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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 17 May 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 19 April 2016 |
| 12:30pm | New applications (see over for details) |
|  | i 16/STH/53  ii 16/STH/54  iii 16/STH/59  iv 16/STH/64  v 16/STH/62  vi 16/STH/63 |
| 2:50pm | General business:   * Noting section of agenda |
| 3:00pm | 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 | Apologies |
| 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 Dr Sarah Gunningham.

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 19 April 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/STH/53** |
|  | Title: | The nature of microbial involvement in the development of adenotonsillar hyperplasia. |
|  | Principal Investigator: | Dr James Johnston |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 05 May 2016 |

Dr James Johnston 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 thanked the Secretariat and the Researcher for their work prior to the meeting following up on Māori consultation as this provided further required information prior to the meeting.
2. This study involves collecting, with consent, adenoids and tonsils that are being removed as part of standard care from paediatric patients at Starship and testing these to investigate the microbiomes that are causing disease processes.
3. Matched control participants will also be recruited that do not have any problems with their tonsils or adenoids to compare the microbiomes present between these groups. Control participants will have their adenoids and tonsils swabbed while under anaesthetic for another procedure.
4. The research will also involve comparing the microbiomes present for participants requiring the removal of their adenoids and tonsils, compared to those only having their adenoids removed.
5. It is hoped that this research will provide more information on why some children require their adenoids and/or tonsils to be removed and give more information about what is going on in terms of microbiomes present in this area for this group.
6. The committee appreciated that the independent peer review and noted that it was good that the researchers had adjusted their protocol in response to this peer 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 questioned the eligibility criteria for control participants as although the protocol included eligibility criteria for case participants it was not included for control participants. The Committee also questioned whether the control participants would be matched in any way to case participants. The Researcher explained that control participants would be matched to case participants but this was not formalised in the protocol.
2. The Committee questioned how controls and cases would be matched. The Researcher stated that they intend to match controls with cases by age, ethnicity, and gender. The Committee stated that it is important that the inclusion criteria and matching information is detailed in the study protocol. As the control group would not be recruited until the bulk of the case group had been enrolled into the study, it was suggested that and amended protocol could be submitted before recruitment of control participants commenced; this amendment would include details about the matching and inclusion criteria for control participants in the protocol.
3. The Committee noted that the study protocol states that in all cases the participant’s adenoids and tonsils will be removed, however, some case participants will only be having their adenoids removed as part of standard care. The Researcher confirmed that some participants will only have their adenoids removed and stated that they have more data about the microbiomes found on tonsils for this group from a related study, the information from this related study means that not being able to collect tonsils from all participants is not expected to negatively impact their results to a significant degree.
4. The Committee noted that the question in the application form regarding new information being found that could influence participant’s willingness to be in the study, such as new safety information, seemed to be answered incorrectly. The Researcher stated that in the case of any such information being discovered that participants, or their parents in the case that the informed consent was provided by the participant’s parents, would be informed as soon as possible.
5. The Committee questioned who would initially approach potential participants about the study. The Researcher stated that the treating clinician would be informed about the study and would ask participants, or their parents, if they would like to find out more about this study. Interested participants would then be contacted by the researcher to complete the informed consent process. The committee noted that this is a suitable consent process and it is appropriate for participants to initially hear about the study from someone involved in their care.
6. The Committee noted the importance of Māori consultation for this study as it involves the head and neck as well as collection of tissue. They stated that this had been covered well by the Secretariat in emails with the Researcher prior to the meeting.
7. The Committee noted that some older participants are likely to be competent to provide their own informed consent. The Committee stated that this is a judgement call that must be made by the person collecting consent, if an older participant (for example a 15 year old) was deemed competent to provide informed consent they must provide their own informed consent. The Committee also noted that all participants aged 16 years or older must provide their own informed consent. The Researcher confirmed that they were comfortable to do this for the study.
8. The Committee questioned who would be taking the swabs of control participant’s throats. The Researcher stated that he hoped to take these swabs himself as he hoped to be present for all surgeries of participants in this study.

Summary of ethical issues (outstanding)

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

1. Please remove the reference to age of consent in the Participant Information Sheet, there is no legal age of consent for research in New Zealand and all competent participants, including every participant aged 16 years or older, must provide their own informed consent. Participants deemed not competent to provide informed consent, aged under 16 years, should provide assent and consent will be provided by their parent or legal guardian.
2. Please alter the statement in the Participant Information Sheet that says that a swab will be taken to reflect that each participant will have 6 swabs taken.
3. The Participant Information Sheet for 7-12 year olds includes information about standard care that is not study specific. However, the Participant Information Sheet should only include information on study specific procedures and does not need details such as that the participant’s adenoids and tonsils will be removed through their mouth. Please remove information from the Participant Information Sheet regarding procedures that will occur as part of standard care.
4. Please ensure that the Participant Information Sheet states that the study was approved by the Southern HDEC, rather than Northern A.
5. The control Participant Information Sheet states that the swabs will be taken while the participant is under general anaesthetic, however, this is not clear in the case Participant Information Sheet. Please adjust this to clarify that swabs for all participants will be taken under general anaesthetic.
6. Please rephrase the parent/caregiver Participant Information Sheet and Consent Form to be clear that this is being signed by the participant’s parent or legal guardian, as not all caregivers can provide legal consent on behalf of child participants.
7. Please provide a suitable Participant Information Sheet for participants deemed competent to provide their own informed consent, including all participants aged 16 and over.

Decision

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

* You must submit an amendment before starting to recruit control participants. This amendment needs to include an updated protocol detailing the inclusion criteria (specifically matching criteria) for controls.
* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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| **2** | **Ethics ref:** | **16/STH/54** |
|  | Title: | Cancer management in the context of severe mental illness |
|  | Principal Investigator: | Dr Ruth Cunningham |
|  | Sponsor: |  |
|  | Clock Start Date: | 02 May 2016 |

Dr Ruth Cunningham 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. There is evidence to suggest that there is a large survival difference between cancer patients with and without severe mental illness.
2. This study is a retrospective review of identifiable health information to investigate why people with severe mental illness have worse outcomes from cancer. This study will investigate whether there are differences in cancer treatment for people with and without severe mental illness by data matching mental health records with cancer registry data.
3. Cancer treatment is generally quite guideline based and if a difference in treatment is found for patients with severe mental illness this may offer some insight into their lower survival rates.
4. Possible reasons for the different outcomes reported for patients with severe mental illness may be attributed to their cancer being identified later and, therefore, being more advanced by the time treatment is accessed. However, it seems that even when this is taken into account patients with severe mental illness have worse outcomes, suggesting that another factor is contributing.
5. As well as accessing routinely collected health information the researchers intend to speak with clinicians to gain further insight into treatment and the potential differences between these groups.
6. This application is for a pilot study involving the health information of 80 breast and colorectal cancer patients in the Wellington region, 40 with severe mental illness and 40 without. This pilot study will inform a larger study and the results of this study will be communicated to clinicians with the hope that they may help reduce the outcome disparity for patients with severe mental illness.

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, as presented in this application, involves accessing health information from patients, and speaking to their clinicians, without consent.
2. The Committee noted that participants have a right to know that their health information is being used in research. Right 6(1)(d) of the HDC Code of Rights states:
   1. *Every consumer has the right to information that a reasonable consumer, in that consumer’s circumstances, would expect to receive, including … notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval.*
3. The Committee noted that they can approve access to identifiable health information without consent for research in certain circumstances. The Ethical Guidelines for Observational Studies states at Paragraph 6.43:
   1. *Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:*
      1. *the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and*
      2. *there would be no disadvantage to the participants or their relatives or to any collectives involved; and*
      3. *the public interest in the study outweighs the public interest in privacy.*
4. To approve a study involving access to health information without consent the Committee must be satisfied that these requirements are met by the study concerned.
5. The reasons given for conducting this study without consent are that it would be impractical to obtain consent from 80 participants in the pilot stage of this study, and several hundred in the full study, that requiring consent may introduce significant bias to the study results if not all results are included, and that for participants that may have died obtaining consent from their next of kin may be distressing.
6. The Committee asked the Researcher whether there was any way to conduct this study if informed consent was required. The Researcher explained that they expect it would be difficult to obtain consent and they are concerned about causing distress to participants and/or their families. The Researchers stated their concern regarding the potential bias that a requirement for consent may introduce to the study results. The Researcher stated that they are not sure that the study would be feasible if they are required to obtain informed consent.
7. The Committee noted that although the full study may have several hundred participants, this application is only for the pilot study which only includes 80 participants. The Committee stated that they felt that it would not be impractical to obtain consent for 80 participants in the pilot study.
8. The Committee questioned whether many of the participants would have died given their ages and the nature of their cancer. The Researcher confirmed that most of the participants would probably still be alive, however, some participants would have died and if they were required to obtain informed consent they would need to approach at least some next of kin for consent and this may be distressing.
9. The Committee questioned whether the results of this study would be published, and if so whether the researchers believe that this may allow participants to be identified. The Researcher explained that they had no intention to publish the results of the pilot study, and any publication would not include identifiable information or specifics about individual patients, rather it would include general information and statistics.
10. The Committee stated that the pilot study involves 40 participants with breast and colorectal cancer and severe mental illness in the Wellington region and this specific inclusion criteria may allow participants to be identified, at least by their friends and family if the study results are picked up by the media. The Committee stated that this may be more distressing for participants and their family, to find that their health information had been used without consent, than to approach participants or their family for consent to use their medical records.
11. The Researcher stated that they felt that a requirement to obtain informed consent would introduce significant bias to the study results, especially considering the study population group as they expect it would be more difficult to obtain informed consent from individuals with severe mental illness. The Committee noted this concern and stated that although the potential for bias in the study results is an important factor, it is the committee’s responsibility to protect participants from harm, including the loss of privacy, especially for this vulnerable group.
12. The Committee noted that although they can approve studies involving accessing health information without consent that to do so they must be convinced that the benefits from the research outweigh the harm from the loss of privacy and that there is sufficient reason to warrant not obtaining consent. The Committee stated that in this case the study involves accessing and data matching sensitive information from a vulnerable group of patients and that the study involves an in depth look at these records.
13. The Committee stated that while they appreciated the researcher’s reasons for not wanting to obtain consent, that they did not feel these sufficiently justified the loss of privacy from this study. The Committee felt that it was not impractical to obtain consent from the 80 participants required for this pilot study, that approaching these participants (or their families in the case of deceased participants) would not cause unnecessary distress, and that the potential bias from requiring consent could be accounted for in the study results.
14. The Committee further noted that if significant difficulty or bias from the requirement to obtain consent was found in attempting to obtain consent for this study that this may be able to be used as further justification of not obtaining consent for the full study in a later application. The Committee noted that a further application may be able to include information regarding any difficulties encountered in obtaining informed consent and the bias that this introduced to the study results as further evidence of the need to include all participants and conduct the full study without consent.
15. The Researcher stated that they are concerned with the ethics of accessing patients’ health information to identify suitable potential participants and then sending them letters, or otherwise contacting them, asking for permission to use this health information for research. The Committee stated that only limited information would need to be accessed for the purposes of contacting potential participants and that for the pilot study the researcher needs to have in depth access to sensitive health information and that they must obtain consent to do so as the Committee are not satisfied that the potential benefits from the study are sufficient to outweigh the loss of privacy and, therefore, they are unable to approve the study to go ahead without informed consent from participants.
16. The Committee suggested that if the Researcher believed that obtaining consent for the pilot study would be too onerous that another option would be to reduce participant numbers, as 80 is a large sample size for a pilot study.
17. The Committee noted that the evidence of scientific review provided is not independent from the study co-ordinator as it was completed by their previous PHD supervisor. The Committee stated that it would be beneficial to obtain further, independent, peer review to assure them of the scientific validity of this study.
18. The Committee noted that it was not initially clear that this application is for a pilot study and requested that the study is renamed to reflect the pilot nature of the study.
19. The Committee requested further information on how detailed and in depth information would be accessed for the study, not just how detailed the information recorded would be. This is unclear from the application form and supporting documents as at times it states that only limited specific information will be used and other places indicates that the study involves an in depth review of each participants medical records.

Decision

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

* You must obtain consent from participants in this study as the Committee is not satisfied that the justifications for conducting this study without informed consent are met by this study as currently presented. Please provide suitable Participant Information Sheets and Consent Forms and amend the protocol to detail the informed consent procedures for this study.
* Please obtain further evidence of independent scientific peer review for this study.
* Please rename the study to reflect the pilot nature of this study.
* Please clarify what information will be accessed from participant’s medical records and talking to their clinicians.

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

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| **3** | **Ethics ref:** | **16/STH/59** |
|  | Title: | Very Early Rehabilitation in SpEech (VERSE) |
|  | Principal Investigator: | Dr Meghann Grawburg |
|  | Sponsor: | Edith Cowan University |
|  | Clock Start Date: | 05 May 2016 |

Dr Meghann Grawburg 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 intervention study involves an early intervention post stroke for patients with communication difficulties.
2. This study is a Phase III study designed to demonstrate that a standardised and prescribed aphasia therapy regimen is more effective and cost saving than non-standardised usual care speech therapy in the very early post-stroke
3. Often patients with communication difficulties are not included in research due to the difficulties obtaining informed consent.
4. Participants will be recruited within 14 days post-stroke.

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 who recruits participants for this study. The Researcher explained that clinicians, including speech therapists, will be informed of the study and able to inform their patients about the study and refer those that may be interested to the research team.
2. The Committee questioned who would determine whether participants are competent to provide informed consent. The Researcher explained that this decision would be made by the participant’s clinical team who are familiar with the participant, and their competencies.
3. The Committee questioned how unexpected findings would be handled. The Researcher explained that the most likely unexpected finding would be depression and that this would be handled within the care team through the normal referral routes.
4. The Committee noted that the application form stated that stroke is non-discriminatory and affects all ethnicities. However, Māori are disproportionately affected by stroke and have worse outcomes than non-Māori. The Committee requested that further information of this kind is included in any future applications.

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 percentage of participants the Researcher expect to be able to understand the simple aphasia information sheet and therefore be unable to provide informed consent. The Researcher estimated that it would be about 50% of participants. The Committee noted that as approximately 50% of participants will be unable to provide informed consent that this study will need to be considered as a non-consensual study for these participants and in order to approve this the committee must be convinced that it meets the relevant legal requirements.
2. The Committee noted that the non-consensual nature of this study had been partially discussed by email prior to the meeting. The Committee went on to consider this aspect of the study, including the inclusion of a ‘Persons Responsible’ information sheet and consent form, keeping in mind the information discussed with the Researcher prior to the meeting by email with the Secretariat.
3. Because it is not possible to have someone provide consent for research on behalf of another adult in New Zealand, this study is considered as a non-consensual intervention study (in the case of participants unable to provide their own informed consent). 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 (as mentioned above), 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.
4. The Committee noted that this means that to approve this study to include non-consenting participants the Committee must be convinced that participation is in the best interest of each individual participant.
5. The Committee asked the Researcher if it was their clinical judgement that participation in this study would be in the best interest of each participant. The Researcher stated that they feel that based on the evidence from previous studies that participation in this study is in the best interest of patients.
6. The Committee noted that it appeared from the application form and discussion with the researcher that this study would meet the Right 7(4) best interest test. However, the email dated 05 May 2016 from Fiona Ellery, the project manager for this study, suggests that there may not be enough information to make a clinical decision that participation is in the best interest of each participant. Consequently, the Committee requires further information regarding whether this study meets the best interest test. Please provide further information regarding this.
7. In New Zealand, proxy consent for research is only legally acceptable in cases where the medical experiment would save the person’s life or prevent serious damage to the person’s health. Therefore, the form currently for the ‘Persons Responsible’ should only be used to gauge views of relatives/ friends/ EPOA of potential participants involved that are unable to consent for themselves. This means that the forms should not involve language whereby the relative/friend/EPOA consent on behalf of someone else. As an alternative, the language should reflect that the document seeks the friend/relative/EPOA’s view that the non-consenting person would be agreeable in participating. This is in line with Right 7(4)cii of the HDC Code of Rights: If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.
8. The Committee questioned whether this study had independent data safety monitoring, as indicated in the application form. The Researcher stated that they were unsure but would follow up. The Committee noted that they expect that this study does not have independent data safety monitoring but asked the researcher to please confirm the data safety monitoring arrangements.

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

1. Please revise the form for the participant's family/representative to reflect that it is being used to gauge their views on whether the participant would want to participate if they were able to provide informed consent (rather than this person providing legal consent).
2. The Committee noted that the Participant Information Sheet contains a lot of repetition of the word ‘participant’ and suggests that this is revised to improve readability.
3. The Committee noted that the main Participant Information Sheet is very complicated and difficult to understand and that all of the required information to understand participation is contained in the aphasia friendly Participant Information Sheet. The Committee suggested either dramatically simplifying the main Participant Information Sheet or changing the main Participant Information Sheet to the aphasia friendly Participant Information Sheet as all participants will have aphasia.

Decision

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

* Please provide more information on whether participation in this study meets the best interest requirements of Right 7(4) of the HDC Code of Rights, specifically in relation to the email dated 05 May 2016 from Fiona Ellery, regarding whether participation is in the best interest of each participant.
* Please provide more information regarding how non-consenting participants will be recruited under Right 7(4) of the HDC Code of Rights. This should include who made the clinical decision that study participation is in the best interest of the individual participant, and what steps were taken to obtain the views of suitable persons, such as the participant’s family or friend.
* Please confirm the data safety monitoring arrangements for this study.
* Please rephrase the family and friend information sheet to ensure it is consistent with Right 7(4) and is used to obtain the views of suitable persons regarding whether the participant would want to participate in the study, if they were able to provide informed consent, rather than this person providing consent on the participant’s behalf.

This following information will be reviewed, and a final decision made on the application, by Dr Mathew Zacharias and Mrs Angelika Frank-Alexander.

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| **4** | **Ethics ref:** | **16/STH/64** |
|  | Title: | MNK14224049: Study of H.P. Acthar® Gel for the Treatment of Protein in the Urine Due to Resistant or Treatment Intolerant Idiopathic Focal Segmental Glomerulosclerosis (FSGS) |
|  | Principal Investigator: | Dr KANNAIYAN RABINDRANATH |
|  | Sponsor: | Mallinckrodt Pharmaceuticals |
|  | Clock Start Date: | 05 May 2016 |

Ms Deborah Peek 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 the use of H.P. Acthar Gel for the treatment of protein in the urine due to resistant or treatment intolerant idiopathic focal segmental glomerulosclerosis (FSGS).
2. All participants will have received standard care and will only be offered enrolment in the study if standard care fails.
3. The study application form indicated that incidence of this condition is increasing worldwide but the reasons for this are unknown. There are also reportedly higher rates in Māori and Pacifica.
4. The study drug has been available and licenced for various uses in the United States for over 50 years. However, in New Zealand and other countries this is an experimental medicine.
5. The study drug has already been trialled in 25 patients with this condition and steroidal type side effects were noted.
6. The Committee noted that the disease is well explained in the 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 questioned whether participants not being able to get some kinds of vaccinations would cause a problem. The Researcher stated that they do not believe this is a significant problem.

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 the study drug will continue being available to participants following the end of the study. The researcher explained that the study drug is not approved in New Zealand and not funded by PHARMAC so participants will be unable to access the study drug outside the study. The Committee noted their preference that participants are allowed continued access to the study drug if they are experiencing a benefit from it. The Committee asked the researcher to confirm with the study sponsor whether the study drug could continue to be available to participants who experience a benefit.
2. The Committee noted that a comment was included in one of the consent forms regarding what the sponsor is doing with samples collected as part of this study. Please confirm what the sponsor is doing with the samples.
3. Please provide the name of the CRO contact.
4. Please provide more information on the data safety monitoring arrangements for this study.

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

1. The Committee noted that the Participant Information Sheet is quite long and that it is not initially clear that participants will need to self-inject the study drug. Please revise the Participant Information Sheet to ensure that self-injection is one of the first pieces of information.
2. Please add a lay study title to the Participant Information Sheet, this should be above the current study title and in a larger font. The Committee suggested that this lay title could include “self-injected”.
3. Although the expected side effects are well explained in the Participant Information Sheet please add the expected frequencies of these. The Committee expects more information regarding side effects to be available as the study drug has been used for a long time.
4. Please adjust the emergency number in the Participant Information Sheet to a New Zealand contact number.
5. The Committee noted that the Participant Information Sheet has a section on genetic testing, however, genetic testing will only occur as part of the optional future unspecified use of tissue aspect of the study. Please ensure this information is only included in the future unspecified use of tissue participant information sheet and consent form, as it is not relevant to the main consent form or information sheet.
6. The Participant Information Sheet states that the study drug is very safe, however limited information is available on this indication for the study drug. Please rephrase this wording to ensure it is clear that although the drug is safe for other uses it has not been widely tested for this use.

Decision

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

* Please respond to the outstanding ethical concerns detailed above.
* 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 Assc Prof Mira Harrison-Woolrych and Ms Raewyn Idoine.

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| **5** | **Ethics ref:** | **16/STH/62** |
|  | Title: | CLDK378A2X01B |
|  | Principal Investigator: | Professor Mark McKeage |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 05 May 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 application is for an extension/rollover study.
2. 8 people in New Zealand are already using this study drug and this extension study will allow them continued access based on clinical judgement that it is successful and providing a benefit.
3. This study drug has been licensed for use in the United Kingdom.

Summary of ethical issues (resolved)

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

1. Participants in this study are potentially vulnerable as they have limited chance of survival, however, the committee has no ethical concerns regarding participants with no other options being allowed continued access to a drug that is providing a benefit.

Summary of ethical issues (outstanding)

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

1. Please consider removing the interpreter box from the consent form.
2. Please provide further information about the expected side effects of the study drug, such as frequencies, that should be available following the earlier successful study.

Decision

This application was *approved* by consensus, subject to the following non-standard condition:

* 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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| **6** | **Ethics ref:** | **16/STH/63** |
|  | Title: | A study comparing how fast the trial drug RVX000222 is cleared from the body, in healthy adults and in adults with severely reduced kidney function. |
|  | Principal Investigator: | Dr Richard Robson |
|  | Sponsor: | Resverlogix Corp. |
|  | Clock Start Date: | 05 May 2016 |

Dr Devonie Eglinton 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 Devonie Eglinton declared a potential conflict of interest, and the Committee decided that she would not participate in the decision making for this application but would remain in the room as a member of the research team.

Summary of ethical issues (resolved)

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

1. The Committee questioned the data safety monitoring arrangements for this study. The Researcher explained that as this is a single site study that the study doctors would be well placed to notice any safety concerns and they felt satisfied that the research team was well equipped to monitor the participants for any safety concerns. The Committee noted that this is effectively an informal internal data safety monitoring arrangement, suitable for a single centre trial.

Summary of ethical issues (outstanding)

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

1. Please rephrase the contraception section, this section currently states that participants must use ‘acceptable’ contraception. However, it is unclear what this means, please revise to state that participants must use contraception that is acceptable to the study as this has a different meaning.
2. Please include female sterilisation in the listed acceptable contraception methods.

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).

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 21 June 2016, 12:00 PM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

The following members tendered apologies for this meeting.

* Dr Mathew Zacharias

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 3:00pm