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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 18 October 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 20 September 2016 |
| 12:30pm | New applications (see over for details) |
|  | i 16/STH/161  ii 16/STH/163  iii 16/STH/164  iv 16/STH/166  v 16/STH/167  vi 16/STH/168  vii 16/STH/170  viii 16/STH/171 |
| 4:00pm | * General business: |
| 4:20pm | Meeting ends |

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

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 20 September 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/STH/170** |  |  |
|  | Title: | A study of RO7049389 in healthy subjects and patients chronically infected with hepatitis B virus infection |  |  |
|  | Principal Investigator: | Prof Edward Gane |  |  |
|  | Sponsor: | Covance NZ Ltd |  |  |
|  | Clock Start Date: | 06 October 2016 |  |  |

Prof Ed Gane and 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 new hepatitis B medication. The aim of this study is to show that the medicine is effective in treating hepatitis B. If the medication is effective it will be the first step from moving away from lifelong treatment. The medicine operates by preventing the virus from reproducing or protecting itself.
2. The researcher explained that COR inhibitors are commonly used and are very effective.
3. The study involves three parts. A single dose on day one, a multiple dose on day 14, and then treatment at 4 weeks.
4. The Committee noted that animal showed the virus disappearing.
5. The Committee noted the quality of the application.

Summary of ethical issues (resolved)

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

1. The Committee noted that only individuals who have a fully suppressed hepatitis B virus will be eligible to participate in the study.
2. The Committee noted that the study is going to the Standing Committee on Therapeutic Trials.
3. The Committee asked how many participants would be recruited in New Zealand and worldwide. The researcher explained that there will be 100 New Zealand participants and 130 recruited worldwide.
4. The Researcher explained that Auckland Clinical Studies will perform the healthy volunteer part of the study and that the second part of the study will be done across multiple sites in New Zealand and worldwide; due to the distribution of patients.
5. The Committee noted that the study is open to both male and female participants but that the advertising material only mentions men. The researchers stated that this will be changed.
6. The Committee enquired about how the reimbursement for the study was calculated as they had noted that it was high enough to be considered a possible inducement. The researchers explained that the formula used to calculate this is a standard one used by the locality and that it was designed in order to compensate people for time and inconvenience to an amount equal to the New Zealand minimum wage. The Committee suggested that the upper limit be re-examined if possible as anything over $5000 can be considered an inducement.

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

1. Please include the in-house stay information under the “How Long Will I Be Under The Study” section of the PIS. The Committee noted that these stays were optional and can vary.
2. Please check the PIS for technical terms and use language more suited to a lay audience.
3. Please make the ‘no medications from first dose’ rule stand out.
4. Please revise the reproductive risks statements to clarify that all women of child-bearing potential are excluded from this study. For example, please move the postmenopausal statement to the front of the PIS. It may be necessary to state that pregnancy and breastfeeding are also exclusion criteria, in the unlikely event that either of these occurs in a woman who thought she was sterile.
5. Please change the advertising material to make clear that the study is open to both female and male participants.

Decision

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

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| **2** | **Ethics ref:** | **16/STH/163** |
|  | Title: | Shockwave BTK Study |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | Shockwave Medical Inc |
|  | Clock Start Date: | 06 October 2016 |

Associate Professor Andrew Holden and Ms Donna Katae were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the use of the Shockwave lithoplasty balloon in below the knee arterial calcifications. The balloon uses high energy ultrasound to fragment calcium in a way that has no adverse effects on soft tissue. The researchers hope to show that the device can be used safely in the tibial arteries. The Committee noted that Austrian tests of the device in these arteries have shown that the procedure is safe.
2. The study will include up to 20 patients in six centres in three different countries.
3. The Committee noted the good quality of the application.

Summary of ethical issues (resolved)

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

1. The Committee queried if this study would be done concurrently or before the Disrupt PAD III Study (Ref 16/STH/164). The researchers explained that they will be done concurrently and it was clarified that there had been 3 earlier feasibility studies for the PAD III Study.
2. The Committee asked if any adverse events occurring in one study will be used to inform the other study. The researchers explained that they won’t but both studies have a well-developed safety protocol.
3. The Committee asked about the narrower arteries in the leg and how this issue will be managed. The researchers explained that they are using a device designed for his purpose which can fit inside these arteries.

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

1. Please check the PIS for typographical errors and phrasing.
2. The Committee noted that standard care would be implemented in the case of adverse events. The Committee suggested that this be made clear in the information sheet.
3. The Committee suggested a diagram explaining the device and how it works, if possible.
4. Please amend page four of the information sheet and separate out reproductive risks under their own subheading.

Decision

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

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| **3** | **Ethics ref:** | **16/STH/164** |
|  | Title: | Disrupt PAD III |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | Shockwave Medical Inc |
|  | Clock Start Date: | 06 October 2016 |

Associate Professor Andrew Holden and Ms Donna Katae 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. There have been three previous feasibility studies and the aim of this study is to compare the Shockwave angioplasty device with a drug-coated balloon in comparison to the standard care pathway for peripheral arterial disease. The researchers aim to show that the Shockwave device when combined with a drug-coated balloon will be superior.
2. The device will be tested in calcified peripheral arteries in the lower leg and foot.

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 peer review is not independent as it was completed by the Principal Investigator and another reviewer on the company board. Following discussion they felt that, given that the device is a relatively new technology, the number of individuals who could provide a truly expert opinion was low and therefore the Committee was largely satisfied with the peer review for the study. *(National Ethics Advisory Committee, Ethical Guidelines for Intervention Studies, Appendix 1)*
2. The Committee queried if potential participants will initially be approached by clinical staff or a researcher. The researchers explained that they will meet with the research group at their locality and following discussion clinical staff will approach potential participants and ask if they wish to be approached regarding participation.

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

1. Please make sure that the participant information sheet is worded in such a way as to communicate that the two arms of the study have equipoise. The Committee noted that the wording of the information sheet may imply that the shockwave device is superior.
2. Please make it clear in the information sheet that the study is a sponsored trial and that the site is being reimbursed.
3. The committee noted that page 2 of the information sheet states that the device is unapproved but that it has CE marks. The Committee suggest that this be explained clearly to lay people. The Committee suggested that any wording after the sentence ending with ‘New Zealand’ be removed.

Decision

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

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| **4** | **Ethics ref:** | **16/STH/166** |
|  | Title: | TransCon hGH CT301 |
|  | Principal Investigator: | Prof Paul Hoffman |
|  | Sponsor: | Pharmaceutical Solutions Ltd |
|  | Clock Start Date: | 06 October 2016 |

Professor Paul Hoffman 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 will investigate the effectiveness of a new weekly human growth hormone injection, compared with the standard daily one in pre-pubertal children. The current regimen has poor patient compliance, with approximately half of all patients missing 40%-50% of their injections. Earlier pilot studies have shown that a weekly injection regimen has been effective.
2. The researchers in this study are taking part in an international trial across 20 countries and 150 sites. The study aims to recruit between two and four patients in New Zealand.
3. The Committee noted that the study is well justified as the possibility of moving to once-weekly dosing would hopefully benefit children and their parents in terms of convenience and compliance
4. There are three participant information sheets for this study. These were designed in order to help inform young children, young children who cannot read, and the parents of children.

Summary of ethical issues (resolved)

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

1. The Committee queried how old the youngest participants will likely be. The researcher explained that the youngest children will be around four to five years old.
2. The Committee noted that a human growth hormone deficiency means that some children may have an intellectual disability.
3. The Committee noted that the trial has gone to the Standing Committee on Therapeutic Trials.
4. The Committee asked if the patients will be under the researchers’ care. The researchers explained that they will be.
5. The Committee asked how the researchers will identify and recruit potential participants. The researchers explained that they will screen a database for potential participants but that it will be clinical staff who are not connected with the research who make the initial approach about research participation.

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

1. The Committee queried what the upper age limit would be in this study. The researcher explained that it will be about 10 years for girls and 11 years for boys. The Committee requests that the second consent form’s title be amended to say assent.
2. Please list the frequencies of the possible side effects of the medicine in the information sheet. Please use ratios (e.g. ‘1 in 100 people’) when listing the chances of these occurring rather than percentages.
3. Please explain that the possible side effects are based on previous clinical experience with daily injections and that if any side effects are more likely (due to the change in regimen) that this is stated clearly.
4. Please remove the reference to playing with researchers from the assent forms.

Decision

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

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| **5** | **Ethics ref:** | **16/STH/167** |
|  | Title: | The Midland Lung Cancer Database. |
|  | Principal Investigator: | Professor Ross Lawrenson |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 October 2016 |

Professor Ross Lawrenson and Dr Charis Brown were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigators wish to link two datasets of patient information in order to determine the outcomes of lung cancer patients in the Midland region. They are particularly interested in the utilisation of secondary treatments such as thoracic surgery and determining Māori outcomes, as Māori tend to have worse outcomes overall.
2. The rationale behind linking the datasets is that they will therefore include individuals who have not been a patient at a site where their data would have been entered into a database. By linking the de-identified data the researchers can then get a comprehensive view of patient 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 noted that the letter written to the Committee was very helpful and addressed some of their concerns.
2. The Committee noted that the databases are being merged and de-identified before being given to researchers.
3. The Committee noted that they were satisfied to approve the release of data without consent on the grounds of public good and the number of patients.

Summary of ethical issues (outstanding)

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

1. The Committee asked if the researchers had sought a legal opinion around the privacy implications of the study. The researchers explained that they had not, however ADHB locality assessment includes a review and potential veto by legal counsel. The researchers were asked to check the privacy implications with ADHB legal counsel. The Committee requests that they be given a copy of the legal opinion.

Decision

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

* Please provide the evidence of legal consultation and provide the legal outcome of this process.

This response will be reviewed by the Secretariat.

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| **6** | **Ethics ref:** | **16/STH/168** |
|  | Title: | Deprescribing in Aged Residential Care |
|  | Principal Investigator: | Dr Claire Heppenstall |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 October 2016 |

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 seeking to determine how many individuals in Aged Residential Care (ARC) would be willing to undergo a medications review.
2. The researchers believe that polypharmacy is leading to individuals having a reduced quality of life in the final ~6 months of their lives. Therefore it would be beneficial to reduce these medications.
3. The Committee noted that the researcher had an interest in eventually determining if the number of medicines prescribed can be reduced. However this was not the aim of this study.
4. The Committee commented that the quality of this application was poor and did not clearly outline some aspects of the study aims and endpoints.

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 aim of the study was not initially clear and sought clarification from the researcher. The researcher explained that this is a feasibility study seeking to determine how many individuals in ARC would be prepared to undergo a medicines review with specialist pharmacist and whether the patients GP would take this advice into consideration in future prescriptions.
2. The Committee noted that participants in this study will generally have around half a year to live at most. The Committee was of the opinion that this period of life was no less valuable than any other. The Committee noted the patients views should be taken into account as the patients quality-of-life is of great importance. The Committee were concerned that that neither the pharmacist nor the residential care home’s GP will have a long term history of participants. The researcher explained that they will manage this risk as the pharmacist discuss what patients want with patients and family and whānau members as part of the review process.
3. The Committee noted that there is no quality of life assessment in this study and encouraged this to be added. At present it appears that the number of study drugs is the main outcome to be considered but that stopping drugs may not be in the patient’s best interest.
4. The Committee noted that there was no control cohort in this study but the committee explained to the researchers that this can be added later as an amendment to the study protocol.
5. The Committee noted that polypharmacy can cause numerous issues in patients because of drug interactions.
6. The Committee asked who would be initially approaching patients to ask if they were interested in study participation. The researcher explained that they would be. The committee requested that this initial approach be done by normal clinical staff at the aged care facility.
7. The Committee stated that it is not possible for HDECs to approve an application unless it is consistent with New Zealand law, including the right not to be subjected to medical or scientific experimentation without that person's consent (section 10 of the New Zealand Bill of Rights Act 1990). Research involving participants who are not competent to consent is inconsistent with the Bill of Rights unless it is undertaken in accordance with Right 7 (4) of the of the Code of Health and Disability Services Consumers’ Rights. In addition to requirements regarding ascertaining the views of the consumer and other suitable persons (forms consistent with this aspect are currently included in this application), Right 7(4) of the Code requires that any health services provided without the informed consent of the consumer must be in the best interests of the consumer. This means that there must be some benefit, or potential benefit, to the participant beyond what they would receive if they were not participating in the research. The Committee notes that proxy consent 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 documents 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. The researchers agreed that they would only recruit patients who could consent for themselves.
8. The Committee noted that the number of prescriptions stopped was not a health outcome and that there did not seem to be sufficient focus on improving the care of the study population. The researcher explained that this is a feasibility study and thus is not powered. The aim of the study is to determine the number of people entering aged residential care who would be willing to undergo a medications review.
9. In order to clarify their concerns over the stated aims of the study and what the researcher was saying to them in the discussion the Committee directly asked if this studies’ aim is only to determine how many elderly people entering aged residential care would be willing to undergo a medications review. The researcher stated that yes, this was the only aim of the study.
10. The Committee noted that other measures discussed in the application are not present, such as a quality of life measure. The Committee reminded the researcher that they will not be able to undertake these measures until they have received ethical approval, at which point they will be able to submit amendments to their protocol. The researcher acknowledged this.

Summary of ethical issues (outstanding)

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

1. The Committee noted that there was not a process in place to notify participant’s GPs that they were taking part in a review. The Committee also noted that there was not a method in place to notify GPs about the outcomes of the medications review. Please provide a letter to GPs, explaining the study, and how they may be involved. Please provide participant’s GPs with a letter detailing the outcome of the medications review process and discussion with the patient and their family and whānau.
2. The Committee were concerned about the quality of the study protocol and that what is stated in the protocol and what would be provisionally approved were at odds. The Committee noted that they would approve the study on the basis that it was a feasibility study. Please provide a new protocol that correctly describes the study aims, methods, and objectives as a feasibility study measuring the number of patients entering aged residential care who are willing to undergo a medications review.

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

1. Please provide an information sheet and consent form for family and whānau members.
2. The Committee noted that the language in the information sheets could be considered leading. Please re-write these in a way that is neutral.
3. Please add more detail to the information sheets.

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 provide a letter notifying the participant’s GP about the outcomes of their medications review process.
* .Please provide a letter to the participant’s GP, explaining the study, and how they may be involved.
* Please make sure that the initial recruitment approach for this study is done by clinical staff and not researchers.
* Please provide a revised study protocol that responds to the Committees’ concerns.

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

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| **7** | **Ethics ref:** | **16/STH/161** |  |  |
|  | Title: | FRISCO Trial |  |  |
|  | Principal Investigator: | Dr Dick Ongley |  |  |
|  | Sponsor: |  |  |  |
|  | Clock Start Date: | 06 October 2016 |  |  |

Ms Aya Cervantes 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. Frailty is commonly being used as a measure of assessing patient risk when having surgery, however there is no framework that has been put in place for doctors to assess and measure frailty in patients. This study seeks to determine which tests can be done quickly and accurately to assess frailty in patients.
2. Participants in this study will undergo tests and surveys on their experiences of the tests. The results will be analysed in comparison with the clinical frailty scale in order to see if they are accurate.

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 this study addresses an important issue in contemporary care.
2. The Committee noted that risks to participants in this study appear to be low, with only one extra blood test required in addition to normal care.
3. The Committee noted that the peer review raises several questions and requests that the researchers inform them of how these suggestions and questions were addressed.
4. The Committee noted that they were happy to approve the study on the basis that all participants are fully capable of providing their own informed consent. The Committee stated that it is not possible for HDECs to approve an application unless it is consistent with New Zealand law, including the right not to be subjected to medical or scientific experimentation without that person's consent (section 10 of the New Zealand Bill of Rights Act 1990). Research involving participants who are not competent to consent is inconsistent with the Bill of Rights unless it is undertaken in accordance with Right 7 (4) of the of the Code of Health and Disability Services Consumers’ Rights. In addition to requirements regarding ascertaining the views of the consumer and other suitable persons (forms consistent with this aspect are currently included in this application), Right 7(4) of the Code requires that any health services provided without the informed consent of the consumer must be in the best interests of the consumer. This means that there must be some benefit, or potential benefit, to the participant beyond what they would receive if they were not participating in the research.

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

1. Please include information on who will be performing the study at each site in the information sheet.
2. Please consider using an alternative word to comorbid in the title.
3. Please use a single measure of time, either days or months.

Decision

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

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| **8** | **Ethics ref:** | **16/STH/171** |
|  | Title: | A PHASE IIB, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER,DOSE-RANGING STUDY TO ASSESS THE EFFICACY AND SAFETY OF MSTT1041A INPATIENTS WITH UNCONTROLLED SEVERE ASTHMA |
|  | Principal Investigator: | Dr James Fingleton |
|  | Sponsor: | PPD |
|  | Clock Start Date: | 06 October 2016 |

Dr James Fingleton 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 effectiveness of the study drug, MSTT1041A, versus a placebo in a population with uncontrolled severe asthma. Three doses (70mg, 210mg and 490mg) given sub-cutaneously every four weeks, will be tested against placebo. The researchers also hope to assess the safety and pharmacokinetics of the drug.
2. Participants will continue to take their standard asthma medicines during the course of the study.
3. It is intended that 500 participants will be included in this international study which will be conducted in Canada, USA and NZ. 15 participants will be sought from NZ.
4. Blood and urine will be sent overseas for analysis.
5. There is also the option of consenting to provide samples for future unspecified 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 requests that an alternative title of the study be created for lay people and included in the PIS. The Committee feels that the current one is too long and technical.
2. The Committee requests that the study organisers inform participants’ GPs that they are participating in the clinical trial, not participants themselves.

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

1. Please rephrase the statement around the rescue inhaler to be more definite. The Committee was concerned that it may create doubt in participants about if they could use their rescue inhaler in an emergency.
2. Please amend the information sheet to suggest that the partners of men also use contraception, in conjunction with a condom, to increase contraceptive effectiveness and prevent pregnancies occurring during this study.

Decision

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

## General business

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

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| **Meeting date:** | 22 November 2016, 12:00 PM |
| **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 4:20pm.