific, ethical, or practical) and the benefits of the research are sufficient to outweigh the public interest in privacy.
5. The Committee questioned whether the researchers could obtain consent from patients going forward, as this would only be 20-25 patients per year and the Committee did not believe that obtaining this consent would be overly burdensome. The Researcher stated that this may be possible, however, they were concerned that not obtaining consent from all patients would lead to an incomplete data set and may introduce bias that would compromise the scientific validity of the registry. The Committee stated that they believed that a minimal number of patients would decline to have their data included in the registry, similar to the number that would choose to opt-out if this consent model was followed instead. Consequently, the Committee stated that they did not feel that the scientific or practical justifications justified obtaining this information without consent in this case, the Committee could see no ethical reason not to obtain consent from participants.
6. The Committee conceded that the Researchers may discover that they are unable to obtain consent from a number of patients for a variety of reasons, however, the Committee did not feel that they currently have enough reason to believe this would be a significant problem. The Committee suggested that if after 1 year of obtaining consent from patients the Researchers find that they have a significant number of patients who they were unable to obtain consent from they could contact the HDEC and submit an amendment to apply to change the consent arrangements, as at this stage they may have more information to justify an opt-out consent model.
7. After determining that consent should be obtained from all participants going forward, the Committee considered the possible justifications (scientific, practical, or ethical) for obtaining the retrospective information about patients from the past 10 years without consent.
8. Scientific: The Committee noted that if consent was sought from past patients, the number of patients that they expected to decline to participate would not be significant enough to result in a bias or loss of scientific integrity for the registry. Because of this, the Committee felt unable to approve the obtaining of past patients’ records without consent on scientific grounds.
9. Practical: The Committee expected that approximately 250 patients (20-25 per year) would be eligible for their data to be included in the registry from 2005-present. The Committee stated that they did not believe that these numbers were sufficient to justify obtaining health information without consent under practical grounds, as they believe the Researchers could obtain consent from this number of participants.
10. The Committee stated that they did not feel that the practical or scientific justifications were sufficient to justify obtaining health information without the authorisation of the individual concerned in this case.
11. Ethical: The Committee noted that as some participants would be deceased it would not be possible to obtain their consent. Contacting the next of kin of deceased participants could be distressing for the family, and it was felt that that this may outweigh the benefits of obtaining consent in that sub-group. The Committee also raised concerns about the potential distress to patients’ families if attempts were made to contact an individual who the researchers were unaware was deceased. The Committee stated that although the researchers could check medical information in an attempt to determine if potential participants are alive this may not always be accurate.
12. The Committee stated that although some patients may have died, and would therefore be unable to provide informed consent, the Committee do not have sufficient information to know how significant the number of deceased patients is and, from their understanding of the disease progression, they do not expect it to be significantly more than the general population.
13. However, the Committee stated that in this case they cannot justify allowing the access of health information without consent for patients who are deceased while not approving the use of health information for patients who are still alive as only including the data from deceased individuals in the registry would compromise the scientific basis of the registry.
14. The Researcher questioned whether they could seek consent from patients who are still alive from the past 3 years to use their health information for the registry, as they are going to obtain consent from new patients over the coming years.
15. The Committee noted that they must consider these justifications against the potential benefits of the research, and that as this is an application for a registry the potential benefits are less clear.
16. The Researcher noted that a number of other registries operate on an opt-out basis. The Committee stated that although this is the case they must obtain HDEC approval to do so and the HDECs consider each application on an individual basis. Further, the Committee stated that many of the registries that operate on an opt-out basis have a far greater number of eligible patients, making obtaining consent more impractical, and some are for diseases with a higher mortality rate, meaning that for some registries patients died before they were able to provide informed consent as the time between diagnosis and death was very limited. The Committee stated that they did not justifications applied to this registry sufficiently to justify an opt-out consent model.
17. In summary, the Committee approved the inclusion of participants recruited in clinic going forward, however, they did not approve the use of an opt-out consent model for these participants. Therefore, all future participants must provide informed consent for their data to be included in the registry. For retrospective participants, the Committee feel that they have insufficient information to make a decision by weighing up the benefits of obtaining consent, against the potential harms of contacting the family of deceased participants, against the potential benefits of the registry including data from patients from the past 10 years.
18. The Committee stated that they require further information about the justifications for using health information from the past 10 years without consent. Please provide details regarding the scientific, practical, and/or ethical justifications for not obtaining consent from these individuals. Please also provide more information about the expected benefits from this registry and how these may be compromised by not including information from these retrospective patients.

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

1. Please provide a short information sheet and consent form for participants being recruited prospectively.

Decision

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

1. 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*).
2. Please provide more information about the justifications for not obtaining consent from participants from the past 10 years, or please justify obtaining consent from these participants in light of the potential distress this may cause their family members if a letter is sent to a deceased participant (Ethical Guidelines for Observational Studies para 6.43).
   * Please note that the justifications will be different for a range of participant types, such as past patients who are known to be deceased, patients who are believed to be alive, and patients who are alive and are yet to attend clinic (noting that the Committee has currently determined that consent must be obtained from this group of participants). The benefits from inclusion of these participants must be clearly explained with reference to potential studies that would use registry data.
3. Please provide more information on the potential benefits of this registry, including information on how these benefits may be compromised if a complete data set is not obtained.

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

## Substantial amendments

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| **1** | **Ethics ref:** | **MEC/07/11/150/AM07** |
|  | Title: | AALL06N1 A Study of Neurocognitive Function in Chi |
|  | Principal Investigator: | Dr Rob Corbett |
|  | Sponsor: |  |
|  | Clock Start Date: | 07 June 2016 |

No member of the research team was present 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.

Decision

This amendment was *approved* by consensus.

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| **2** | **Ethics ref:** | **MEC/07/01/006/AM04** |
|  | Title: | AHOD0031 Dose Intensive Response-Based Chemotherap |
|  | Principal Investigator: | Dr Rob Corbett |
|  | Sponsor: |  |
|  | Clock Start Date: | 07 June 2016 |

No member of the research team was present 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.

Decision

This amendment 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:** | 19 July 2016, 12:00 PM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

The following members tendered apologies for this meeting.

* Mrs Angelika Frank-Alexander
* Dr Devonie Eglinton

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 4:30pm.