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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 10 April 2018 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 11:30am | Welcome |
| 11:35am | Confirmation of minutes of meeting of 13 March 2018 |
| 11:40 – 11:45 | General business:  Noting section  Review of approved studies |
| 11:45am | New applications (see over for details) |
|  | i 18/STH/71  ii 18/STH/72  iii 18/STH/73  iv 18/STH/74  v 18/STH/84  vi 18/STH/82  vii 18/STH/80  viii 18/STH/83  ix 18/STH/79  x 18/STH/81  xi 18/STH/76 |
| 4:20pm | Substantial amendments (see over for details) |
|  | i 17/STH/111/AM01 |
| 4:45pm | 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 |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Nicola Swain | Non-lay (observational studies) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Devonie Waaka | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 | Apologies |
| Ms Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | 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 | Apologies |
| Dr Anna Paris | Lay (other) | 24/08/2017 | 24/08/2020 | Present |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that apologies had been received from Dr Nicola Swain, Dr Devonie Waaka, and Dr Fiona McCrimmon.

The Chair noted that fewer than five appointed members of the Committee were present, and that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Dr Jane Wylie and Ms Sandy Gill confirmed their eligibility, and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 13 March 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/STH/71** |
|  | Title: | Effect of Warm Humidified Insufflation on Lens Fogging |
|  | Principal Investigator: | Professor John A. Windsor |
|  | Sponsor: | Fisher & Paykel Healthcare |
|  | Clock Start Date: | 29 March 2018 |

Professor John A. Windsor was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates whether a new surgical humidifier can reduce lens fogging by warming and humidifying the carbon dioxide gas used during laparoscopic cholecystectomies.
2. Videos of the surgery will be recorded and clinicians will review the footage to determine whether the humidifier makes a significant difference in clarity.

Summary of ethical issues (outstanding)

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

1. The Committee stated that the participant information sheet was very long and should be shortened whilst checking for technical jargon.

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

1. Please condense information in the sheet and replace technical terminology with lay friendly terms.
2. Please explain the purpose of the trial in more lay-friendly terms.
3. Remove yes and no tickboxes from the consent form except for where ticking no would allow someone to continue to participate.
4. Update the approving HDEC details to be correct.
5. Please update the interpreter statement so that only those languages for which you can provide an interpreter for are listed.

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 provide the updated insurance documentation. (*Ethical Guidelines for Intervention Studies* *para 8.4*).

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

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| **2** | **Ethics ref:** | **18/STH/72** |
|  | Title: | PATHMED Tissue Bank |
|  | Principal Investigator: | Professor Lisa Stamp |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 March 2018 |

Professor Lisa Stamp was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This application seeks permission to establish a tissue bank at the University of Otago Christchurch for the storage of human tissue for future unspecified research purposes.

Summary of ethical issues (resolved)

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

1. The Committee queried what data associated with the tissue would be retained and how this will be stored. The Researchers explained that a minimal dataset associated with each sample would be retained. The Committee suggested a numerical system with a suffix as an appropriate way of listing minimal data.
2. The Committee asked how this data would be managed. The Researchers stated that it would be physically decentralised, with samples stored in several locations, but with a central tracking and management structure. Staff at each site will be able to communicate to with one another and track who is accessing samples and when.
3. The Committee queried how new governance staff will be appointed. The Researchers explained that the board will elect new people to positions.
4. The Committee asked if samples would be collected from patients who were undergoing care or if samples would only be sourced as an optional part of research. The Researchers explained that only research participants would be approached for consent for future unspecified research.

Summary of ethical issues (outstanding)

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

1. The Committee stated that the documentation should list the coordinating investigator as named tissue bank manager.
2. Please amend the protocol to explain what happens when a board member leaves and how replacements will be assigned.
3. The Committee asked that the information sheet and consent forms be updated. *(Ethical Guidelines for Observational Studies para 6.10)*

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

1. Please remove the ACC statement as this is not required.
2. The Committee suggested that the participant information sheet be shortened and simplified by removing irrelevant information, jargon and technical terms such as “aetiology”.

Decision

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

* 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)*
* Please amend tissue bank protocol taking into account the discussion and suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)

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

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| **3** | **Ethics ref:** | **18/STH/73** |
|  | Title: | Tonsillectomy Technique Study |
|  | Principal Investigator: | Dr Eric Levi |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 March 2018 |

Dr Eric Levi 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 aims to investigate the efficacy of Paediatric Tonsillectomy technique using BiZact Device compared with traditional methods.

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, as presented, the study frames benefits associated with the study in terms of cost savings and reduction of inter-operative bleeding and asked if there was any evidence of improved outcomes in patients when the device is used. The Researcher explained that the study device has only recently been taken up at ADHB and therefore there is not enough evidence to show a direct benefit yet.
2. The Committee noted that other district health boards have used the BIZact device in children and adults.

Summary of ethical issues (outstanding)

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

1. The Committee stated that they had concerns over the study design, particularly in regards to the scientific validity of the study. The Committee noted that participants will not be randomised, despite the title of the project, and that this would introduce significant biases into the study. The Committee stated that subjecting vulnerable participants to research of unacceptable validity was unethical. (*Ethical Guidelines for Intervention Studies* *para 5.5 & 5.11*).
2. The Committee stated that further peer review that specifically addresses the design of the project, particularly the randomisation issue. *(Ethical Guidelines for Intervention Studies Appendix 1)*
3. The Committee suggested that a smaller feasibility study would be a more appropriate before commencing a randomised controlled trial. (*Ethical Guidelines for Intervention Studies* *para 5.5 & 5.11*).
4. 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*).
5. Please provide suitable information sheets and assent forms. This includes an information sheet and consent form for parents of participants unable to provide informed consent, an information sheet and consent form for participants able to provide their own informed consent (this includes all participants aged 16 years or older and may include some younger participants if they are deemed competent), an information sheet and assent form for children, and a very simple information sheet and assent form for young children that should very simply explain their participation in the study. Guidance on assent can be found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>. *(Ethical Guidelines for Intervention Studies Appendix 2)*

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

1. Substitute lay terms for technical jargon throughout.
2. Remove any potentially leading statements.
3. Please make sure that HDEC, HDC, and Māori cultural support details are all available in all information sheets and all located together at the end of the information sheet.

Decision

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

* The Committee stated that they had concerns over the scientific validity of the study and the evidence of favourable independent peer review of the study protocol did not address the issues around randomisation. (*Ethical Guidelines for Intervention Studies Appendix 1)*
* The Committee stated that, as presented, the project poses an unjustified risk to participants. (*Ethical Guidelines for Intervention Studies* *para 5.5 & 5.11*).
* The Committee stated that suitable information sheet and assent forms for minors had not been provided. *(Ethical Guidelines for Intervention Studies Appendix 2)*

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| **4** | **Ethics ref:** | **18/STH/74** |
|  | Title: | Proof of Concept Study For Next Generation Intraocular Lens Model MER001 |
|  | Principal Investigator: | MD Dean Corbett |
|  | Sponsor: | Johnson & Johnson (New Zealand) Limited |
|  | Clock Start Date: | 29 March 2018 |

Dr Dean Corbett was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the rotational stability of the test Intraocular lens (IOL), MER001, compared to the control IOL, MER000.

Summary of ethical issues (resolved)

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

1. The Committee noted the study was well designed and there were likely no more risks to participants than those associated with routine care.
2. The Committee queried if public patients (i.e. those not in private healthcare systems) would be recruited. The Researcher explained that there would be this opportunity for this study. The Committee noted that in the interests of equity that public patients should be recruited where possible. This would also help benefit Māori access to research and Māori health outcomes.

Summary of ethical issues (outstanding)

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

1. The Committee requested some changes to the participant information sheet. (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

1. Please make sure all explanations are given in lay-friendly language and no technical terminology is used.
2. Please list financial figures in New Zealand Dollar amounts.
3. Please increase the font size and use it consistently throughout.
4. Please make sure that line spacing is consistent throughout the document.
5. Please refer to study participants, not subjects.
6. Please clarify who the study sponsor is (AMO or Johnson & Johnson) and then refer to this consistently throughout.
7. Please remove background information on Johnson & Johnson.
8. 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 *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*).

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

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| **5** | **Ethics ref:** | **18/STH/84** |
|  | Title: | BCX7353-204: A study of the long-term safety of BCX7353 in people with hereditary angioedema |
|  | Principal Investigator: | Dr Karen Lindsay |
|  | Sponsor: | BioCryst Pharmaceuticals, Inc. |
|  | Clock Start Date: | 29 March 2018 |

Dr Karen Lindsay was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates BCX7353 (an investigational medicine) as a potential treatment for preventing hereditary angioedema (HAE) attacks.

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 previous studies have shown efficacy of BCX7353 reducing attacks and that this study will compare two specific doses.
2. The Committee noted the study is well designed and has been reviewed by overseas regulatory agencies.
3. The Committee stated more care should have been taken in the application when explaining how the study and hereditary angioedema effect Māori. For example by providing relative statistics or examples.

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 it needed to be clarified if there are any co-investigators for the project.
2. Please clarify if there will be any NZ participants under 16 years of age and if so, provide suitable information sheets and assent forms for this age group.
3. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

1. Check the information sheet for spacing and consistent formatting.
2. Please amend the ‘reproductive risks’ wording to that provided on the HDEC website and only list contraceptives that are commercially available in New Zealand.
3. The Committee requested the compensation wording is updated for accuracy and 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.”*
4. Include a statement that tissue will be sent overseas in the Future Unspecified Research information sheet.
5. Please explain what ‘pseudonymous’ means in plain English.
6. Refer to ‘your child’ in the parental information sheet and consent form.
7. Please remove any references to study termination due to commercial reasons as this is not supported by HDECs.
8. Check all sheets for typographic errors.
9. 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 *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 clarify if there are any co-investigators for the study. (*Ethical Guidelines for Intervention Studies* *para 5.36*).
* Please clarify if minors will be involved in the NZ arm of this study and if so, provide suitable information sheets and assent forms. (*Ethical Guidelines for Intervention Studies Appendix 2*).

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

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| **6** | **Ethics ref:** | **18/STH/82** |
|  | Title: | TOPAZ:A study to look at how safe and effective is the study drug in participants with retinal vein occlusion. |
|  | Principal Investigator: | Dr Philip Polkinghorne |
|  | Sponsor: | INC Research New Zealand Limited |
|  | Clock Start Date: | 29 March 2018 |

Dr Philip Polkinghorne 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 is a randomized, masked, controlled trial that investigates the safety and efficacy of suprachoroidal CLS-TA in combination with an intravitreal anti-VEGF agent in subjects with retinal vein occlusion.

Summary of ethical issues (resolved)

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

1. The Committee queried if any regulatory bodies will be reviewing the protocol for scientific validity. The Researcher explained that the FDA will be reviewing the study.
2. The Committee asked if there was any evidence indicating that there are interactions between the new drug and VEGF inhibitors. The Researcher stated that they have used similar drugs together and in their experience there have not been.
3. The Committee noted that all advertisements need to be approved by HDEC and asked if patients will be recruited through public healthcare systems. The Researcher confirmed that this is the case.
4. The Committee noted that in normal clinical practice the periods between injections lengthens as the condition improves and asked why this was not the case during the study. The Researcher explained that due to co-lateral development of the condition then they can reduce the frequency as time goes on, but near the start the regimen must be consistent.
5. The Committee noted that for Māori the head is considered tapu and therefore the Researchers should take care that participants’ views are respected.

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

1. Please reduce duplication of details throughout the information sheet. For example that participation is voluntary, how medical information will be shared, and how to withdraw.
2. Remove statements about collecting information on participant’s sex lives.
3. Please use the HDEC standard wording for reproductive risks and contraception (for women and male participants), which can be found on the HDEC website.
4. Clarify that data will be sent overseas in a de-identified form and once overseas it will be subject to local laws.
5. The Committee noted that termination of studies for commercial reasons are not acceptable to NZ HDECs and that this should be removed as a reason for stopping in the ICF.
6. 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.”*
7. Explain that tissue will be sent overseas and that it may not be possible for tissue to be destroyed with a karakia.

Decision

This application was *approved with non-standard conditions* by consensus. The non-standard conditions for this study are:

* 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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| **7** | **Ethics ref:** | **18/STH/80** |
|  | Title: | Comparison of the blood levels of two forms of ketamine in healthy volunteers under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas Pharmaceuticals America Ltd |
|  | Clock Start Date: | 29 March 2018 |

**Closed Meeting**

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| **8** | **Ethics ref:** | **18/STH/83** |
|  | Title: | Recovery from sports-related concussions, what is the place of aerobic exercise in the process? |
|  | Principal Investigator: | Mr Luke Barker |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 29 March 2018 |

Mr Luke Barker was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates if the early introduction of graduated return to either low or high-intensity exercise in the early recovery phase of sports-related concussion is safe and not worse than previously published outcomes.

Summary of ethical issues (resolved)

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

1. The Committee queried if cerebral blood flow has been used as a measure of recovery in previous studies. The Researcher stated that it had not.
2. The Committee asked why minors will be included in the project when studies should be conducted in the least vulnerable groups (in this case adults) wherever possible. The Researcher explained that adolescents commonly suffer from sports related concussion and are likely to differ in recovery responses, thus the results would not be generaliseable to this group if the study was performed in adults only. The Committee accepted this explanation as justification for including younger people in this study.
3. The Committee asked what percentage of the study population would be minors. The Researcher stated they are aiming for 20 – 30 %.

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

1. Please retitle the ‘recovery’ document to explain that it is a simplified assent form.
2. Please change the consent form for children document to be an assent form and amend any other references to reflect this.
3. Please include that, as per New Zealand law, all health information in the study must be kept for ten years. In the case of minors, this must be held for ten years after they turn 16.
4. Please consider using the image of the transcranial device from the protocol in the information sheets to provide further information and reassurance to participants.
5. The Committee suggested that the Researchers consider any other diagrams that may help explain the study or procedures.
6. Please remove the item in the consent form referring to compensation. This should be covered in the information sheet.

Decision

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

* 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:** | **18/STH/81** |
|  | Title: | Comparing low versus high Salbutamol MDI doses in mild to moderate asthma exacerbations presenting to the Emergency Department. |
|  | Principal Investigator: | Dr Saptarshi Mukerji |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 29 March 2018 |

Dr Saptarshi Mukerji was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates a higher dose against a lower dose of nebulised salbutamol in mild to moderate asthma exacerbations presenting to the emergency department.
2. Outcomes measured will be improvement in lung function, length of hospital stay, rates of admission to hospital and adverse events

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 patients who are too unwell to be approached will not be invited to participate.
2. The Committee noted that the study is important and that the application was of high quality
3. The Committee noted that while it is best practice to have different people making the initial research approach to those treating the patient. This approach was deemed not necessary due to the study setting and it would not be appropriate to delay treatment to find an independent clinician.

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

1. The Committee suggested a better wording than transient for the long information sheet.
2. 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.”*
3. Please amend the approving HDECs details

Decision

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

* 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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| **10** | **Ethics ref:** | **18/STH/79** |
|  | Title: | Comparison of low versus high dose of nebulised salbutamol in acute severe and life-threatening asthma in the Emergency Department. |
|  | Principal Investigator: | Dr Saptarshi Mukerji |
|  | Sponsor: | Medical Research Institute of New Zealand. |
|  | Clock Start Date: | 29 March 2018 |

Dr Saptarshi Mukerji was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates a higher dose against a lower dose of nebulised salbutamol in acute severe and life-threatening asthma presentations to the emergency department.
2. Outcomes measured will be improvement in lung function, length of hospital stay, rates of admission to hospital and adverse events

Summary of ethical issues (resolved)

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

1. The committee noted the proposed use of a brief PIS for unwell patients in A&E and commented this was appropriate and useful.
2. The Committee noted that the study is important and that the application was of high quality
3. The Committee noted that patients who are too unwell to be approached will not be invited to participate.
4. The Committee noted that while it is best practice to have different people making the initial research approach to those treating the patient. This approach was deemed not necessary due to the study setting and it would not be appropriate to delay treatment to find an independent clinician.

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

1. For the title of the information sheets, please use an alternative term than “life-threatening” as this may distress participants.
2. The Committee suggested a better wording than “transient” for the longer information sheet.
3. 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.”*
4. Please amend the approving HDECs details

Decision

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

* 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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| **11** | **Ethics ref:** | **18/STH/76** |
|  | Title: | Medication review in Aged Residential Care |
|  | Principal Investigator: | Dr Claire Heppenstall |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 March 2018 |

Dr Claire Heppenstall was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is a feasibility study of a pharmacist-led intervention to improve appropriate prescribing for older people entering Aged Residential Care.

Summary of ethical issues (resolved)

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

1. The Committee noted that the study is well designed, similar to previous applications made by the Researcher, and has incorporated feedback given by the HDEC during the reviews of these applications. .
2. The Committee noted that it would have been beneficial to include statistics about how polypharmacy effects Māori in the application.

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

1. Please change the title of the EPOA Declaration Form to EPOA Opinion Form.
2. Please remove tickboxes from the consent forms except for those items where ticking no would not exclude someone from participation.

Decision

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

* 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*)

## Substantial amendments

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **17/STH/111/AM01** |
|  | Title: | NZ RHD Registry |
|  | Principal Investigator: | A/Prof Nigel Wilson |
|  | Sponsor: | A/Prof Nigel J Wilson |
|  | Clock Start Date: | 05 March 2018 |

A/Prof Nigel Wilson was not present for discussion of this amendment.

Potential conflicts of interest

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

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

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee noted that it would be appropriate to approve the proposed amendment under paragraph 6.43 of the Ethical Guidelines for Observational Studies.

Decision

This amendment was *approved* by consensus.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 08 May 2018, 08:00 AM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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 4:45pm.