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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 16 April 2013 |
| **Meeting venue:** | Hunter Centre - Dunedin |

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| **Time** | **Item of business** |
| 11:00 am | Welcome |
| 11:10 am | Confirmation of minutes of meeting of 19 March 2013 |
| 11:30–3:00pm | New applications (see over for details) |
|  | i 13/STH/28  ii 13/STH/29  iii 13/STH/30  iv 13/STH/31  v 13/STH/32  vi 13/STH/33  vii 13/STH/34 |
| 3:00 pm | General business:  Noting section of agenda |
| 3:30 pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mr Doug Bailey | Lay (the law) | 01/07/2012 | 01/07/2015 | Apologies |
| Mrs Angelika Frank-Alexander | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Apologies |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Apologies |
| Ms Gwen Neave | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Apologies |
| Dr Nicola Swain | Non-lay (observational studies) | 01/07/2012 | 01/07/2014 | Present |
| Dr Martin Than | Non-lay (intervention studies) | 01/07/2012 | 01/07/2014 | Present |
| Dr Mathew Zacharias | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 11:00 am and welcomed Committee members, noting that apologies had been received from Mr Doug Bailey, Mrs Angelika Frank-Alexander, Dr Sarah Gunningham and Ms Gwen Neave.

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. Mrs Helen Walker confirmed her eligibility, and was co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 19 March 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **13/STH/28** |
|  | Title: | MIB-C |
|  | Principal Investigator: | Dr. Mary Berry |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 April 2013 |

Dr Berry 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 ethical issues

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

* The benefits of this study are very clear and the risks are well managed.
* The Committee queried the age of inclusion, does this include babies >35 weeks gestation?
* The Committee queried who would be carrying out the pharmacokinetic modelling and analysis of samples. Dr Berry clarified that the PhD student will be carrying out the pharmacokinetic modelling and the blood samples will be analysed in Newcastle.
* The Committee requested evidence of independent favourable peer review.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* format of page numbering to be ‘1 of 4’ so participants can ensure they have received all pages,
* be clear that the blood samples (plasma) will be sent overseas and acknowledge cultural sensitivities this may raise,
* review typographical and punctuation errors in the title and through the document,
* consent form should be titled ‘Consent Form for Parents/Guardians’,
* prefer the term ‘NICU’ rather than ‘nursery’,
* it is only necessary to include the national Health and Disability Advocacy number (0800 555 050 or advocacy@hdc.org.nz),
* suggest using the following ACC compensation statement: “If you were injured in this study, which is unlikely, you would be able to apply for compensation from ACC just like if you were injured in an accident at work or at home. 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”,
* remove information related to PhD student on page 2.

Decision

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

* Please provide evidence of favourable independent peer review of the study (*Ethical Guidelines for Intervention Studies* Appendix 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*).

This following information will be reviewed, and a final decision made on the application, by the Chair and Dr Mathew Zacharias.

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| **2** | **Ethics ref:** | **13/STH/29** |
|  | Title: | Levetiracetam neonatal seizure treatment trial |
|  | Principal Investigator: | Dr Cynthia Sharpe |
|  | Sponsor: | Food and Drug Administration (FDA)US Department of |
|  | Clock Start Date: | 04 April 2013 |

Dr Cynthia Sharpe 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 ethical issues

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

* Dr Sharpe clarified to the Committee that the neurologist at each site will make the final decision as to when babies will receive treatment based on their EEG monitoring.
* The Committee queried how EEG data will be monitored. Dr Sharpe explained that the research team will remotely access EEG data on a computer rather than uploading the data to a server as difficulties with internet speed can cause delay.
* Dr Sharpe acknowledges that in an emergency setting it won’t always be possible for parents/guardians to consult with whānau, but researchers will be available to answer questions at any point during the study.
* Please note the data should be kept for 10 years after the participants turn 16 years of age.
* Dr Sharpe clarified that the New Zealand site will not be involved in pharmacokinetic testing.
* Dr Sharpe clarified that parents/guardians will express interest in the study before being approached by fax/email for consent.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* labelled for ‘parent/guardian’ rather than ‘participant’,
* clarify that even though intravenous LEV is not currently FDA approved this study is supported and funded by the FDA,
* clarify the term ‘brain injury’ in page five.

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **13/STH/30** |
|  | Title: | A clinical trial to study the safety and efficacy of MK-1293 in comparison with Lantus in subjects with Type I diabetes |
|  | Principal Investigator: | Dr Simon Carson |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited |
|  | Clock Start Date: | 04 April 2013 |

Dr Carson 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 ethical issues

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

* For future applications please keep in mind that the plain brief summary in a1.5 and b.1.1 of the application form should be in lay language. It is essential that lay members of the Committee understand the information provided in the application form.
* The Committee noted this experimental drug has previously only been trialled in 24 healthy males.
* This study is mainly for the benefit of the manufacturer without benefit to participants and the Committee has noted that participants will not be reimbursed for their extensive time commitment.
* The Committee was not clear as to the purpose of the study and requested clarification on what are the expected benefits of MK-1293 in comparison to Lantus, as they both have the same amino acid sequence, physio-chemical properties and formulation.
* SCOTT review is pending.
* Please provide assurance of the independence of the Data Monitoring Committee. Please note that a randomised phase III study requires independent data monitoring (*Ethical Guidelines for Intervention Studies* *para 6.58*).
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* expand on the purpose of the study, if the drugs are similar why is this study being carried out?,
* include the following clause: *“I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy”*,
* clarify what the blood/samples are collected for (page 4),
* be clear that tissue samples will be sent overseas and acknowledge cultural sensitivities this may raise.

Decision

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

* Please clarify what are the expected benefits of MK-1293 in comparison to Lantus Committee (*Ethical Guidelines for Intervention Studies* *para 3.11*).
* Provide assurance of the independence of the Data Monitoring Committee (*Ethical Guidelines for Intervention Studies* *para 6.58*).
* 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 the Chair.

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| **4** | **Ethics ref:** | **13/STH/31** |
|  | Title: | A clinical trial to study the safety and efficacy of MK-1293 in comparison with Lantus in subjects with Type II diabetes |
|  | Principal Investigator: | Dr Simon Carson |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited |
|  | Clock Start Date: | 04 April 2013 |

Dr Carson 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 ethical issues

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

* For future applications please keep in mind that the plain brief summary in a1.5 and b.1.1 of the application form should be in lay language. It is essential that lay members of the Committee understand the information provided in the application form.
* The Committee noted this experimental drug has previously only been trialled in 24 healthy males.
* This study is mainly for the benefit of the manufacturer without benefit to participants and the Committee has noted that participants will not be reimbursed for their extensive time commitment.
* The Committee was not clear as to the purpose of the study and requested clarification on what are the expected benefits of MK-1293 in comparison to Lantus, as they both have the same amino acid sequence, physio-chemical properties and formulation.
* SCOTT review is pending.
* Please provide assurance of the independence of the Data Monitoring Committee. Please note that a randomised phase III study requires independent data monitoring (*Ethical Guidelines for Intervention Studies* *para 6.58*).
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* expand on the purpose of the study, if the drugs are similar why is this study being carried out?,
* include the following clause: *“I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy”*,
* clarify what the blood/samples are collected for (page 4),
* be clear that tissue samples will be sent overseas and acknowledge cultural sensitivities this may raise.

Decision

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

* Please clarify what are the expected benefits of MK-1293 in comparison to Lantus Committee (*Ethical Guidelines for Intervention Studies* *para 3.11*).
* Provide assurance of the independence of the Data Monitoring Committee (*Ethical Guidelines for Intervention Studies* *para 6.58*).
* 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 the Chair.

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| **5** | **Ethics ref:** | **13/STH/32** |
|  | Title: | ZiPP Study |
|  | Principal Investigator: | Prof Tim Cundy |
|  | Sponsor: | The University of Edinburgh/NHS Lothian |
|  | Clock Start Date: | 04 April 2013 |

Professor Cundy 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.

Dr Mathew Zacharias declared a potential conflict of interest. The Committee did not require Dr Zacharias to leave the meeting room nor to abstain from the discussion.

Summary of ethical issues

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

* Paget’s disease of the bone is very rare in Māori and Pacific populations.
* The Committee discussed the use of placebo and queried if the preventative treatment is found to be effective will participants receiving the placebo be offered Zoledronic Acid.
* Please provide further details as to why this study (or a substantially similar study) was previously declined by an overseas ethics committee (a.7.3).
* The Committee does not consider it appropriate for this study to be covered by ACC and have noted a Clinical Trial Liability Insurance has been provided.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* the titles are confusing, please simplify these so they refer to the relevant part of the study rather than using part 1, part 2 and so on,
* include the following clause: *“I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy”*,
* remove the ACC compensation clause.

Decision

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

* Please clarify if the preventative treatment is found to be effective will participants receiving the placebo be offered Zoledronic Acid (*Ethical Guidelines for Intervention Studies* *para 5.13*).
* Please provide further details as to why this study (or a substantially similar study) was previously declined by an overseas ethics committee *(Standard Operating Procedures for Health and Disability Ethics Committees, para 40.4.8).*
* 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 the Chair.

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| **6** | **Ethics ref:** | **13/STH/33** |
|  | Title: | Acetazolamide and lihtium induced nephrogenic diabetes insipidus |
|  | Principal Investigator: | Professor Robert Walker |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 April 2013 |

Professor Robert Walker 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.

Mrs Helen Walker and Dr Mathew Zacharias declared a potential conflict of interest. The Committee did not require them to leave the meeting room nor to abstain from the discussion.

Summary of ethical issues

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

* The Committee made efforts to contact Professor Walker for discussion of this application.
* Adequate evidence of peer review has been provided.
* The Participant Information Sheet states that the study will not interfere with how lithium treats mood disorders. However, according to the data monitoring sheet, Acetazolamide increases lithium excretion due to impaired reabsorption of lithium in the proximal tube, therefore potentially decreasing the effect of lithium. Please clarify if additional monitoring of lithium absorption will be performed to ensure lithium concentration in participants remains stable during and after the end of the study.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* include information as to how frequently blood lithium levels will be checked,
* include the following ACC clause: *“If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. 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”*,
* participants must refrain from taking salicylate,
* please proof read for punctuation and formatting errors.

Decision

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

* Please clarify if additional monitoring of lithium absorption will be performed to ensure lithium concentration in participants remains stable during and after the end of the study (*Ethical Guidelines for Intervention Studies* *para 4.12*).
* 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 the Chair.

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| **7** | **Ethics ref:** | **13/STH/34** |
|  | Title: | COG ACNS1022 - Phase II Randomised Trial of Lenalidomide in Paediatric Patients with Recurrent, Refractory or Progressive Juvenile Pilocytic Astrocytomas and Optic Pathway Gliomas |
|  | Principal Investigator: | Dr Stephen Laughton |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 04 April 2013 |

Dr Sarah Hunter and Dr Mark Winstanley 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 ethical issues

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

* Dr Hunter clarified that counselling will provided to participants prior to each treatment cycle to ensure understanding and adherence to contraception requirements and pregnancy testing.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* use lay language in the flow diagram,
* the Information Sheet for 7-12 year olds to be reworded to be more age appropriate.

Decision

This application 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:

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| **Meeting date:** | 21 May 2013, 12:00 PM |
| **Meeting venue:** | Heartland Hotel Cotswold, 88-96 Papanui Road, Christchurch |

The following members tendered apologies for this meeting.

Dr Mathew Zacharias.

The meeting closed at 3:00 pm.