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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 23 October 2018 |
| **Meeting venue:** | Room GN.7, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 28 August 2018 |
| 12:15pm | General business:   * Noting section |
| 12:30pm | New applications (see over for details) |
|  | i 18/CEN/187  ii 18/CEN/188  iii 18/CEN/189  iv 18/CEN/190  v 18/CEN/191  vi 18/CEN/196  vii 18/CEN/197  viii 18/CEN/199  ix 18/CEN/200  x 18/CEN/201  xi 18/CEN/202  xii 18/CEN/203 |
| 5:30pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members.

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 28 August 2018 were confirmed.

## General Business

The Committee discussed the appropriateness of the use of pictures in information sheets and assent forms for young children. The Committee was responding to correspondence from researchers who had stated that the researchers have been instructed to exclude pictures from documents. The committee resolved to write to the researchers and ask for proof of this claim.

## New applications

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| **1** |  | **Ethics ref:** | **18/CEN/202** |
|  |  | Title: | Study of RO7239958 in Healthy Volunteers and Patients with Chronic Hepatitis B |
|  |  | Principal Investigator: | Prof Edward Gane |
|  |  | Sponsor: | Covance NZ Ltd |
|  |  | Date submitted: | 11 October 2018 |
|  |  | Clock Start Date: | 11 October 2018 |

Prof Gane and Ms Emily Shearer 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 evaluates the safety, tolerability, pharmacokinetics and pharmacodynamics of RO7239958 in healthy volunteers and patients with chronic hepatitis B virus infection

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 is an umbrella protocol.
2. The Committee asked if the study would be a parallel design or a dose escalation design. The researcher stated that the project is a multi-ascending dose design in the healthy volunteers and once safety data has been collected then they will move into dosing patients. Patients will receive a lower dose.
3. The Researcher explained that they may look at frequency of administration in a later part of the study but that all doses will be the same.
4. The Committee noted that the study has gone to SCOTT.
5. The Committee noted there is an internal data safety monitoring committee for the study.
6. The Researcher confirmed that they will be using sentinel dosing and the safety data of the sentinels for each group will be reviewed before proceeding to dose the rest of the group.

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

1. Explain that tissue will be held at most for fifteen years.
2. Explain the rules around data until withdrawal in the main ICF and not in the consent form.
3. Please remove references to consenting for the collection of unborn children’s medical information in the main information sheet.
4. Be more specific about the level of alcohol that participants should consume.

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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| **2** |  | **Ethics ref:** | **18/CEN/197** |
|  |  | Title: | START |
|  |  | Principal Investigator: | Dr Nikki Moreland |
|  |  | Sponsor: |  |
|  |  | Date submitted: | 11 October 2018 |
|  |  | Clock Start Date: | 11 October 2018 |

Dr Nikki Moreland, Dr Rachel Webb, and Dr Julie Bennett was present for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates a new blood test to look for unique immune response signatures in acute rheumatic fever patients and volunteers.

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 there is future unspecified research in the project and how it would work. The Researcher explained that they would like to do future research on the immunology of rheumatic fever.
2. The committee asked how many participants will be recruited. The Researcher stated that 120 broken up into four groups of 15 participants. The Committee noted that this project is an international project and so the data will be pooled with Australian information.

Summary of ethical issues (outstanding)

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

1. 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)*
2. Please provide the details of the HDEC-approved tissue bank where samples collected for future unspecified research will be held or amend the study protocol, information sheet, consent forms, and assent forms to remove references to this. *(Ethical Guidelines for Observational Studies para 6.10 & Ethical Guidelines for Intervention Studies para 5.41 )*
3. The Committee stated that health information in the study must be held for ten years after the youngest child turns 16. (*Ethical Guidelines for Intervention Studies para 5.41 )*
4. The Committee asked if it would be possible for a researcher to make the initial approach. The Researcher stated the treating clinician will mention the study is happening and provide a flyer but then they will refer to the study team. Please provide the flyer to HDECs.

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

1. Please explain why participants are being approached for consent for participation.
2. “What will my child’s participation involve” – explain what volume of blood will be collected.
3. “We will collect information about my child’s symptoms” – explain that this is from clinical records and what type of information, e.g. echo reports, will be collected.
4. Remove reference to the $50 voucher from the child information sheets.
5. Please provide separate information sheet and consent, and assent forms for future unspecified research. And consent for FUR upon turning 16yr old
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/whānau 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. Please provide the name of lab in Singapore where blood will be sent and explain why blood needs to be sent overseas.
8. The Committee suggested using the HDEC template information sheet and consent forms.
9. Please explain all study processes that will involve participants, their information, or tissue and explain why these must happen.
10. 5-10 year old info sheet- use pictures in these and make sure it is clear that they can say no even if their parents say yes.
11. Remove reference to ‘better’ medications.
12. Remove statement “this is very important” – rather just state that rheumatic fever can be a serious disease that affects children.
13. In the ICF for controls please explain that ‘although your child does not have rheumatic fever’ their participation is very helpful as part of a comparison group.
14. Explain that clinical history, echo, etc, will be taken and reviewed from controls to make sure that they do not have rheumatic fever as other diseases can present similarly.
15. Please produce a separate ICF for the control group who do not have rheumatic fever and tailor this to the situation of the volunteers.
16. Explain that this is a trans-Tasman project and that records will be shared with Australian collaborators and analysed alongside Australian data.

Decision

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

* 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 the details of the HDEC-approved tissue bank where samples collected for future unspecified research will be held or amend the study protocol, information sheet, consent forms, and assent forms to remove references to this. *(Ethical Guidelines for Observational Studies para 6.10 & Ethical Guidelines for Intervention Studies para 5.41 )*
* The Committee stated that health information in the study must be held for ten years after the youngest child turns 16. (*Ethical Guidelines for Intervention Studies para 5.41 )*
* The Committee asked if it would be possible for a researcher to make the initial approach. The Researcher stated that they will have the treating clinician will mention the study is happening and provide a flyer but then they will refer to the study team. Please provide the flyer to HDECs. *(Ethical Guidelines for Observational Studies para 6.10)*

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| **3** |  | **Ethics ref:** | **18/CEN/199** |
|  |  | Title: | The Hospital Operating Theatre Randomised OXygen study (HOT-ROX) |
|  |  | Principal Investigator: | Dr Daniel Frei |
|  |  | Sponsor: | Medical Research Institute of New Zealand |
|  |  | Date submitted: | 11 October 2018 |
|  |  | Clock Start Date: | 11 October 2018 |

Dr Daniel Frei 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 investigates the impact of both a liberal and a conservative approach to oxygen therapy during and after major surgery on important patient outcomes, compared to standard oxygen therapy.

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 it is unclear if high levels of oxygen during surgery, as recommended by the World Health Organisation, correlate with better outcomes for patients.
2. The Committee noted that the researchers had responded to comments by reviewers about the design of the study and changed their design to incorporate this feedback.
3. The Committee noted that there is potential for cultural issues associated with the tapu of the head but that this will not be more than standard care.
4. The Committee noted that the information sheet was clear and simple to understand.
5. The Committee asked at what point patients will be approached for participation.

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

1. Explain that major surgery = longer than 2 hrs and will require a one night stay.
2. Explain that participants will be randomly assigned to an oxygen level and the percentage chance of being assigned to each arm.
3. Explain acronyms at first use, e.g. PACU.
4. Explain when study participation ends e.g. discharge from PACU or 6 hours after PACU etc.

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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| **4** |  | **Ethics ref:** | **18/CEN/203** |
|  |  | Title: | V160 2-Dose and 3-Dose Regimens vs. Placebo in Healthy CMV Seronegative Females |
|  |  | Principal Investigator: | Dr Joanna Joseph |
|  |  | Sponsor: | MSD Global Clinical Trial Operations (GCTO) |
|  |  | Date submitted: | 11 October 2018 |
|  |  | Clock Start Date: | 11 October 2018 |

Dr Joanna Joseph 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 Dean Quinn declared a conflict of interest for this application. The Committee resolved that he could remain but not participate in the review of this application or any subsequent amendments.

Summary of Study

1. The study investigates the safety, tolerability, efficacy and immunogenicity of a 2-dose and a 3- dose regimen of V160 (Cytomegalovirus [CMV] Vaccine) in healthy seronegative women, 16 to 35 years of age.

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 there is no vaccine for this condition and that the virus has severe effects on children’s development in utero and leads to lifelong issues.
2. The Committee noted that CMV can be devastating for families due to the difficulty of detecting the disease and symptoms in children not always being detected for the first 8 months of life.
3. The Committee noted the study has been approved by the Standing Committee on therapeutic Trials.

Summary of ethical issues (outstanding)

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

1. Please amend the 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. Move the section explaining what CMV is to the front of the ICF.
2. Please specify in the information sheet which types of birth control are allowed.
3. Please clarify how much participants will be reimbursed, e.g. a $50 voucher.
4. In the section on withdrawal explain that the processes that the study doctor can only do the procedures described with patient consent.
5. In the child follow-up ICF please refer to the child throughout, not the parents.
6. Please use separate ICFs for during pregnancy and post-natal follow-up. Do not bundle the two together. The pregnancy ICF should not include specific consent for the collection of information about the unborn child, as this is not possible under New Zealand law until the child is born. The mother’s consent to participation also includes the unborn child.
7. Include the direct exposure inclusion criterion in the introduction to the information sheets.
8. On the main information sheet explain that samples will be sent overseas and where and then include the standard HDEC wording for sending samples overseas.
9. Remove references to Māori support services provided by the Health and Disability Commission as they do not provide this service.

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 Mrs Helen Walker and Dr Patries Herst.

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| **5** |  | **Ethics ref:** | **18/CEN/191** |
|  |  | Title: | ATHENA: Study of Rucaparib and Nivolumab in Patients with Ovarian Cancer |
|  |  | Principal Investigator: | Dr Michelle Wilson |
|  |  | Sponsor: | Clovis Oncology |
|  |  | Date submitted: | 05 October 2018 |
|  |  | Clock Start Date: | 11 October 2018 |

Dr Michelle Wilson, Mrs Pallavi Wyawahare, and Ms Sonja Erikson were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is a randomized, multinational, double blind, dual placebo-controlled, 4-arm, Phase 3 study evaluating rucaparib and nivolumab as monotherapy and in combination as maintenance treatment following response to front-line treatment (surgery and platinum-based chemotherapy) in newly diagnosed ovarian cancer patients.

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 there are no drugs available to improve survival and so the use of placebo is equivalent to standard care.
2. The Committee asked if there will be any crossover for participants who are on placebo who experience a worsening of their conditions. The Researcher stated that there would not but there may be post-trial options for these participants.
3. The Committee noted that neither of the study drugs are funded outside of the trial.

Summary of ethical issues (outstanding)

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

1. 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. Amend “You may be reimbursed” to “You will be reimbursed”.
2. Please better explain the section on genetic testing not being covered by the public health system and that the sponsor will cover these costs.
3. Please amend the statement about fever to explain that if participants get a fever at any point they should seek medical assistance immediately.
4. Please remove information about EU member states etc. from p22 of the information sheet as this is not relevant to New Zealand.
5. Please remove the requirement for written withdrawal from p22 of the information sheet.
6. Explain what significant abnormal results are in the information sheet and explain. Please explain what this section of the consent form refers to.
7. Clarify the process around getting family history.
8. Explain that samples must be stored for ten years if the samples will be stored in New Zealand.
9. Please create a table that explains what will occur at each study visit. This can use tick boxes to indicate which procedures occur during which visit.
10. Pg 3 – research has been designed to interpret the results in a fair and appropriate way. Remove the rest of the sentence after this statement.
11. Please refer to placebo pills not sugar pills.

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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| **6** |  | **Ethics ref:** | **18/CEN/196** |
|  |  | Title: | Breathlessness Exertion and Morphine Sulphate (BEAMS) |
|  |  | Principal Investigator: | Dr Michael Epton |
|  |  | Sponsor: | Flinders University |
|  |  | Date submitted: | 11 October 2018 |
|  |  | Clock Start Date: | 11 October 2018 |

Dr Caralyn Purvis was not 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 placebo-controlled, parallel arm, dose increment, randomised trial of regular, low dose extended release morphine for chronic breathlessness,

Summary of ethical issues (resolved)

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

1. The Committee stated that the responses to how the study may benefit Māori did not adequately explain the background of emphysema rates in Māori.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. Please explain in the protocol and the information sheet what procedures are in place to protect participants who disclose high scores on the depression questionnaire. (*Ethical Guidelines for Intervention Studies* *paras 6.22 & 5.41*).
3. Clarify which aspects of the project are part of the main study and part of the sub study both in the information sheet and in the protocol. (*Ethical Guidelines for Intervention Studies* *paras 6.22 & 5.41*).
4. Please explain in the information sheet and protocol what processes are in place for weaning participants off of the study drug. (*Ethical Guidelines for Intervention Studies* *paras 6.22 & 5.41*).

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

1. In the section of the caregiver information sheet that states “The aim of the sub-study.” Please replace *burden* with *stress*.
2. Please use a diagram to explain the relatively complicated randomisation processes and allocation for the study.
3. Please explain why participants will be provided with a small fan.
4. Please thoroughly proofread the information sheet and consent forms for spelling and grammar errors.
5. Please explain that the study drug will not be available after the study.
6. Please explain the risks of morphine in greater detail as these are known. Please also instruct participants what the signs and symptoms of opiate withdrawal are, and what they should do in the event that these are severe.
7. “Samples will be stored until there are a number…” please rephrase this statement as it is unclear.
8. Please explain what remuneration will be provided and how much. Explain if this will be a pro-rata payment.
9. Please provide separate information sheet and consent forms for any future unspecified research or remove references to this.
10. Clarify if pharmacogenetics is required as part of the main study and if not then create a separate information sheet and consent form for it as an optional study.
11. Explain that samples will be sent overseas to the UK and say where.
12. State either participants can or cannot drive after participation. This should not be ambiguous.

Decision

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

* 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 explain in the protocol and the information sheet what procedures are in place to protect participants who disclose high scores on the depression questionnaire. (*Ethical Guidelines for Intervention Studies* *paras 6.22 & 5.41*).
* Clarify which aspects of the project are part of the main study and part of the sub study both in the information sheet and in the protocol. (*Ethical Guidelines for Intervention Studies* *paras 6.22 & 5.41*).
* Please explain what processes are in place for weaning participants off of the study drug in the information sheet and protocol. (*Ethical Guidelines for Intervention Studies* *paras 6.22 & 5.41*).

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| **7** |  | **Ethics ref:** | **18/CEN/200** |
|  |  | Title: | Comparison of the blood levels of two forms of isotretinoin capsule in healthy male volunteers under fed conditions. |
|  |  | Principal Investigator: | Dr Noelyn Hung |
|  |  | Sponsor: | Douglas Pharmaceuticals America Ltd |
|  |  | Date submitted: | 11 October 2018 |
|  |  | Clock Start Date: | 11 October 2018 |

Dr Tak Hung, and Ms Linda Folland were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is an open-label, two-way crossover, bioequivalence study in healthy male subjects comparing 1 x 40 mg isotretinoin capsule with 1 x 40 mg Absorica capsule under fed conditions.

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

1. Specify how recently people have used recreational drugs. Please ask participants to tell the doctor which drug and how recently it was used.
2. Check for typos and correct use of apostrophes.

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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| **8** |  | **Ethics ref:** | **18/CEN/201** |
|  |  | Title: | Comparison of the blood levels of two forms of isotretinoin capsule in healthy male volunteers under fasting conditions. |
|  |  | Principal Investigator: | Dr Noelyn Hung |
|  |  | Sponsor: | Douglas Pharmaceuticals America Ltd |
|  |  | Date submitted: | 11 October 2018 |
|  |  | Clock Start Date: | 11 October 2018 |

Dr Tak Hung, and Ms Linda Folland were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is an open-label, two-way crossover, bioequivalence study in healthy male subjects comparing 1 x 40 mg isotretinoin capsule with 1 x 40 mg Absorica capsule under fasting conditions.

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

Specify how recently people have used recreational drugs. Please ask participants to tell the doctor which drug and how recently it was used.

1. Check for typos and correct use of apostrophes.

Decision

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

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

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| **9** |  | **Ethics ref:** | **18/CEN/187** |
|  |  | Title: | Comparison of the blood levels of two forms of methylphenidate in healthy volunteers under fasting conditions |
|  |  | Principal Investigator: | Dr Noelyn Hung |
|  |  | Sponsor: | Mundipharma Pty Ltd |
|  |  | Date submitted: | 05 October 2018 |
|  |  | Clock Start Date: | 11 October 2018 |

Dr Tak Hung, and Ms Linda Folland 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 relative bioavailability of the test formulation, a 60 mg methylphenidate controlled release capsule, to that of the reference formulation, 6 x 10 mg Ritalin immediate release tablets under fasting conditions.

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

1. Explain that if participants are from outside of Dunedin then they will need to stay in a motel or stay with Zenith for longer for observation. They should not return to their homes.
2. Contraception – explain that women over 50 who have not had a period for >12 months will be considered post-menopausal.
3. Use the current ACC wording. – from our website. 188 onwards.

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/CEN/188** |
|  |  | Title: | Comparison of the blood levels of two forms of methylphenidate in healthy volunteers under fasting conditions |
|  |  | Principal Investigator: | Dr Noelyn Hung |
|  |  | Sponsor: | Mundipharma Pty Ltd |
|  |  | Date submitted: | 05 October 2018 |
|  |  | Clock Start Date: | 11 October 2018 |

Dr Tak Hung, and Ms Linda Folland 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 relative bioavailability of the test formulation, 1 x 10 mg methylphenidate controlled release capsule compared to that of the reference formulation, 1 x 10 mg Ritalin immediate release tablet under fasting conditions.

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

1. Explain that if participants are from outside of Dunedin then they will need to stay in a motel or stay with Zenith for longer for observation. They should not return to their homes.
2. Explain that women over 50 who have not had a period for >12 months will be considered post-menopausal.
3. Please use the current ACC wording which can be found on our website.
4. Explain what the process is for patients who disclose suicidal ideation.
5. Please clarify that the meal before arrival means enough food to get through the night.
6. Please use layterms in contraception paras. The Committee suggested using the HDEC template contraception wording.
7. Amend references to correct HDEC.

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/CEN/189** |
|  |  | Title: | Comparison of the blood levels of two forms of methylphenidate in healthy volunteers under fed conditions |
|  |  | Principal Investigator: | Dr Noelyn Hung |
|  |  | Sponsor: | Mundipharma Pty Ltd |
|  |  | Date submitted: | 05 October 2018 |
|  |  | Clock Start Date: | 05 October 2018 |

Dr Tak Hung, and Ms Linda Folland 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 relative bioavailability of the test formulation, a 60 mg methylphenidate controlled release capsule, to that of the reference formulation, 6 x 10 mg Ritalin immediate release tablets under fed conditions.

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

1. Explain that if participants are from outside of Dunedin then they will need to stay in a motel or stay with Zenith for longer for observation. They should not return to their homes.
2. Explain that women over 50 who have not had a period for >12 months will be considered post-menopausal.
3. Please use the current ACC wording which can be found on our website.
4. Explain what the process is for patients who disclose suicidal ideation.
5. Please use layterms in contraception paras. The Committee suggested using the HDEC template contraception wording.
6. Amend references to correct HDEC.

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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| --- | --- | --- | --- |
| **12** |  | **Ethics ref:** | **18/CEN/190** |
|  |  | Title: | Comparison of the blood levels of two forms of methylphenidate in healthy volunteers under fasting conditions and at steady state. |
|  |  | Principal Investigator: | Dr Noelyn Hung |
|  |  | Sponsor: | Mundipharma Pty Ltd |
|  |  | Date submitted: | 05 October 2018 |
|  |  | Clock Start Date: | 11 October 2018 |

Dr Tak Hung, and Ms Linda Folland 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 relative bioavailability of the test formulation, 1 x 10 mg methylphenidate controlled release capsule compared to that of the reference formulation, 1 x 10 mg Ritalin immediate release tablet under fed conditions.

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

1. Explain that if participants are from outside of Dunedin then they will need to stay in a motel or stay with Zenith for longer for observation. They should not return to their homes.
2. Explain that women over 50 who have not had a period for >12 months will be considered post-menopausal.
3. Please use the current ACC wording which can be found on our website.
4. Explain what the process is for patients who disclose suicidal ideation.
5. Please clarify that the meal before arrival means enough food to get through the night.
6. Please use lay terms in contraception paras. The Committee suggested using the HDEC template contraception wording.
7. Amend references to correct HDEC.

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*).

## 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:** | 27 November 2018, 12:00 PM |
| **Meeting venue:** | Room GC.3, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington, 6011 |

The following members tendered apologies for this meeting.

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 5:30pm.