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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 18 June 2013 |
| **Meeting venue:** | Heartland Hotel Cotswold, 88-96 Papanui Road, Christchurch |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:10pm | Confirmation of minutes of meeting of 21 May 2013 |
|  | New applications (see over for details) |
|  | i 13/STH/52  ii 13/STH/53  iii 13/STH/54  iv 13/STH/55  v 13/STH/56  vi 13/STH/57  vii 13/STH/58  viii 13/STH/60  ix 13/STH/61  x 13/STH/62 |
|  | General business:  Noting section of agenda |
| 1.56pm | 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 | Present |
| 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 | Present |
| 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 |

## Welcome

The Chair opened the meeting at 11:51pm and welcomed Committee members, noting that apologies had been received from Dr Sarah Gunningham and Dr Martin Than.

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 21 May 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **13/STH/52** |
|  | Title: | ICON8 - Weekly Chemotherapy in Ovarian Cancer |
|  | Principal Investigator: | Dr Kathryn Chrystal |
|  | Sponsor: | University of Sydney |
|  | Clock Start Date: | 06 June 2013 |

Dr Peter Fong 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.

Dr Mathew Zacharias declared a potential conflict of interest, and the Committee decided to let Dr Zacharias contribute to the discussion and vote on the decision.

Summary of ethical issues

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

* The Committee noted the Independent Data Monitoring Committee in place to evaluate emerging safety data from this study.
* Please clarify the emergency procedures in place for serious adverse events.
* The Committee queried if the emergency card contact numbers were robust with 24/7 coverage. Dr Fong clarified that consultants will always be available to respond to the number on the card.
* The Committee suggested the study short title be above the main title on the PIS/CF.
* Please submit an updated emergency card as an amendment.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **13/STH/53** |
|  | Title: | 20120138 - Osler 2 |
|  | Principal Investigator: | Prof Russell Scott |
|  | Sponsor: | Amgen Australia |
|  | Clock Start Date: | 06 June 2013 |

Lainie Hanan, the sponsor, 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.

* The study is an extension study which analyses a novel drug.
* For future applications please ensure all peer review is listed in the application.
* Please ensure that the ‘Optional Use of Samples for Future Research’ is a separate document from the main study noting it requires its own header and Information Sheet.
* Please clarify which Maori health group the study was submitted to.
* In future applications please give more information about the Maori consultation process.
* The Committee noted that SCOTT review is pending.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please explain technical terms but not more than once i.e. ‘high cholesterol’.
* please use lay language when possible,
* the Committee suggests the first sentence remain in the **second** paragraph in 1a - but the rest of the paragraph is not required.

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **13/STH/54** |
|  | Title: | GadaCAD1 |
|  | Principal Investigator: | A/Professor Brett Cowan |
|  | Sponsor: | Bayer New Zealand Ltd |
|  | Clock Start Date: | 06 June 2013 |

Brett Cowan 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 study is an international FDA regulatory study.
* Please submit evidence of Maori consultation.
* The Committee queried the peer review noting that only the sponsor had reviewed the study. Associate Professor Cowan explained that he and his colleagues Professor Alistair Young and Associate Professor Christopher Occleshaw, experts in the field, had also provided peer review.
* In future applications please list all forms of peer review.
* The Committee queried what participant data will be published if participants withdraw from the study noting there is an inconsistency in the PIS relating to what happens to participant’s images. Associate Professor Cowan explained that participant data collected up until the withdrawal would be analysed unless the participant writes a letter to their doctor.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please review the language in the PIS to make it more accessible to participants,
* Please delete the requirement for participants to write a letter regarding the opt-out clause and reword to ensure the onus is on the research team.

Decision

This application was *approved*

Please submit an updated copy of the PIS for completeness.

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| **4** | **Ethics ref:** | **13/STH/55** |
|  | Title: | Paracetamol in febrile neutropenia feasibility study |
|  | Principal Investigator: | Dr Robert Weinkove |
|  | Sponsor: | Malaghan Institute of Medical Research |
|  | Clock Start Date: | 06 June 2013 |

Dr Robert Weinkove 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.

* The study is a feasibility study.
* Current practice results in an approximate 50/50 chance of being treated for fever with Paracetamol. The study aims to control the variables to generate empirical evidence to determine if treatment is effective.

Decision

This application was *approved* by consensus.

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| **5** | **Ethics ref:** | **13/STH/56** |
|  | Title: | Genetic studies of malformation disorders |
|  | Principal Investigator: | Professor Stephen Robertson |
|  | Sponsor: | Otago University |
|  | Clock Start Date: | 06 June 2013 |

Professor Stephen Robertson 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 application is to extend approval for an existing study that has been conducted over the past 10 years.
* The application increases the number and type of genetic tests and procedures in the study.
* The genetic testing ranges from gene specific to full genome sequencing.
* The Committee queried how tissue will be disposed of. Prof Robertson clarified that an option to send tissue back to participants was available otherwise the tissue would be dissolved, adding that burying the tissue was not possible due to bio-security concerns.
* The Committee queried why results will be stored and published in an identifiable form (R.2.6). Prof Robertson explained that the disorders are very rare and the study results are of clinical use to the participants. Participants have the option of not having identifying information published alongside their genetic information.
* The Committee clarified that any patients recruited overseas would have the option of having the Participant Information Sheet translated to them, if required.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **13/STH/57** |
|  | Title: | Genetic background of susceptibility to Rheumatic Fever |
|  | Principal Investigator: | Professor Diana Lennon |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 June 2013 |

Pedro Azevedo 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 ethical issues

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

* Study aims to provide evidence that Rheumatic Fever has a genetic factor.
* Please ensure the data derived from the study is stored according to the [Health (Retention of Health Information) Regulations 1996](http://www.legislation.govt.nz/regulation/public/1996/0343/latest/DLM225616.html) (for at least 10 years).
* The Committee suggests amending the PIS/CF format and wording. Please refer to the PIS/CF template (http://ethics.health.govt.nz/).
* Please submit evidence of peer review.
* Please clarify the consent process for the control group.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please remove the expected length of time it will take to read,
* please remove the tick box option to opt out,
* Please remove statement ‘data will be held for 6 years’.

Decision

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

* + Please submit an updated PIS/CF taking into account the suggestions above (Ethical Guidelines for Intervention Studies para 6.22).
  + Please clarify the consent process for the control group.

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/58** |
|  | Title: | Enroll-HD |
|  | Principal Investigator: | Dr Richard Roxburgh |
|  | Sponsor: | CHDI Foundation |
|  | Clock Start Date: | 06 June 2013 |

Dr Richard Roxburgh 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.

* Please ensure the data derived from the study is stored according to the [Health (Retention of Health Information) Regulations 1996](http://www.legislation.govt.nz/regulation/public/1996/0343/latest/DLM225616.html) (for at least 10 years).
* Please upload a populated clean copy of the PIS/CF for completion.

Decision

This application was *approved* by consensus.

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| **8** | **Ethics ref:** | **13/STH/60** |
|  | Title: | Neuromodulation for Uncontrolled Hypertension |
|  | Principal Investigator: | Dr Mark Webster |
|  | Sponsor: | Valencia Technologies Corporation |
|  | Clock Start Date: | 06 June 2013 |

Dr Mark Webster 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 ethical issues

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

* The Committee queried if there is an Independent Data Monitoring Committee in place to evaluate emerging safety data from this study.
* Please submit evidence of peer review.
* Committee requested clarification on the process in place for removing the device.
* Queried who would be responsible if an SAE resulted in long term on-going pain.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please add tick boxes next to each point on the Consent Form.

Decision

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

* + Provide evidence of independent peer review.
  + Clarify process in place in the event that a device needs to be removed (by participant request, serious adverse event or unexpected termination to the trial).
  + Clarify the process in place for long term health consequences relating to the device and who will be responsible for any long term costs.
  + Please clarify if the Data Safety Monitoring Committee is independent to the sponsor, and if not please outline how conflicts of interest will be managed to avoid bias in the analysis of the data, and its role in monitoring participants in the long term (*Ethical Guidelines for Intervention Studies para 6.56*).
  + Please upload an updated copy of the PIS/CF taking into account the suggestions of 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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| **10** | **Ethics ref:** | **13/STH/62** |
|  | Title: | Determining if early ankle exercises are beneficial after ankle fracture surgery. |
|  | Principal Investigator: | Dr Alex Jae-Jin Lee |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 June 2013 |

Dr Alex Jae-Jin Lee was not 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.

* Committee acknowledged that the PIS/CF was concise.
* Please upload evidence of peer review.
* Committee suggested removing the interpreter box and replace with a tick box for “I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.”

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:** | 16 July 2013, 11:00 AM |
| **Meeting venue:** | Dunedin Airport |

The following members tendered apologies for this meeting.

Mrs Angelika Frank-Alexander

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 1:56pm