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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 28 May 2013 |
| **Meeting venue:** | Deloitte House, 10 Brandon Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12.10pm | Confirmation of minutes of meeting of 23 April 2013 |
| 12:30–5:00pm | New applications (see over for details) |
|  | i 13/CEN/63  ii 13/CEN/64  iii 13/CEN/65  iv 13/CEN/67  v 13/CEN/68  vi 13/CEN/69  vii 13/CEN/70  viii 13/CEN/71  ix 13/CEN/72 |
| 5:00 – 5:15pm | General business:  Noting section of agenda |
| 5:15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 01/07/2012 | 01/07/2015 | Present |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2014 | Present |
| Mrs Gael Donoghue | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2014 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Lynne Russell | Non-lay (observational studies) | 01/07/2012 | 01/07/2014 | Present |

## Welcome

The Chair opened the meeting at 12:00 pm and welcomed Committee members, noting that no apologies had been received.

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 23 April 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **13/CEN/63** |
|  | Title: | Asenapine 1 x 10 mg bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Alembic Pharmaceuticals Limited |
|  | Clock Start Date: | 16 May 2013 |

Dr Noelyn Hung, Dr Cheung-Tak Hung and 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 ethical issues

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

* The Committee queried why Māori Consultation with Ngai Tahu is not possible. The Committee feels the acknowledgement and understanding of cultural issues (p.4.1 and p.4.2) is lacking, specifically in reference to how the study may benefit Māori (inclusion is not a benefit). Please refer to the HRC Guidelines for Researchers on Health Research Involving Māori*.*
* The Committee queried if it is routine to contact participant GPs. Dr Hung clarified that this is not routine unless the screening tests raise an abnormal result. The Committee commented on the wide exclusion criteria and consider that some participants may not disclose all medical history; hence it would be important to contact the GPs prior to beginning the study.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* remove references to the Southern Health and Disability Ethics Committee,
* please make section of risks more succinct and less repetitive,
* participants will be able to request the return of their remaining tissue samples after the study; this should also be an option on the consent form that participants can tick,
* include Māori support contact details.

Decision

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

* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).
* 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 Gael Donoghue and Mrs Helen Walker.

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| **2** | **Ethics ref:** | **13/CEN/64** |
|  | Title: | REnal SymPathECTomy in Heart Failure (RESPECT-HF) |
|  | Principal Investigator: | Professor Mark Richards |
|  | Sponsor: | Medtronic International Ltd |
|  | Clock Start Date: | 16 May 2013 |

Associate Professor Richard Troughton 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.

* This study involves renal denervation *vs*. standard practice for participants with “stiff hearts”.
* The Committee noted that researchers are currently seeking HRC funding for this study.
* The Committee queried if this study will involve setting up a new tissue bank (r.3.1). Associate Professor Troughton clarified that plasma would be kept in an existing tissue bank. Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research.
* Please note that if advertisements are used to recruit participants these advertisements must first be submitted to the Committee for review.
* The Committee raised the issue of patient confidentiality, as potential participants will be identified from the hospital management system (p.3.1). Associate Professor Troughton explained that participants will mostly be identified by word of mouth (from ED staff and cardiologists), as well as access to admission details.
* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* include information about radiation exposure,
* include inclusion and exclusion criteria in lay language,
* clearer explanation as to what the standard treatment is (for control group),
* the safety record of the method extends to about 5 years post-procedure, please clarify to participants that there may be unknown long term side effects,
* inform that Māori participants will be offered the choice of disposal of any remaining tissue samples after the study with a karakia,
* include Māori support contact details.

Decision

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

* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).
* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* 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 Dr Dean Quinn and Dr Angela Ballantyne.

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| **3** | **Ethics ref:** | **13/CEN/65** |
|  | Title: | Hospital readmission after Neonatal Intensive Care |
|  | Principal Investigator: | Dr Susan Joubert |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 May 2013 |

Dr Phil Weston 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 Committee discussed the lack of consent and consider this is appropriate as seeking consent could cause necessary anxiety to parents, may prejudice the scientific validity of the study (as a representative sample of the population is required), there would be no disadvantage to participants or relatives and the public interest in the study outweighs the public interest in privacy (*Ethical Guidelines for Observational Studies* *para 6.43*).
* Please provide evidence of favourable independent peer review (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Please provide more information as to how data confidentiality will be protected (i.e. locked filing cabinets, password protected etc.) (*Ethical Guidelines for Observational Studies* *para 8.3*).

Decision

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

* Please provide evidence of favourable independent peer review (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Please provide more information as to how data confidentiality will be protected (i.e. locked filing cabinets, password protected etc.) (*Ethical Guidelines for Observational Studies* *para 8.3*).

This following information will be reviewed, and a final decision made on the application, by Dr Angela Ballantyne.

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| **4** | **Ethics ref:** | **13/CEN/67** |
|  | Title: | LCH-IV |
|  | Principal Investigator: | Dr Scott Macfarlane |
|  | Sponsor: | Monash Institute of Medical Research |
|  | Clock Start Date: | 10 May 2013 |

Dr Tim Prestidge and Ms Paula Murray 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.

* Due to the complexity of the disease presentation and outcomes the participants will be allocated to the different strata of the study according to how they present and how well they respond to treatment.
* The Committee queried the criteria for terminating the study (r.1.6).
* The Committee queried the incidence of LCH in Māori vs. non-Māori. Dr Prestidge explained that there is no clear trend that indicates a difference in the prevalence of this disease among Māori and non-Māori.
* The Committee requested the following changes to the Participant Information Sheet and Consent/Assent Forms:
* please refer to the ACC Act 2001 rather than its previous title,
* please provide age appropriate information sheets and assent forms for participants aged 7-11,
* please simplify the participant information sheets and assent forms for participants aged 12-15 (use age appropriate language).

Decision

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

* Please provide information regarding the criteria for terminating the study (*Ethical Guidelines for Intervention Studies* *para 6.64*).
* Please provide age appropriate information sheets and assent forms for participants aged 7-11 and amend the existing information sheets and assent/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 Dr Patries Herst and Mr Paul Barnett.

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| **5** | **Ethics ref:** | **13/CEN/68** |
|  | Title: | Parenting Whispering: Parent-Child Interaction Therapy in New Zealand |
|  | Principal Investigator: | Mrs Tania Anne Cargo |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 May 2013 |

Mrs Tania Anne Cargo 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 ethical issues

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

* This is a very worthwhile study and the Committee commended Mrs Cargo on such a well written application.
* Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **13/CEN/69** |
|  | Title: | Flixene Silver Registry |
|  | Principal Investigator: | Mr Thodur Vasudevan |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 May 2013 |

The CI 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 a.1.5 of the application form should be in lay language. It is essential that lay members of the Committee clearly understand the information provided in the application form.
* Due to repeated needle punctures patients undergoing dialysis tend to develop infections. This study aims to assess the infection and complication rates when using the Flixene Silver vascular graft (silver is known to have antimicrobial properties).
* Please ensure Māori Consultation is sought. As a general rule, consultation should take place if Māori are to be involved as participants in a project or the project relates to a health issue of importance to Māori (refer to the HRC Guidelines for Researchers on Health Research Involving Māori).
* Please provide evidence of independent peer review. Please refer to appendix 1 of the NEAC Guidelines for Intervention Studies for guidance on the features of robust peer review.
* The Committee does not consider it appropriate for this study to be covered by ACC, as the study is for the benefit of the manufacturer. Please clarify the involvement of the manufacturer in this study (regarding design, funding, monitoring, publication of results, termination etc.)
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* include inclusion and exclusion criteria,
* please refer to the Central Health and Disability Ethics Committee.

Decision

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

* Please provide evidence of independent peer review (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Please clarify the involvement of the manufacturer in this study.
* 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 Gael Donoghue and Mr Paul Barnett.

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| **7** | **Ethics ref:** | **13/CEN/70** |
|  | Title: | A study to investigate the duration of the effects of an investigational treatment for asthma on lung function |
|  | Principal Investigator: | Professor Richard Beasley |
|  | Sponsor: | GlaxoSmithKline |
|  | Clock Start Date: | 16 May 2013 |

Dr Sharon Power and Dr James Fingleton were 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 ethical issues

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

* The Committee noted SCOTT approval has been granted for this study.
* The Committee queried the lack of a Data Safety Monitoring Committee (r.1.5). Dr Fingleton clarified that this is due to the short duration of the study (72 hours as opposed to an on-going study).
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* include a heading (i.e. Participant Information Sheet and Consent Form),
* include the inclusion and exclusion criteria,
* be clear as to what lifestyle restrictions will be in place (i.e. the duration participants must abstain from caffeine and alcohol),
* include specific details regarding the need for contraception,
* include specific details of participant remuneration,
* please include a compensation clause (for guidance refer to the Participant Information Sheet and Consent Form template available on www.ethics.health.govt.nz).

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 Dr Dean Quinn and Dr Lynne Russell.

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| **8** | **Ethics ref:** | **13/CEN/71** |
|  | Title: | The effect of remote ischaemic preconditioning on the late immune response and nervous system. |
|  | Principal Investigator: | Ms Jenni Williams |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 16 May 2013 |

Ms Jenni Williams and Associate Professor Anne La Flamme were 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 ethical issues

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

* The Committee noted that this study does not involve the establishment or maintenance of a tissue bank as was initially stated in the application form.
* The Committee noted that approval was granted from the Wellington Medical Research Foundation, who has conducted peer review. The Committee requested a copy of the funding approval.
* The Committee queried why ethnicity data will not be collected and suggested this is done. Ms Williams explained that based on the sample size this would not be statistically significant, but this can be collected as per the Committee’s suggestion.
* The Committee raised the issue of Maori Consultation. Please note that as a general rule, consultation should take place if Māori are to be involved as participants in a project or the project relates to a health issue of importance to Māori (refer to the HRC Guidelines for Researchers on Health Research Involving Māori).

Decision

This application was *approved* by consensus.

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| **9** | **Ethics ref:** | **13/CEN/72** |
|  | Title: | Effect of early exercise engagement on the health of stroke patients |
|  | Principal Investigator: | Dr James Faulkner |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 16 May 2013 |

The CI 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.

* Research strongly suggests that rehabilitation of stoke patients should be started early, but there is limited evidence available to guide standard practice.
* If researchers intend to use tissue samples for future unspecified research then please provide a separate detailed participant information sheet (not only consent form) for the optional use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes)*.
* Please provide evidence of independent peer review. Please refer to appendix 1 of the NEAC Guidelines for Intervention Studies for guidance on the features of robust peer review.
* Please clarify what medical oversight will be available for the study.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* please clarify that whānau health information will also be collected during the study,
* include Māori support contact details.

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Please clarify what medical oversight will be available for the study (*Ethical Guidelines for Intervention Studies* *para 6.66*).
* 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 Sandy Gill and Dr Angela Ballantyne.

## 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:** | 25 June 2013, 12:00 PM |
| **Meeting venue:** | Terrace Conference Centre, 114 The Terrace, Wellington, 6011 |

No members tendered apologies for this meeting.

The meeting closed at 4:05 pm.