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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 20 September 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 16 August 2016 |
| 12:30pm | New applications (see over for details) |
|  | i 16/STH/108  ii 16/STH/154  iii 16/STH/144  iv 16/STH/145  v 16/STH/147  vi 16/STH/148  vii 16/STH/150  viii 16/STH/152  ix 16/STH/153 |
| 4:00pm | General business:   * Noting section of agenda |
| 4:10pm | 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 | Apologies |
| 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 | Present |
| Dr Mathew Zacharias | Non-lay (health/disability service provision) | 27/10/2015 | 27/10/2018 | Present |
| 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 Mrs Angelika Frank-Alexander.

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 16 August 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/STH/108** |
|  | Title: | Reducing bladder stones using Potassium Citrate after acute SCI |
|  | Principal Investigator: | Dr Peter Aspell |
|  | Sponsor: | Canterbury District Health Board |
|  | Clock Start Date: | 20 July 2016 |

Dr Peter Aspell 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. Most patients in the spinal unit require a catheter and due to their reduced mobility and other risk factors they have increased chances of developing bladder stones or debris.
2. Between 10 and 20% of these patients are expected to develop stones or debris.
3. Currently Potassium Citrate is frequently used to treat bladder stones or debris in this patient group, among others, and is considered very safe.
4. This study proposes providing Potassium Citrate to some patients in the spinal unit to determine whether this reduces their risk of developing bladder stones or debris.

Summary of ethical issues (resolved)

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

1. The Committee noted that the current application includes non-consenting participants, who are enrolled in the study before they are able to provide consent. The Committee questioned whether it was necessary to include participants who did not consent prior to their inclusion. The Researcher stated that they expected this to be a very small number of potential participants and it would not reduce the feasibility or compromise the results of their study to exclude these patients. The Committee agreed to consider the study going forward as only including participants who could provide informed consent prior to their enrolment in the study. The Committee noted that, if a benefit is found, a future study including participants unable to provide informed consent may be possible but would need to be submitted for HDEC review with justification relating to the legal status of enrolling participants unable to provide informed consent.
2. The Committee questioned how long after the study beginning would the researchers look at study data and bring the control group on to the study drug if it is showing a benefit. The Researcher explained that they will only be looking at results at current standard time points and do not expect to bring the control arm on to the study drug as due to the expected rates of bladder stones or debris they do not expect to find strong evidence of the effectiveness, or lack thereof, of the study intervention. However, any participants who develop bladder stones or debris during the study will revert to standard care, which usually includes the use of the study drug.
3. The Committee questioned whether the researchers expect to get sufficient evidence from their sample size, given the frequency of bladder stones and debris expected in this population group. The Researcher explained that their sample size is limited by practicality and they expect to see a minor difference between groups, if any difference is detected.
4. The Committee questioned how participants would be randomised. The Researcher stated that they will use a computer randomization programme on their personal electronic devices at time of recruitment.
5. The Committee noted that the question regarding managing of conflict of interest in the study was answered incorrectly, this question relates to the potential conflict of interest from the researcher also being the participant’s treating clinician and how this may influence the participant’s agreement to be in the study. The Committee asked the Researcher to clarify their response to this question. The Researcher explained that participants could be approached and consented by the ICU staff, who are not members of the research team. The Committee agreed this is an appropriate way to minimise conflict of interest.
6. The Committee noted that the question regarding formal Māori consultation was incorrectly answered and that this is required. The Researcher explained that they have undertaken formal Maori consultation for this study. The Committee agreed this is appropriate.

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 due to an incorrect answer in the application form some later questions regarding informed consent did not populate. The Committee requested answers to these questions are provided for their records.

**p.1.9.** Will informed consent be recorded in writing? If not please explain why not and how consent will be recorded.

**p.2.1.** Briefly explain the process by which potential participants in your study will be provided with information on the study, have the opportunity to ask questions, and asked to give their informed consent.

**p.2.3.** How have you checked that the participant information sheet is appropriate for your study population?

**p.2.4.** How many words does your participant information sheet contain?

**p.2.5.** What is the Flesch Reading Ease Score for your participant information sheet?

*You can use Microsoft Word to calculate this score.*

*While there are no hard and fast rules for the readability of information sheets, a score of 65 or above usually indicates that a document is written in plain English.*

**p.2.6.** Does your study involve deliberately withholding or concealing information from participants?

*Blinding procedures in randomised controlled trials are not normally considered to involve withholding or concealing information from participants.*

**p.2.7.** How will you ensure that participants receive information that becomes available during the study and that may be relevant to their continued participation?

**p.2.8.** Will you inform participants of the results of your study?  
**p.2.9.** Please *either* explain how you will inform participants or explain why you do not intend to do so.

**p.3.1.** Please explain how potential participants will be identified and approached in a way that ensures they can give informed consent free from undue influence.

**p.3.2.** Will your study involve potentially vulnerable people – that is, people who may have a restricted ability to make independent decisions about their participation?

**p.3.2.1.** Please explain how your study’s informed consent process takes the needs of these potentially vulnerable people into account.

**p.3.2.2.** Will informed assent also be sought from people responsible for the welfare of potentially vulnerable people involved in your study?

If yes,

**p.3.2.2.2.** Please explain how informed assent will be obtained.

**p.3.3.** Will participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in your study?

**p.3.3.1.** Please describe these, and explain why they are appropriate.

1. The Committee questioned whether the study would benefit from a placebo, rather than just standard care for the control arm. The Researcher explained that they had considered this but did not believe the benefits were sufficient to warrant the difficulties and cost in developing a placebo. The Committee noted that the lack of a placebo would reduce the impact of their results as it would impact their ability to rule out bias. The Researcher stated the study drug has a bad taste that would be hard to replicate in a placebo. The Committee requested that the Researcher looks in to the possibility of a placebo, but agreed that if it is not realistically possible that the study is acceptable without it.
2. The Committee noted the lack of peer review provided with the initial application and appreciated the Researcher bringing this to the meeting. The Committee will consider this peer review as part of the provisional approval.
3. Please amend the study protocol to be clear that only participants able to provide informed consent will be enrolled in this study.
4. The Committee noted that the question regarding screening health information was incorrectly answered. The Committee explained that participants’ health information will need to be screened before they provide informed consent to allow the researchers to identify potential participants who can then be approached regarding the study. Please respond to the below question that did not populate in the form due to the previous incorrect answer

**r.2.1.1.** Please briefly explain how you will ensure the confidentiality of this health information before the study.

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

1. The Committee requested the compensation wording is added for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
2. Please remove the front page from the Participant Information Sheet, this is included in the HDEC template for researchers but is not needed for participants.
3. Please revise the Participant Information Sheet to remove formatting issues.
4. Please clarify in the Participant Information Sheet what is meant by ‘tummy upset’, the Committee noted that this could mean different things to different participants.
5. Please include the expected rates of all side effects or risks in the Participant Information Sheet.
6. Please remove the yes/no tick boxes from the consent form for all statements that aren’t truly optional, meaning that a participant could select ‘no’ and still participate in the study.
7. Please remove the interpreter box from the top of the consent form as this is a note to researchers from the template. Please replace this with a statement regarding the availability of an interpreter for participants.
8. Please revise the Consent Form to remove statements that aren’t relevant to this study.
9. Please remove the Participant Information Sheet for participants who decline to participate as this is not necessary.
10. Please clarify in the Participant Information Sheet and Consent Form whether participants can choose to withdraw the data already collected about them if they choose to withdraw from the study. This should be an option if it is possible to withdraw their data, such as if it retains identifiers and can be removed. However, not all participants who withdraw from active participation in the study will wish to also withdraw data already collected about them.
11. Please proof read the Participant Information Sheet and Consent Form to remove any typographical or grammatical errors.

Decision

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

* Please respond to the Committee’s outstanding ethical concerns detailed above, it may be appropriate to respond to these in the form of a cover letter as the application form cannot be modified after submission.
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Studies para 6.22).

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

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| **2** | **Ethics ref:** | **16/STH/154** |
|  | Title: | Kaumātuatanga o te roro |
|  | Principal Investigator: | Dr Margaret Dudley |
|  | Sponsor: | The University of Auckalnd |
|  | Clock Start Date: | 08 September 2016 |

Dr Margaret Dudley and Dr Gary Cheung 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. This study aims to develop a Māori theoretical basis for dementia to help inform and treat Māori with dementia.
2. The study involves hui and interviews with Kaumātua and whanau to investigate their current understanding and views of dementia.
3. Current tools and systems for people with dementia are developed from a Western experience and may not be suitable for Māori in New Zealand.
4. The Committee commended the study and stated that it is an important area of research.

Summary of ethical issues (resolved)

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

1. The Committee raised concerns about the proposed inclusion of patients unable to provide informed consent in this study, noting that participants must be competent enough to have a discussion with researchers. The Researchers explained that some participants may provide consent at one study visit but forget about the study before the next study visit. The Committee noted that this does not seem to be a problem of capacity to understand and consent to their participation in the study, just their ability to remember providing consent to the study, which could be overcome by re-informing participants about the study at each study visit and confirming they are willing to participate at each point. The Researcher agreed that they could restrict the study to ensure only participants able to provide informed consent are included.
2. The Researcher stated that other studies they have been involved with have included participants unable to provide informed consent under Right 7(4) of the HDC Code of Rights. The Committee stated that this requires that participation is in the clinical best interests of each individual participant, they asked the researcher if this was the case in this study. The Researcher explained that it was their view that participation would benefit the community rather than each individual participant. The Committee stated that this is insufficient for enrolment of participants unable to provide informed consent under Right 7(4) and stated that for this study all participants must be deemed capable to provide informed consent to their participation, which should be possible due to the fact that participants will only have mild dementia.
3. The Committee noted that it is the responsibility of the enrolling clinician to determine capacity to provide consent for each participant at each study visit.

Summary of ethical issues (outstanding)

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

1. Please amend the protocol to reflect that only participants able to provide informed consent will be included in this study, please ensure this details how competency to consent will be determined, including who will determine this.
2. The Committee noted that due to an incorrect answer in the application form some later questions regarding informed consent did not populate. The Committee requested answers to these questions are provided for their records.

**P.1.9.** Will informed consent be recorded in writing? If not please explain why not and how consent will be recorded.

**p.2.1.** Briefly explain the process by which potential participants in your study will be provided with information on the study, have the opportunity to ask questions, and asked to give their informed consent.

**p.2.3.** How have you checked that the participant information sheet is appropriate for your study population?

**p.2.4.** How many words does your participant information sheet contain?

**p.2.5.** What is the Flesch Reading Ease Score for your participant information sheet?

*You can use Microsoft Word to calculate this score.*

*While there are no hard and fast rules for the readability of information sheets, a score of 65 or above usually indicates that a document is written in plain English.*

**p.2.6.** Does your study involve deliberately withholding or concealing information from participants?

*Blinding procedures in randomised controlled trials are not normally considered to involve withholding or concealing information from participants.*

**p.2.7.** How will you ensure that participants receive information that becomes available during the study and that may be relevant to their continued participation?

**p.2.8.** Will you inform participants of the results of your study?  
**p.2.9.** Please *either* explain how you will inform participants or explain why you do not intend to do so.

**p.3.1.** Please explain how potential participants will be identified and approached in a way that ensures they can give informed consent free from undue influence.

**p.3.2.** Will your study involve potentially vulnerable people – that is, people who may have a restricted ability to make independent decisions about their participation?

**p.3.2.1.** Please explain how your study’s informed consent process takes the needs of these potentially vulnerable people into account.

**p.3.2.2.** Will informed assent also be sought from people responsible for the welfare of potentially vulnerable people involved in your study?

If yes,

**p.3.2.2.2.** Please explain how informed assent will be obtained.

**p.3.3.** Will participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in your study?

**p.3.3.1.** Please describe these, and explain why they are appropriate.

1. The Committee noted that the question regarding how health information will be protected was not correctly answered, please provide a more detailed response to this question.

**r.2.1.1.** Please briefly explain how you will ensure the confidentiality of this health information before the study.

1. Please remove the form for clinicians to enrol participants unable to provide informed consent as all participants in this study must be able to provide their own informed consent.

Decision

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

* Please respond to the Committee’s outstanding ethical concerns detailed above. The Committee suggest that a cover letter may be best to answer some questions as the application form cannot be modified after submission.

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

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| **3** | **Ethics ref:** | **16/STH/144** |
|  | Title: | Postoperative Pain Management Following Pterygium Surgery |
|  | Principal Investigator: | Dr Riyaz Bhikoo |
|  | Sponsor: |  |
|  | Clock Start Date: | 08 September 2016 |

Dr Riyaz Bhikoo 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 noted that overall this was a good application with quite a good Participant Information Sheet.

Summary of ethical issues (resolved)

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

1. The Committee noted that the question regarding minimising conflict of interest was answered incorrectly, the Committee are looking for an answer relating to minimising the conflict of interest that exists from the researcher also being the participant’s treating clinician. The Researcher explained that this will be minimised by the study not being mentioned until the patient has had standard surgery explained and have consented to this, then the researcher will offer the patient enrolment in the study and make sure it is clear that their participation in the study will not impact the eligibility for standard of care and study participation is a fully optional extra. The Committee agreed that this is acceptable.
2. The Committee questioned how the researcher and participant will be blinded to the participant’s group allocation. The Researcher explained that the scrub nurse will prepare either the placebo solution or the study solution and the researcher will not know which one the participant is getting.

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 question regarding how health information will be protected was not correctly answered, please provide a more detailed response to this question.

**r.2.1.1.** Please briefly explain how you will ensure the confidentiality of this health information before the study.

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

1. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
2. Please revise the Participant Information Sheet to reduce technical language to make the Participant Information Sheet more suitable for lay participants. For example, participants may not understand a ‘systematic complication’ and this should be revised to be in lay language.
3. Please add a footer and page numbers to the Participant Information Sheet.
4. Please remove the letterhead from all pages of the Participant Information Sheet except the first page.
5. The Committee suggested revising the wording of ‘blunt needle’ in the Participant Information Sheet as although they understand why this is the case they feel this may make participants needlessly uncomfortable. The Committee suggested that simply calling it a ‘needle’ may be appropriate. The Researcher agreed to determine a different name to give the needle in the Participant Information Sheet.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Studies para 6.22).
* Please respond to the Committee’s outstanding ethical concern detailed above. The Committee noted that a response in the form of a cover letter may be appropriate as the application form cannot be modified after submission.

This following information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine and Dr Sarah Gunningham.

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| **4** | **Ethics ref:** | **16/STH/145** |
|  | Title: | Evaluation of a device (GT'Nhaler) to assist in the administration of GTN aerosol spray for patients with angina and impaired manual dexterity. |
|  | Principal Investigator: | Dr Arthur Collins |
|  | Sponsor: | New Zealand Health Innovation Hub |
|  | Clock Start Date: | 08 September 2016 |

Dr Arthur Collins 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 is a simple usability study for a prototype device for patients with heart disease who cannot use current spray devices as they are very small and some participants (especially those with arthritic conditions or other disabilities) have difficulty holding these.
2. The study will involve only 20 participants and the aim is to recruit patients with a range of reasons for having difficulty using the current GTN sprays..
3. The primary purpose of the study is to get feedback from participants about the usability of the study device (into which both brands of GTN spray may be loaded), as a proof of concept/field test type of study.

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 what would happen if an issue with the prototype arose and participants couldn’t administer enough of the spray. The Researcher explained that all participants will carry a standard GTN spray to use without the study device as backup.
2. The Committee questioned the risk of overdosing as the GTN may be easier to dispense. The Researcher acknowledged this is a possibility, but that the risk is not greater than for patients who have no difficulties using the current spray device, as the study spray device does not administer a larger dose, just makes it easier for participants to use the GTN spray. Further, the Researcher explained that all potential risks will carefully be explained to participants to minimise any risk.
3. The Committee questioned risks such as the participant spraying it in their eyes. The Researcher explained that they do not believe that the risk of this is higher than with the standard spray and the study device has locators to help minimise this risk, however, they will also warn participants about this risk.
4. The Committee questioned how participants will be recruited. The Researcher explained that it will be from his general practice and through the Christchurch cardiology rehabilitation unit , possibly through a poster. The Committee agreed that recruitment through advertising would be appropriate (and preferable to direct recruitment by the researchers) and stated that if they pursue this recruitment method that any advertising must be provided for HDEC approval.
5. The Committee questioned whether participants can keep the study device at the end of the study. The Researcher explained that as the study will only use prototypes, these will need to be returned after the study as they cannot be sure of their longevity. The Committee noted their preference that participants should be able to use the device after the study if they felt it was helpful for them. The Researcher agreed that this was their preference also and they would aim to inform participants when the device became available after the study so they could get one to use.
6. The Committee questioned how children would be prevented from using the study device by mistake. The Researcher explained that making the device child-proof would also make it difficult for participants to use. However, the device would include a warning on it that it is not a toy and to keep it away from children, further, during recruitment participants would also be informed of the risk to children and advised to keep it away from children.
7. The Committee questioned whether there are any legal concerns about the development of the device and whether the pharmaceutical companies who manufacture the two GTN sprays available in NZ were aware of development of this device. The Researcher explained that they have spoken with a lawyer to ensure they are not infringing on any patents and are confident they will not encounter any legal issues.
8. The Committee stated that their approval of this study is not an approval of the study device or concept, rather relates only to the ethical approval of the study.

Summary of ethical issues (outstanding)

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

1. The Committee noted that the Participant Information Sheet suggests that participants should inform their GP about their participation in the study, however the Committee feel it would be more appropriate to require participants’ GPs to be informed of their study participation by the researchers, in case of any adverse events arising. Please modify the Participant Information Sheet to reflect this.
2. Please revise the Participant Information Sheet to remove formatting issues such as inappropriate italics and blank pages.
3. Please remove the information from the Participant Information Sheet about what is involved for people not in the study as this is not necessary.
4. Please give more detail about how frequently participants will be contacted by the researchers.
5. Please clarify in the Participant Information Sheet that how long study involvement is for participants will depend on how frequently they use the device, and this will be between 6 and 12 weeks.
6. Please revise the Participant Information Sheet to remove the current bias toward the study device. Currently the Participant Information Sheet states that participants will get a benefit, however, this is not yet known. For example, please revise the PIS to say that participants ‘may or may not’ get a benefit, and that the study device ‘may’ make it easier, not ‘will’ make it easier.
7. Please revise the Consent form to remove unnecessary statements such as those regarding risks to pregnant partners and samples being sent overseas as these do not apply to this study.
8. Please remove the yes/no tick boxes from the Consent Form for statements that are not truly optional, meaning that participants could answer ‘no’ and still be involved in the study.
9. Please remove the box on the consent form aimed at researchers regarding interpreters, this should be replaced with a statement regarding whether interpreters are available for participants.
10. Please add to the Participant Information Sheet that if participants have any issues or concerns about the use of their medication or the study device, they should contact their GP or the study doctor.

Decision

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

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

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| **5** | **Ethics ref:** | **16/STH/147** |
|  | Title: | RAUORA |
|  | Principal Investigator: | Dr Natalie Walker |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 08 September 2016 |

Dr Natalie Walker and Joanne Barnes 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. This is a HRC funded head-to-head non-inferiority study of two smoking cessation medications in Māori participants in the Lakes DHB region.
2. This study proposes to only have Māori participants due to them having the highest rates of smoking and greatest need for smoking cessation treatments.
3. The study investigates a new (cheaper) medication, Cytosine, against the current best medication which is very expensive.
4. The new study medication is not approved or available in New Zealand currently, consequently this study has also been submitted for SCOTT review.
5. The Committee noted that this study has excellent peer review as it will have both HRC and SCOTT review.

Summary of ethical issues (resolved)

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

1. The Committee noted that the question regarding equipoise in the study was incorrectly answered as this question relates to how the study intervention arms compare to each other. The Researcher clarified that it is their view that the study arms are in equipoise.
2. The Committee questioned what would happen if participants took too much of the study drugs. The Researcher explained that taking too much would cause a participant to be sick and throw up the drug. The Researcher explained that the risk of overdose is minimised by the supervision of participants in the study.
3. The Committee raised concerns about the use of telephone consent to the study. The Researcher explained that participants would be recruited through a website that included the Participant Information Sheet and the Consent Form then telephoned to confirm their consent. The Committee questioned the suitability of this, given that participants will need to meet with a study doctor to be prescribed the study medication, however, agreed that it is acceptable as participants will have all forms and information in front of them.

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 raised that it is unusual for participants to be charged for study participation, in this case they need to pay a fee for the study medication. The Committee questioned who this fee goes to, considering that one of the study drugs is not available in New Zealand. The Researchers clarified that participants will obtain the study drugs from the pharmacy as they would in a real world situation, necessitating a $5 dispensing fee. The Researchers also clarified that they would provide the study drug to the pharmacy to allow them to dispense it. This is done to test the practicality of both study treatments in a real world situation for participants.
2. The Committee questioned that if the study drugs are provided in 3 lots whether participants will need to pay the $5 fee 3 times, a total of $15 rather than the $5 stated in the Participant Information Sheet. Please clarify this for the Committee. Further, please clarify whether participants with Prescription Subsidy Card will be able to have the $5 fee waved, as they would for regular prescriptions from their GP, if they have reached the 20 prescription threshold.
3. The Committee raised concerns about the exclusion of non-Māori participants in the study, they requested further information on the reasons for this from the researchers. The Researcher explained that Māori have higher rates of smoking and a greater need than other groups. The Committee agreed that Māori may have a greater need, however they are uncertain if this ethically justifies the exclusion of other groups such as Pacific Islanders, Asian, or Pakeha participants who may also have a need for smoking cessation treatments. Further, the Committee raised a concern that the exclusion of non-Māori participants may prevent the study from achieving one of its goals, to compare the effectiveness of the study treatments for Māori patients (as opposed to those from other ethnicities) as the study results would not allow the researchers to compare results between ethnicity groups in New Zealand. The Committee requested either further information and justification for the exclusion of non-Māori participants, or that the study protocol is changed to remove the inclusion criteria of participants being Māori. The Committee stated that the study could remain targeted at Māori participants and they did not need to actively recruit non-Māori participants but it was the Committee’s view that non-Māori participant should not be excluded from the study if they wished to participate.
4. The Committee raised concerns about the legality of the prescription of a non-approved medicine to patients who aren’t in the care of the prescribing doctor. The Researcher explained that they have not discussed this with the medical council in this instance, however for previous similar studies they have. The Committee requested further information to assure them of the legality of this prescription.
5. The Committee noted that the professional indemnity provided with the application has expired. Please provide a current indemnity information.

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

1. Please ensure the information on the prescription fees is clear and accurate in the Participant Information Sheet.
2. The Committee questioned the information in the Participant Information Sheet regarding the testing of participants’ breath as although it states that this is done to check the carbon-monoxide levels in participants’ breath it is not clear that this is done to check that participants are telling the truth about their rates of smoking. The Researcher stated that this wasn’t an intentional deception and they will revise this section to ensure it is clear why participants’ breath will be tested.
3. The Committee questioned the inclusion of a separate Participant Information Sheet for clinical studies with this application, they stated that this is not appropriate to them and that all information participants need to know about their participation in a study must be included in the main Participant Information Sheet. Please combine these forms to ensure all relevant information is in the main Participant Information Sheet.
4. The Committee raised that they felt that the risk section of the Participant Information Sheet was difficult to find and needed to be revised for increased clarity regarding the risks associated with study participation, such as the potential or known risks/side effects of each study medication. Please bullet point all potential side effects and provide expected frequencies.
5. Please provide very clear and detailed information about the potential psychiatric side effects of the study medications, including who to contact if participants experience these and are concerned.
6. Please ensure it is very clear in the Participant Information Sheet that one of the study drugs is not approved or registered in New Zealand.
7. Please review the inclusion criteria (as discussed above) in relation to Maori only

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Studies para 6.22).
* Please respond to the Committee’s outstanding ethical concerns detailed above.
* Please provide evidence of this study being approved by SCOTT.

This following information will be reviewed, and a final decision made on the application, by the Full Southern HDEC at an Online Meeting.

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| **6** | **Ethics ref:** | **16/STH/148** |
|  | Title: | Diagnostic delay in AYA sarcoma patients – does it exist and what are contributing factors? |
|  | Principal Investigator: | Dr Tristan Pettit |
|  | Sponsor: |  |
|  | Clock Start Date: | 08 September 2016 |

Dr Trystan Pettit 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 diagnostic delay in AYA sarcoma patients in New Zealand.

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 data from participants’ GPs’ is required for the study. The Researcher said they could do the study without this data. The Committee stated it was their preference that this data was not collected due to the risks associated with contacting GPs directly. The Researcher agreed to exclude this information.

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 explained two concerns about the consent arrangements for this study.
2. First, the Committee is concerned that the exclusion of deceased participants, when a primary outcome for the study is mortality, may compromise the integrity of the study results. The Committee understands that the reasons for exclusion of this group is due to the inability to obtain consent from the participant as they are deceased, and the distress obtaining consent from grieving next-of-kin would be likely to cause. The Committee appreciates the intention behind exclusion of data from participants unable to consent, however, they feel that the exclusion of this group would seriously compromise the scientific validity of the study.
3. Second, the Committee is concerned about the potential for undue anxiety to be caused to living participants if they are contacted to obtain consent for the use of their data in this retrospective study. The Committee stated that if these patients are contacted about a study seeking to investigate if a delay in their diagnosis may contribute to increased risk of mortality, this is likely to cause them and their family significant distress about their future and cause them to question the decisions they (and their doctors) have previously made. The Committee believed that this would be an unacceptable harm to these participants.
4. Because of these significant concerns the Committee were not comfortable to approve this study as currently presented.
5. The Researcher stated that they had not considered conducting the study without consent but could understand the Committee’s views, and agreed that the inclusion of data from deceased patients would be ideal.
6. The Committee explained that studies using routinely collected information could sometimes be conducted without consent if sufficient justification was provided regarding the reasons for not obtaining consent and the expected benefits of the study. The Committee noted that in some cases, an argument may be able to be made for the use of data without consent for the reasons of scientific bias and undue anxiety to participants. However, it is the responsibility of the researchers to make these arguments.
7. The Committee requested that the researchers respond in writing with information regarding potential justifications for not obtaining consent, with specific reference to the Health Information privacy Code 1994.
8. The Committee also noted that as the researchers have agreed to not source information from participant’s GP’s that if they do not need to match information from multiple sources they may be able to obtain de-identified information which would be preferable. Please clarify if it is possible for the researchers to only have access to de-identified data for this study, or if the data needs to retain some identifiers.

Decision

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

* Please respond to the Committee’s outstanding ethical concerns detailed above regarding the scientific validity of the proposed study and the requirement to obtain informed consent. If this response incudes justifications please explain these clearly in a cover letter, and modify the study protocol to reflect any proposed changes to the study design.
* Scientific inadequacies in a study proposal have ethical implications. The scientific quality of a proposal should be such that the proposal’s objectives can reasonably be expected to be achieved. (Ethical Guidelines for Observational Studies para. 5.7)
* Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:
  + 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
  + there would be no disadvantage to the participants or their relatives or to any collectivities involved; and
  + the public interest in the study outweighs the public interest in privacy. (Ethical Guidelines for Observational Studies para. 6.43)
* An investigator who proposes not to seek informed consent for use of identified or potentially identifiable data for research must explain to an ethics committee the reasons for not seeking consent, and how the study would be ethical in the absence of consent. (Ethical Guidelines for Observational Studies para. 6.45)
* The investigator must show how safeguards will be maintained to protect confidentiality, and that the study has the goal of protecting or advancing health. (Ethical Guidelines for Observational Studies para. 6.46)

This following information will be reviewed, and a final decision made on the application, by the Full Southern HDEC at an Online Meeting.

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| **7** | **Ethics ref:** | **16/STH/150** |
|  | Title: | 20120124: HAUSER-OLE |
|  | Principal Investigator: | Prof Russell Scott |
|  | Sponsor: | Amgen Australia |
|  | Clock Start Date: | 08 September 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 ethical issues (outstanding)

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

1. The Committee requested that the Participant Information Sheet for parents is revised to reduce repetition and make it clearer. The Committee stated that the Participant Information Sheet for 16 and 17 year old participants is much easier to understand.
2. The Committee noted that some participants will be aged 16 years or older and therefore must provide their own informed consent, while other participants may be aged under 16 and still able to provide their own informed consent. The Committee requested that the titles of the adult participant forms (currently the forms for 16/17 year olds) are revised to reflect that these forms are for all participants able to provide their own informed consent, including all participants aged 16 years or older.
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.”*

Decision

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

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

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| **8** | **Ethics ref:** | **16/STH/152** |
|  | Title: | The DELITEFUL Study: Determining the Effect of Long-acting Insulin Treatment on Endogenous Insulin Functionality in insUlin-resistant individuaLs. |
|  | Principal Investigator: | Professor Geoffrey Shaw |
|  | Sponsor: |  |
|  | Clock Start Date: | 08 September 2016 |

Proff Geoff Chase & Mr Kent Stewart 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 ethical issues (resolved)

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

1. The Committee questioned whether 10 participants is sufficient to answer the study question. The Committee stated that this may be sufficient if this is a feasibility or hypothesis generating study, however if this is not the case further statistical peer review would be required to assure the Committee of the validity of the study design. The Researchers confirmed that this is a hypothesis generating, proof of concept, feasibility study.

Summary of ethical issues (outstanding)

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

1. Please remove the analogy from the Participant Information Sheet as this confuses the form and is unnecessary. Enrolling clinicians can use the analogy verbally to explain the study if necessary.
2. Please revise the study title. The Committee feels that having a short study title that is longer than the long study title is inappropriate, and the use of the word ‘delightful’ to describe the study (although incorrectly spelt) is unacceptable and biases the participant toward the study while minimising the risks of participation. The lay study title should reflect clearly the primary purpose of the study, for example: ‘Study of the Effect of Long-acting Insulin during Surgery’.
3. The first sentence of the Participant Information Sheet currently states ‘subcutaneous’ rather than ‘under the skin’ which is a more lay term, please revise this.
4. Please revise the consent form to remove the yes/no tick boxes for statements that aren’t truly optional, meaning that a participant could select ‘no’ and still participate in the study.
5. Please remove the box at the top of the consent form directed at researchers about interpreters and replace with a statement regarding whether interpreters are available for participants.
6. Please ensure the study title reflects that this is a pilot or feasibility study.

Decision

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

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

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| **9** | **Ethics ref:** | **16/STH/153** |
|  | Title: | The STATUS Trial |
|  | Principal Investigator: | Professor Chris Bullen |
|  | Sponsor: |  |
|  | Clock Start Date: | 08 September 2016 |

Professor Chris Bullen and two co-investigators 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. This is a RCT which aims to recruit 798 NZ patients who want to stop smoking and treat them with the smoking cessation medicine varenicline. After two weeks treatment, participants will be allocated to different treatment groups depending on their initial response to varenicline. In some of these treatment groups participants will receive varenicline in addition to other smoking cessation medicines (bupropion or E-cigarettes containing nicotine).

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 participants for this study will be recruited from CADS and mental health services and that this makes them a potentially vulnerable population. The Researchers agreed and stated that these participants have specific difficulties quitting smoking, which is why this study is targeted at them.
2. The Committee questioned whether all participants will be able to provide informed consent. The Researcher confirmed that all participants would be able to provide informed consent.
3. The Committee noted that e-cigarettes with nicotine are not approved in New Zealand, but also noted that this study is being submitted to SCOTT.
4. The Committee questioned whether the study doctors would be prescribing the study treatment to patients or dispensing it directly. The Researches explained that they had thought they would dispense it directly. The Committee stated this was their preference and the normal situation for a clinical trial.

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 the data safety monitoring arrangements for this study. The Researchers explained that they have requested a HRC data safety monitoring committee. The Committee noted this is acceptable and requested further information is provided about this.
2. The Committee raised concerns about the safety of the study drugs in this combination, in particular psychiatric adverse effects in a population already known to have mental health problems. The Researcher explained that there has recently been more literature about this. The Committee requested that some more information is provided for the Committee about the expected risks and how they will be mitigated.

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

1. The Committee raised concerns about the psychiatric side effects of the study drugs, especially varenicline and bupropion combined as they are in this study and in this population group. The Committee requested more information on these risks in the Participant Information Sheet, including what participants should do if they experience these and are concerned.
2. Please add more information on possible risks and side effects from the study drugs to the Participant Information Sheet, these should be in bullet point format and with expected rates specified.
3. The Committee questioned the inclusion of a separate Participant Information Sheet for clinical studies, they stated that this is not appropriate to them and that all information participants need to know about their participation in a study must be included in the main Participant Information Sheet. Please combine these forms to ensure all relevant information is in the main Participant Information Sheet.
4. The Committee questioned the information in the Participant Information Sheet regarding the testing of participants’ breath, as although it states that this is done to check the carbon-monoxide levels in participants’ breath, it is not clear that this is done to check that participants are telling the truth about their rates of smoking. The Researcher stated that this wasn’t an intentional deception and they will revise this section to ensure it is clear why participants’ breath will be tested.
5. Please revise the lay study title in the Participant Information Sheet to reflect the purpose of the study.
6. Please remove the yes/no tick boxes from the Consent Form for all statements that are not truly optional, meaning that participants could select ‘no’ and still be involved in the study.

Decision

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

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

## 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:** | 18 October 2016, 12:00 PM |
| **Meeting venue:** | Sudima Hotel - Christchurch Airport, 550 Memorial Drive, Christchurch |

The following members tendered apologies for this meeting.

* 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 4:10pm