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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 16 July 2013 |
| **Meeting venue:** | Dunedin Airport |

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| **Time** | **Item of business** |
| 11.00am | Welcome |
| 11.00am | Confirmation of minutes of meeting of 18 June 2013 |
| 11.05am | New applications (see over for details) |
|  | i 13/STH/67  ii 13/STH/68  iii 13/STH/69  iv 13/STH/70  v 13/STH/71  vi 13/STH/78  vii 13/STH/84 |
| 1.15pm | General business:   * Noting section of agenda |
| 1.20pm | 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 |  |
| Brian Fergus (Co-opted) | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present via T/C |
| Mrs Angelika Frank-Alexander | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Apologies |  |
| 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 | Apologies |  |
| Dr Mathew Zacharias | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |  |

## Welcome

The Chair opened the meeting at 11.00am and welcomed Committee members, noting that apologies had been received from Sarah Gunningham, Angelika Frank Alexander and Martin Than.

The Chair noted that Brian Fergus (Chair, Northern A committee) had been co-opted for the 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 18 June 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **13/STH/67** |
|  | Title: | A clinical trial to study the safety and efficacy of linaclotide in participants with Irritable Bowel Syndrome with Constipation (IBS-C) |
|  | Principal Investigator: | Assoc. Prof Michael Schultz |
|  | Sponsor: | Covance New Zealand Limited |
|  | Clock Start Date: | 04 July 2013 |

Dr Michael Schulz 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 Linaclotide has been trialled overseas with no SAEs reported and is an approved drug in the US.
* The researcher clarified that research nurses will train participants on how to use the electronic diary.
* The Committee sought further information about whether negative study results would be published? The researcher will clarify this with the sponsor.
* The Committee questioned why there is no independent data safety monitoring committee established for this trial.
* The Committee noted that there is no evidence of peer review, but that the study will be reviewed by SCOTT.
* The researcher confirmed that some patients may have a colonoscopy if this is clinically indicated.
* The Committee noted that the medication will not be available after the trial.
* Māori consultation needs to be undertaken as part of the locality assessment process.

Decision

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

* Please make the following changes to the PIS (*Ethical Guidelines for Intervention Studies para 6.22)*.
* Please simplify the title. Provide a title in lay language.
* Please provide further information at p 8 of the PIS about female subjects (and partners) having to agree to and comply with birth control requirements.
* Please state in the PIS that blood will be sent to China for analysis and include this in the CF as a separate item. Please also state that samples will be destroyed and cannot be returned.
* Please ensure that the PIS is proof read and spell checked.
* Please justify why there is no independent data monitoring committee for this Phase III trial. (*Ethical Guidelines for Intervention Studies para 6.58).*
* Please advise what restrictions the sponsor may place on publication. (*Ethical Guidelines for Intervention Studies, paras 7.17-7.18).*

This information will be reviewed, and a final decision made on the application, by Gwen Neave and Sarah Gunningham.

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| **2** | **Ethics ref:** | **13/STH/68** |
|  | Title: | Phase 3, A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Elagolix in Subjects with Moderate to Severe Endometriosis-Associated Pain |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 04 July 2013 |

Dr Quinn 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 risks associated with the study medication – which include reduced oestrogen levels. The researcher will monitor this by giving participants a DEXA scan at baseline and at the six month follow up.
* The Committee questioned the teratogenicity of the study medication. – 2 patients had babies with birth defects. The Committee questioned how many patients got pregnant during study and therefore as a proportion how many of those babies were born with defects? The researcher agreed to seek further information and respond to this question.
* The Committee clarified that the sponsor is seeking to retain data for 50 years.
* The researcher clarified that the samples will be destroyed at the end of the study.
* Māori consultation needs to be undertaken as part of the locality assessment process.

Decision

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

* Please provide information about the percentage of patients who have had babies who were born with birth abormalities. (*Ethical Guidelines for Intervention Studies paras 3.8-3.11).*
* The text and footer of PIS merge, please make the footer smaller to make it more readable. (*Ethical Guidelines for Intervention Studies para 6.22).*

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

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| **3** | **Ethics ref:** | **13/STH/69** |
|  | Title: | MDV3100-14: PROSPER - Enzalutamide in non-metastatic CRPC |
|  | Principal Investigator: | Associate Professor Peter Gilling |
|  | Sponsor: | Medivation Inc. |
|  | Clock Start Date: | 04 July 2013 |

Associate Professor 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 commended the clarity of the PIS; the study requirements and potential side effects were clearly described. Similarly, Maori consultation was well addressed, and there were clear recommendations to participants to discuss the study with whanau.
* The Committee noted that the peer review was adequate.
* The Committee noted that information about compensation was sparse.
* Māori consultation needs to be undertaken as part of the locality assessment process.

Decision

This application was *approved* by consensus.

Please make the following minor amendments:

* Please make the following amendments to the PIS (*Ethical Guidelines for Intervention Studies para 6.22).*
* Reword the study title in lay language (for example as described in the opening paragraph).
* Please remove the section relating to interpreters.
* Please state in paragraph 17 that compensation will be in accordance with the RMI guidelines and state what types of compensation might be provided. Please insert the following wording:

“It is important that you tell your study doctor, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him or her at (insert contact details).

The Southern Ethics Committee has certified that this clinical trial is being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which this trial is being carried out. This means that if you suffer injury as a result of your participation, you will not be eligible for cover under accident compensation legislation. Compensation, however, will be provided by the sponsor in accordance with the “New Zealand Researched Medicines Industry Guidelines on Clinical Trials - Compensation for injury resulting from participation in Industry Sponsored Clinical Trials.”

These Researched Medicines Industry Guidelines are only guidelines and until your claim is assessed by the sponsor or the sponsor’s insurers of it cannot be said with any certainty exactly what type or amount of compensation you will receive if you suffer injury as a result of your participation, or what sort of injury will be covered. The guidelines require that compensation must be provided by the sponsor where the injury you suffer is serious and not just temporary and is one caused by the trial medicine or item or where you would not have suffered injury but for your inclusion in this trial.

The guidelines also require that the compensation you receive must be appropriate to the nature, severity and persistence of your injury. This means that you will be unlikely to receive compensation from the sponsor unless your injury is serious and not just temporary.

Compensation may also be dependent upon the likelihood of adverse reactions and warnings given, the risks and benefit of established treatments relative to those of the trial medicine and compliance with study directions.

You might not receive compensation from the sponsor if your injury was caused by the investigators, if there is a deviation from the proposed plan of research, or if your injury was caused solely by you. If you are injured as a result of the trial, but your injury was caused by the investigators (or the institution/hospital where the trial took place) or as a result of a deviation from the proposed plan of research, you will not be covered by ACC and may have to pursue a civil action against the investigators (or institution). Ethics committees require that researchers and their institution have indemnity cover for such risk.

You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.”

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| **4** | **Ethics ref:** | **13/STH/70** |
|  | Title: | Assessment of Tumour Mitotic Rate in Primary Cutaneous Malignant Melanomas ≤1mm in Thickness |
|  | Principal Investigator: | Dr Ben Tallon |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 July 2013 |

Dr Shin 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 questioned why the researchers did not plan to contact participants to seek their consent to using their tissue and asked the researcher to justify why she believed the requirement to seek consent was not needed.
* The researcher stated the study posed minimal risk for participants, and that resource constraints make contacting patients difficult and time consuming.
* The Committee acknowledged the challenges that time and resource constraints impose but said that this does not justify waiving the usual requirementtoseek consent.
* The researcher advised that she would minimize harm by re-contacting patients’ doctors if any previously unidentified condition was identified during the study. However she did not foresee identifying any previously unidentified condition.
* The Committee recommended that the researcher mails a PIS/CF to participants, giving them an opt-out option if they were not happy for their tissue to be used; or alternatively to reformulate the study as an audit which would not require approval.
* Māori consultation needs to be undertaken as part of the locality assessment process.

Decision

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

* The researchers responding to the Committee about how they will obtain participant consent and providing the necessary PIS/CF (*Ethical Guidelines for Observational Studies paras 6.10-6.18, 6.42, see also 6.43-6.47).*

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

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| **5** | **Ethics ref:** | **13/STH/71** |
|  | Title: | Capsular Repair after Arthroscopic Surgery of the Hip |
|  | Principal Investigator: | Doctor Matthew Brick |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 July 2013 |

Doctor Matthew Brick 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 PIS is too brief.
* The information in the PIS about the study indicates that one technique is superior to the other, the PIS should be more neutral about this. If the evidence clearly favoured one technique above the other there would be no equipoise and presumably no need to do the study.
* The Committee noted the absence of peer review.
* Māori consultation need to be undertaken as part of the locality assessment process.

Decision

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

* Please ensure that data is kept for 10 years. (*Health Information Privacy Code*).
* Please revise PIS and CF in accordance with templates on Online Forms. Please ensure you include site specific Maori advisory support contact details. (*Ethical Guidelines for Intervention Studies* *para 6.12*).
* Please revise the PIS to ensure it is more balanced in the presentation of both surgical techniques to reflect the need for equipoise. (*Ethical Guidelines for Intervention Studies, paras 5.18-5.21).*

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

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| **6** | **Ethics ref:** | **13/STH/78** |
|  | Title: | TRIO 022 |
|  | Principal Investigator: | Prof Bridget Robinson |
|  | Sponsor: | Pfizer New Zealand Ltd |
|  | Clock Start Date: | 04 July 2013 |

Professor Bridget Robinson 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 commended the researcher for presenting such a thorough application.

The Committee noted ethical approval for this study has been granted in US, and that this study is endorsed by TRIO and ANZBCTG.

The Committee noted that there are no unreasonable restrictions on publication.

The PIS/CF are clear.

Māori consultation needs to be undertaken as part of the locality assessment process.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **13/STH/84** |
|  | Title: | Optimising PEEP in mechanically ventilated patients |
|  | Principal Investigator: | Associate Professor Geoffrey Shaw |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 July 2013 |

Dr Shaw 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 need to seek (retrospective) informed consent from any participants who regain the capacity to consent.
  + Māori consultation needs to be undertaken as part of the locality assessment process.

Decision

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

* Please make the following changes to the PIS/ CF: (*Ethical Guidelines for Intervention Studies* *para 6.12*).
* Please amend the lay title of the PIS, ie this study is not about insulin treatment in the ICU.
* Please state in PIS that the patient may have already been enrolled in the study.
* Please revise the PIS/CF for patients who regain capacity to enable them to consent retrospectively. (*Ethical Guidelines for Intervention Studies* *Appendix*, p 53).

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

## 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:** | 20 August 2013, 12:00 PM |
| **Meeting venue:** | Heartland Hotel Cotswold, 88-96 Papanui Road, Christchurch |

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 1.20pm.