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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 18 February 2014 |
| **Meeting venue:** | New Zealand Blood Service, 87 Riccarton Road, Riccarton |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 17 December 2013 |
| 12.30pm | New applications (see over for details) |
| 3.00pm | i 13/STH/170  ii 14/STH/7  iii 14/STH/8  iv 14/STH/10  v 14/STH/11  vi 14/STH/12  vii 14/STH/14 |
| 3.05pm | General business:   * Noting section of agenda |
| 3.15pm | 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 |
| 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 | 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 | Apologies |
| Dr Mathew Zacharias | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Dr Sarah Gunningham, Ms Gwen Neave and Dr Matin 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 17 December 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **13/STH/170** |
|  | Title: | Prostate Cancer Imaging Study |
|  | Principal Investigator: | Professor David Lamb |
|  | Sponsor: | University of Otago, Wellington |
|  | Clock Start Date: | 07 November 2013 |

Professor David Lamb 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 noted all requirements set out as provisional conditions were addressed by the response.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **14/STH/7** |
|  | Title: | Innovative assessment of myocardial architecture in congenital heart disease |
|  | Principal Investigator: | Dr. Beau Pontré |
|  | Sponsor: | the University of Auckland |
|  | Clock Start Date: | 06 February 2014 |

Dr. Beau Pontré 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 queried how many samples were going to be tested. Please send a cover letter to HDEC to clarify.
* The Committee queried whether tissue samples from 1980s onwards have consent.
* The Committee discussed the use of the samples.

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **14/STH/8** |
|  | Title: | Enzalutamide |
|  | Principal Investigator: | Associate Professor Peter Gilling |
|  | Sponsor: | Astellas Pharma Global Development (APGD), Inc |
|  | Clock Start Date: | 06 February 2014 |

Ass prof. Peter Gilling 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 the discrepancies in the application relating to withholding standard treatment. The Committee stated the study does not withhold standard treatment as everyone gets the study drug and even though the study is not approved in New Zealand it is at post-market in the United States. Please note for future applications.
* Information about the DSMC information is not clear on the application. Please clarify what the internal monitoring committee will be monitoring. Please clarify if the internal DSMC is independent.
* The Committee noted there is no ionising radiation involved in the procedures for this study.
* The Committee noted the study has conditional SCOTT approval. The Committee confirmed the conditions have been met and approval is now granted.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please include a statement in the PIS ‘what will happen to my samples’ during the study. For example please include culturally appropriate methods of disposal, or explain explicitly that this service is not offered. I.e. some Iwi have strong beliefs about who owns tissue and how it is destroyed.
* The Committee noted there are formatting issues and sentence structure issues. Please review the PIS/CF for structure and formatting.
* Please explain to participants the aim of the study clearly. The current explanation is not accessible to lay participants and is confusing. The study aims to see whether the study drug will increase seizures in a patient population that may be more likely to have a seizure due to ‘certain conditions’. Please make these conditions clear to participants.
* Please describe the study drug at the beginning of the PIS.
* Please explain why the participant has been selected for this study at the beginning of the PIS.

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*).
* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*

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

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| **4** | **Ethics ref:** | **14/STH/10** |
|  | Title: | A Study of IPI-145 and Ofatumumab in Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Previously Enrolled in Study IPI-145-07 |
|  | Principal Investigator: | Dr Bart Baker |
|  | Sponsor: | Infinity Pharmaceuticals, Inc. |
|  | Clock Start Date: | 06 February 2014 |

Dr Bart Baker 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 a phase III study.
* The Committee noted a related study is still on-going.
* The Committee noted that the DSMC is set up for 14/STH/11 but not for 14/STH/10 (R.1.5). Please confirm what avenues and processes are in place to allow safety issues picked up in 11 but not for 10. Please explain the mechanism of safety oversight for 14/STH/10.
* The Committee noted ethical approval is already granted in Hungary, France and Spain.
* The Committee noted on B.4.3 states they will restrict study results, though also noted the study is on the World Health Organization database.
* The Committee queried whether the whole tissue block will be sent to the local lab, please confirm that samples will be destroyed after analysis rather than being sent back to the tissue bank.
* The Committee suggests using two forms of contraception. (insert standard pregnancy paragraph).
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The Committee noted the PIS was very long and had a low Fletch score.
* The Committee commended the bullet points on page 2.
* Please include a statement in the PIS ‘what will happen to my samples’ during the study. For example please include culturally appropriate methods of disposal, or explain explicitly that this service is not offered. I.e. some Iwi have strong beliefs about who owns tissue and how it is destroyed.
* Pg.2 of 24 – please make both options seem similar. Third paragraph down – please state that drug is not approved in any country, for consistency (as the following paragraph states the study drug is not available in New Zealand).
* Please remove the interpreter box.

Decision

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

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| **5** | **Ethics ref:** | **14/STH/11** |
|  | Title: | A Study of IPI145 versus Ofatumumab to treat Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma |
|  | Principal Investigator: | Dr Bart Baker |
|  | Sponsor: | Infinity Pharmaceuticals, Inc. |
|  | Clock Start Date: | 06 February 2014 |

Dr Bart Baker 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 a phase III study.
* The Committee noted a related study is still on-going.
* The Committee noted that the DSMC is set up for 14/STH/11 but not for 14/STH/10 (R.1.5). Please confirm what avenues and processes are in place to allow safety issues picked up in 11 but not for 10. Please explain the mechanism of safety oversight for 14/STH/10.
* The Committee noted ethical approval is already granted in Hungary, France and Spain.
* The Committee noted on B.4.3 states they will restrict study results, though also noted the study is on the World Health Organization database.
* The Committee queried whether the whole tissue block will be sent to the local lab, please confirm that samples will be destroyed after analysis rather than being sent back to the tissue bank.
* The Committee suggests using two forms of contraception. (insert standard pregnancy paragraph).
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The Committee noted the PIS was very long and had a low Fletch score.
* The Committee commended the bullet points on page 2.
* Please include a statement in the PIS ‘what will happen to my samples’ during the study. For example please include culturally appropriate methods of disposal, or explain explicitly that this service is not offered. I.e. some Iwi have strong beliefs about who owns tissue and how it is destroyed.
* Pg.2 of 24 – please make both options seem similar. Third paragraph down – please state that drug is not approved in any country, for consistency (as the following paragraph states the study drug is not available in New Zealand).
* Please remove the interpreter box.

Decision

This application was *approved* by consensus with non-standard conditions. Please provide a cover letter addressing the DSMC processes and updated PIS/CF.

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| **6** | **Ethics ref:** | **14/STH/12** |
|  | Title: | Oraxol PK Study |
|  | Principal Investigator: | Dr Christopher Jackson |
|  | Sponsor: | Kinex Pharmaceuticals Inc |
|  | Clock Start Date: | 06 February 2014 |

Dr Christopher Jackson (T/C), Mr Tony Mann (in person), Doug Kramer (T/C), Tek Hung (T/C) were present in person/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 a bioequivalence crossover study to assess if administration of Oraxol PK through oral consumption is as good as IV.
* Participants will have a dosing period, one week apart. Participants will have either the tablet or the IV drip.
* The Committee noted the inpatient stays are quite long, in particular for sick participants.
* Please explain how patients are transferred between locations and what safety measures are in place. Dr Hung explained it would be either Taxi or special car, with a member of the study team with them to ensure safety.
* Please include information for participants regarding when randomisation occurs. Dr Hung explained that it is not really randomised for the participants or study doctors, only the analyst. The Committee queried if it was on day -1 to know which administration they would receive first. Dr Hung confirmed.
* The Committee noted that the PIS/CF are overly complicated, with unnecessary repetition and appear to be written from a researcher point of view and not a participant’s perspective. This is a note for future applications. Dr Hung explained the sponsor had provided the PIS, adding it was approved by the FDA, but was happy to simplify where possible. The Committee suggested discussing future PIS/CF with the Dunedin based Committee member, Dr Nicola Swain.
* The Committee queried if participant’s bloods would be checked on day 8 before they went on round 2 of study drug, noting to be eligible they had to have adequate haematology stats.
* The Committee noted the usual drug schedule for this drug is three weekly. There are other regimes that use it weekly but they are not approved in New Zealand to the Committees knowledge.
* Please clarify that, due to the space between the first and second dose is only 8 days. Will their pre-dose haematology be tested before the second dose to ensure patient safety.
* Dr Hung explained that all normal procedures for people will apply in this study. The cell count will be checked, before being treated. The Committee confirmed the cycle will be delayed for 1 week if the participant’s bloods are not safe to re-dose.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The Committee requested the length of the stays is made explicit and is earlier in the PIS. Be clear about what is required to participate in the study and where they will stay i.e. 4-5 stays.
* Please include a statement in the PIS ‘what will happen to my samples’ during the study. For example please include culturally appropriate methods of disposal, or explain explicitly that this service is not offered. I.e. some Iwi have strong beliefs about who owns tissue and how it is destroyed.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **14/STH/14** |
|  | Title: | Voriconazole 200 mg bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 06 February 2014 |

Mrs Linda Folland and Dr Tek Hung 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 requested the following changes to the Participant Information Sheet and Consent Form:
* Please remove the first sentence of third paragraph (under Risks).

Decision

This application was *approved* by consensus.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee discussed the structure and layout of the decision letters, noting that it would be beneficial to have points distinguished between, for instance action points, points of discussion (that were resolved during the meeting) and requirements for approval. The Secretariat will discuss with the HDEC manager and find the most appropriate format.
3. Page 2 of 24 – Committee suggested using the bullet point wording relating to principals of the study relating to participants.
4. The Committed discussed bringing new ideas and standards to the Chairs meeting to implement across the board. For example the consent form and the non-optional conditions.
5. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 18 March 2014, 12:00 PM |
| **Meeting venue:** | New Zealand Blood Service, 87 Riccarton Road, Riccarton |

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 2.10pm