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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 21 May 2013 |
| **Meeting venue:** | Heartland Hotel Cotswold |

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| **Time** | **Item of business** |
| 12 noon  12:00–1:30pm | Welcome  Meeting with CDHB Research Committee |
|  | Confirmation of minutes of meeting of 16 April 2013 |
| 1:30 – 5:15pm | New applications (see over for details) |
|  | i 13/STH/37  ii 13/STH/38  iii 13/STH/39  iv 13/STH/40  v 13/STH/41  vi 13/STH/42  vii 13/STH/43  viii 13/STH/44  ix 13/STH/45 |
| 5:15 – 5:30pm | General business:  Noting section of agenda |
| 5:30 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 | Present |  |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |  |
| 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 | Apologies |  |

## Welcome

The Chair opened the meeting at 12:00 pm and welcomed Committee members, noting that apologies had been received from Mr Doug Bailey and Dr Mathew Zacharias.

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 16 April 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **13/STH/37** |  |
|  | Title: | Assessment of the investigational Hepatitis C drugs VX-135 and Daclatasvir, when taken in different doses by adult patients with Chronic Hepatitis C. |  |
|  | Principal Investigator: | Professor Edward Gane |  |
|  | Sponsor: | Quintiles Pty Limited |  |
|  | Clock Start Date: | 09 May 2013 |  |

Professor Edward Gane 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.

* Professor Gane expects that 95% of patients will be cured with this new combination of drugs. The cure rate with standard treatment is 40%.
* There is pre-clinical data to support 12 weeks treatment with VX-135.
* The Committee noted that samples taken during the study will be sent overseas for analysis in a central laboratory, as some of the assays are not able to be performed in New Zealand.
* The Committee queried if the $250 reimbursement for Pharmacokinetic sampling is in total or per visit.
* The Committee noted that the Data Safety Monitoring Committee is not independent to the sponsor and queried how conflicts of interest will be managed to avoid bias in the analysis of the data.
* The Committee noted that SCOTT review is pending.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* please mention the length of participation in section four “what would you participation involve?”,
* clarify there is only one visit required for pharmacokinetic sampling.

Decision

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

* 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 *Ethical Guidelines for Intervention Studies* *para 6.56*).
* 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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| **2** | **Ethics ref:** | **13/STH/38** |  |
|  | Title: | The PRECICE 8.5mm Study |  |
|  | Principal Investigator: | Mr John McKie |  |
|  | Sponsor: | Ellipse Technologies Inc. |  |
|  | Clock Start Date: | 09 May 2013 |  |

Dr Nigel Gilchrist, a co-investigator, 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 no extra risk compared to standard treatment.
* This study will be very beneficial to patients who have had amputations due to the Christchurch earthquake and the leg is not long enough for them to be fitted with a prosthetic limb.
* The Committee noted the peer review provided was not independent, as both reviewers have an involvement with Ellipse technologies. Please ensure independent peer review is sought.
* 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).
* Dr Gilchrist clarified that the distractions will be performed by the orthopaedic surgeon, but in some instances the participants may be taught how to do this themselves at home.
* The Committee discussed the safety of the device and remote control and queried if there is any external way the device can be triggered.
* The Committee suggested the following changes to the Participant Information Sheet and Consent Form:
* categorise risks and side effects as common, rare, long term etc.,
* use a lay title for the child assent form,
* remove “I am happy to take part in this study” on page one of the child assent form as this is covered on page two,
* it is not necessary for parents/guardians to also sign the assent form.

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **13/STH/39** |  |
|  | Title: | Telephone support after discharge from hospital |  |
|  | Principal Investigator: | Dr Claire Heppenstall |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 09 May 2013 |  |

Dr Claire Heppenstall 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 aims to evaluate the use of regular telephone follow up to identify risks in the elderly after discharge from hospital.
* The Committee noted that this study involves a vulnerable population group; however the elderly with dementia will be excluded from the study.
* The Committee queried what would happen if researchers are unable to contact the participant by phone and consider it would be important to contact the carer or GP in a case like this.
* The Committee suggests the following changes to the Participant Information Sheet and Consent Form:
* break up long paragraphs to make it easier to read,
* inform the participant that the carer will be informed of deterioration.

Decision

This application was *approved* by consensus.

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| **4** | **Ethics ref:** | **13/STH/40** |  |
|  | Title: | Middle Eastern Women's Health Study-Phase II |  |
|  | Principal Investigator: | Dr Pamela von Hurst |  |
|  | Sponsor: | Massey University |  |
|  | Clock Start Date: | 09 May 2013 |  |

Dr Pamela von Hurst 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 noted that Persian and Arab Muslim communities have been consulted and queried if this study would only target Arab Muslim women and exclude Christian and Jewish Middle Eastern women? Dr von Hurst clarified that this study would only target Arab Muslim as these women wear very conservative clothing (covered up) and as such have a higher risk of vitamin D deficiency due to lack of sun exposure.
* The Committee queried if there would be any resistance from the males in the Muslim community. Dr von Hurst explained that a pilot study has previously been conducted and there has been no resistance.
* The participants will be randomly assigned to receive 50.000 IU Vitamin D, 100.000 IU Vitamin D or placebo. Dr von Hurst clarified that for the scientific validity of the study it is important to maintain the placebo group, but after the study they will be recommending vitamin D treatment (and giving a referral letter to GP).
* The Committee noted that only female research staff will have contact with the participants.
* Please ensure that information arising from the study will be stored for 10 years after the end of the study, as per the [Health (Retention of Health Information) Regulations 1996](http://www.legislation.govt.nz/regulation/public/1996/0343/latest/DLM225616.html).
* Please modify the title to reflect that this study is conducted in Arab Muslim women in Auckland.

Decision

This application was *approved* by consensus.

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| **5** | **Ethics ref:** | **13/STH/41** |  |
|  | Title: | Vitamin D as an adjunct therapy in community acquired pneumonia |  |
|  | Principal Investigator: | Prof David Murdoch |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 09 May 2013 |  |

Professor David Murdoch and Dr Sandy Slow 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 queried if samples taken will be used for future unspecified research. Professor Murdoch confirmed that these samples would be used for future research into vitamin D (not for unspecified research) and these applications would be submitted for ethical review in due course.
* Professor Murdoch noted that pregnant and breastfeeding women will be excluded from the study.
* The Committee queried the time given for consent (1 hour) and considers this may cause undue pressure as some participants may need more time to discuss this study with family, whānau or friends. Professor Murdoch agreed this would be addressed.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* clarify that samples will be kept for future research into vitamin D only.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **13/STH/42** |  |
|  | Title: | PVI in spontaneously ventilating blood donors |  |
|  | Principal Investigator: | Dr Sam Grummitt |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 09 May 2013 |  |

Dr Grummitt 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 Committee noted that this study poses minimal risk to the healthy volunteers.
* Please clarify to participants that information arising from the study will be stored for 10 years after the end of the study, as per the [Health (Retention of Health Information) Regulations 1996](http://www.legislation.govt.nz/regulation/public/1996/0343/latest/DLM225616.html).

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **13/STH/43** |  |
|  | Title: | COG AEWS1031 A Phase III Randomised Trial in Non-metastatic Ewing Sarcoma |  |
|  | Principal Investigator: | Dr Amanda Lyver |  |
|  | Sponsor: | Children's Oncology Group |  |
|  | Clock Start Date: | 09 May 2013 |  |

Dr Lyver 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 Committee noted this study was well peer reviewed.
* There is an Independent Data Monitoring Committee in place to evaluate emerging safety data from this study.
* Overall the Committee considered this was a well written application and had no concerns.

Decision

This application was *approved* by consensus.

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| **8** | **Ethics ref:** | **13/STH/44** |  |
|  | Title: | Assessment of Tumour Mitotic Rate in Primary Cutaneous Malignant Melanomas ≤1mm in Thickness |  |
|  | Principal Investigator: | Dr Ben Tallon |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 09 May 2013 |  |

Dr Ben Tallon 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 main ethical issue discussed by the Committee is the use of stored human tissue for a purpose it was not initially submitted, without obtaining informed consent for this particular use. The Committee was concerned that informed consent would not be obtained from the patients, especially as this study may detect new or different information to what was initially reported to the patient. The Committee does not believe that the use of human tissue without consent has been adequately justified for this study and considers this does not align with the ethical guidelines (*Ethical Guidelines for Observational Studies* *para 6.43*).
* The Committee was not clear from the application if this would be categorised as observational research or an evaluation study (*Ethical Guidelines for Observational Studies* *para 6.43*).
* The Committee took all reasonable steps to contact Dr Ben Tallon and Dr Christina Shin to clarify these issues, but as contact was not possible the Committee could not approve this application based on the concerns listed above.

Decision

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

* The consent of participants should generally be obtained for using identified or potentially identifiable data for research (*Ethical Guidelines for Observational Studies* *para 6.42*).

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| **9** | **Ethics ref:** | **13/STH/45** |  |
|  | Title: | An RCT on efficacy and safety of micronutrients for the treatment of ADHD in children |  |
|  | Principal Investigator: | Assoc Prof Julia Rucklidge |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 09 May 2013 |  |

Assoc Prof Julia Rucklidge and Jenny Johnston 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.

* 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.
* Associate Professor Chris Frampton is listed as a co-investigator in the study and therefore should not be used provide peer review. Please provide evidence of independent peer review.
* The Committee queried if there is any evidence of the safety of these nutritional supplements in children. Julia Rucklidge clarified that there have been several studies of micronutrients in children and these have shown no risks.
* The Committee recommends discussing this study with psychiatric emergency services so they are aware of the study in case a participant presents with emergency behavioural deterioration.
* The Committee queried if the participant’s GP will be informed of abnormal blood results. Julia Rucklidge confirmed this would be the case.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* include 24 hour emergency contact number (mobile),
* in the child assent form clarify that questionnaires will also be administered.

Decision

This application was *approved* by consensus.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. Suggestions to the screening questions:

* Question E to list tissue from small to large (mucus/sputum/urine to whole body parts)
* Question F use wording “Does one of the above apply?”
* Question I to link to the TGA PDF rather than the website

1. Suggestions to the Participant Information Sheet and Consent Form templates:

* Participants will be informed of any unexpected / abnormal results

1. The Committee met with the CDHB Research Committee and discussed the following issues:

* Low researcher attendance to the Southern HDEC Committee meetings despite efforts to host meetings at the DHBs and universities. The Chair is to send a letter to research offices in the South Island to encourage attendance.
* The requirement for research studies with medical devices categorised as class II or above to be submitted to the HDECs for ethical review.
* The HDECs to implement a peer review template to standardise and clarify what is required.

1. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 18 June 2013, 12:00 PM |
| **Meeting venue:** | Heartland Hotel Cotswold, 88-96 Papanui Road, Christchurch |

Mr Doug Bailey tendered his apologies for this meeting.

The meeting closed at 4:05 pm.