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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 27 November 2012 |
| **Meeting venue:** | Sudima Hotel, 550 Memorial Ave, Christchurch |

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| **Time** | **Item of business** |
| 12noon | Welcome |
|  | Confirmation of minutes of meeting of 30 October 2012  Introduction by NEAC |
|  | New applications (see over for details) |
| 1:00 – 1:30pm | 12/STH/42 (Sarah/Angelika) |
| 1:30 – 2:00pm | 12/STH/30 (Nicola/Gwen) |
| 2:00 – 2.30pm | 12/STH/45 (Doug/Angelika) |
| 2:30 – 3:00pm | 12/STH/47 (Mathew/Sarah) |
| 3:00 - 3:30pm | 12/STH/43 |
|  | General business:  Noting section of agenda |
| 4pm | 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 | Present |
| Mrs Angelika Frank-Alexander | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Apology |
| 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 | Apology |
| Dr Mathew Zacharias | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 12.03pm and welcomed Committee members, noting that apologies had been received from Martin Than and Angelika Frank-Alexander.

The Chair welcomed Andrew Hall from NEAC. Andrew outlined the role of work programmes of NEAC. Members discussed the helpfulness of the new amended guideline publications; the committee noted their concerns regarding researcher’s understanding of peer review and advised that this will be discussed at the upcoming HDEC Chair’s meeting.

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 30 October 2012 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **12/STH/30** |
|  | Title: | A study to establish safety tolerability pharmacokinetics pharmacodyna |
|  | Principal Investigator: | Dr Christian Schwabe |
|  | Sponsor: | Boehringer Ingelheim Pty Limited |
|  | Clock Start Date: | 18 October 2012 |

Dr Chris Wynne was present in person and Dr Christian Schwabe 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 they had two concerns about the Phase 2 process:  
  - when will the patients be recruited for phase 2?  
  - will you be using the same patient information sheet?
* The committee noted that any additional information needs to be in the information sheet at the end of the Phase 1 study, participants need to be notified of any serious issues before beginning Phase 2 of this study.
* The committee asked that the researcher notify the ethics committee of the results of Phase 1.

Decision

This application was approved.

• The committee asked that the researcher notify the ethics committee of the results of the Phase 1 study.

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

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| **2** | **Ethics ref:** | **12/STH/42** |
|  | Title: | Vemurafenib with or without GDC-0973 in Locally Advanced or Metastatic |
|  | Principal Investigator: | Dr Mike McCrystal |
|  | Sponsor: | Roche New Zealand |
|  | Clock Start Date: | 15 November 2012 |

Dr Mike McCrystal 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 there was no cellphone number to contact any researchers in the application form.
* The committee suggested that changes be made to reference to funding of the drug in the Participant Information Sheet.
* The committee noted that the Participant Information Sheet was well written.
* Protection of 3rd parties – Will the partner’s receive the information sheet as well?

Decision

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

• The committee would like the researcher to add both these paragraph’s to the consent form:

*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.*

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

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| **3** | **Ethics ref:** | **12/STH/43** |
|  | Title: | A study of MK-5172 in combination with Ribavirin in patients with Geno |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | Merck Sharp & Dohme (Australia) Pty Limited |
|  | Clock Start Date: | 15 November 2012 |

Dr Ed Gane was present by teleconference for discussion of this application. This is a closed meeting.

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 benefits of this study.
* The committee commended the inclusion of 1.0 Trial Summary.
* The committee discussed the peer review question p.2.2.2.
* The committee discussed page 12 of the patient information sheet regarding study aids tokens of appreciation.
* The committee discussed the issue of 3rd party risk.

Decision

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

* The committee wants the removal of the paragraph regarding the study aids on page 12 of the patient information sheet.
* The committee requested more information of independent peer review.
* The committee would like the researcher to add both these paragraph’s to the consent form:

*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.*

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

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| **4** | **Ethics ref:** | **12/STH/45** |
|  | Title: | Relationship education and intellectual disability. |
|  | Principal Investigator: | Ms Cate Shields |
|  | Sponsor: | Southern District Health Board |
|  | Clock Start Date: | 15 November 2012 |

Ms Cate Shields 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.

* The committee discussed potential risks to the participants. Confirmation from the participant and researcher that an adequate management plan is in place for any adverse behaviour’s.
* The committee would like to see improvement of the two participant information sheets, one for the participant and one for the parent/guardian/or approved caregiver.
* Suggestion that these be re-written in the 3rd person.
* A assent form is required for participants where consent is signed by someone else and a consent form is required for participants who are capable of making their own decision.
* The committee noted that it will be helpful to the researcher to get statistical input for this study.

Decision

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

* The committee would like to see improvement of the two participant information sheets, one for the participant and one for the parent/guardian/or approved caregiver.
* A assent form is required for participants where consent is signed by someone else and a consent form is required for participants who are capable of making their own decision.

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

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| **5** | **Ethics ref:** | **12/STH/47** |
|  | Title: | OmneonTM - 018 |
|  | Principal Investigator: | Dr Helen Lunt |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited |
|  | Clock Start Date: | 15 November 2012 |

Dr Helen Lunt and Helen Heenan 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 discussed a previous side effect of anaphylaxis with the researcher.
* The committee noted that this was a very well written study.
* The numbering in the patient information sheet is incorrect.

Decision

This application was approved.

## General business

1. The Committee noted the content of the “noting section” of the agenda.

* Raewyn Idoine will be attending the Chair’s Meeting on the 30th of November 2012.

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

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| **Meeting date:** | 22 January 2013 |
| **Meeting venue:** | Dunedin Airport, Dunedin |

The meeting closed at 3.50pm