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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 20 August 2013 |
| **Meeting venue:** | Heartland Hotel Cotswold, 88-96 Papanui Road, Christchurch |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 16 July 2013 |
| 12.30pm | New applications (see over for details) |
|  | i 13/STH/87  ii 13/STH/89  iii 13/STH/90  iv 13/STH/91  v 13/STH/92  vi 13/STH/93  vii 13/STH/94  viii 13/STH/95  ix 13/STH/97  x 13/STH/100 |
| 3.00pm | 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 | 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 |
| 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 Sarah Gunningham.

The Chair welcomed Dr. Devonie Waaka to the Committee and each Committee member introduced themselves.   
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The Chair noted that there are four students’ observing today’s meeting from the University of Canterbury as a requirement for a Masters level Bio-ethics paper, supervised by their lecturer.

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 July 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **13/STH/87** |
|  | Title: | SB 9200 - Phase 1a/1b MAD Study SB 9200 in Treatment Naïve HCV |
|  | Principal Investigator: | Prof Murray Barclay |
|  | Sponsor: | Spring Bank Pharmaceuticals Inc |
|  | Clock Start Date: | 08 August 2013 |

Mr Matt Kepple 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 Devonie Waaka declared a potential conflict of interest. The Committee decided to allow Dr Waaka to remain in the meeting room and take a full part in the discussion and decision relating to the application.

Summary of ethical issues

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

* The application is for a Phase I intervention study involving first administration to humans to test a drug for treatment of Hepatitis C.
* The study is a multi-centre international study conducted in Christchurch clinical research organization.
* The purpose of the study is to determine the safety and side-effect tolerability of single and increasing doses of the study drug.
* The Committee noted that as it is a new medicine the study will be submitted to SCOTT for review.
* The Committee noted there are many ways the results plan to be published. The Committee queried whether the sponsors will restrict any publications and whether they would publish results and regardless of positive or negative outcomes. Mr Kepple clarified the sponsor is able to review publications but not stop publication, and that study results, positive or negative, will be published.
* The Committee queried whether the DSMC as independent. Mr Kepple confirmed the DSMC was independent.
* The Committee queried the lack of clear stopping criteria for the study. Mr Kepple stated there was nothing specific for the safety Committee to look for, as there were so few side effects in pre-clinical trials. The first in man was conducted in Australia with no SUSARS to date. The New Zealand study will continue to receive information from the Australian study. The DSMC will assess on-going risk and stop the study if required.
* The Committee queried whether there were any culturally appropriate methods of disposal in place for participants. Mr Kepple confirmed there is no plan in place for samples to be returned, and that there was no alternative to incineration.
* Mr Kepple stated that if a participant wanted a particular disposal of tissue the participant should not enrol.
* The Committee requested an amendment if study A (the Australian first in humans test with 8 participants) reveals information that would alter the PIS/CF for participants in part B.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please clarify how long participants will need to stay at the study centre, in lay language. Mr Kepple clarified that the period of time participants will need to stay will be confirmed once new data is received from study A,
* The Committee requested side effects to be explicitly stated, as side effects are referred to on page 7 of the PIS. This may include pre-study data observations that are relevant to participants – such as risk of liver damage.
* The Committee queried what scan was involved (pg.3 PIS). Researcher clarified it was a fibro scan. Committee requested this was made explicit in the PIS,
* Please change acetaminophen to Paracetamol,
* The Committee requested it was made clear to participants that the dosing in study B is stronger than all doses in study A, and is for multiple doses,
* Please make it clear that only 8 people have trialled the drug in study A,
* Please explain to participants what alternatives are available to them, if they were not to take part in this study,
* The Committee noted that participants may be refused access in any future therapeutic trials as some therapeutic trials will not allow participants to enrol if they have been involved in a non-therapeutic trial. Please make this clear to participants,
* Please review formatting, noting the footers are inconsistent.

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*).

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

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| **2** | **Ethics ref:** | **13/STH/89** |
|  | Title: | Homicide, mental illness and parole |
|  | Principal Investigator: | Dr Jeremy Skipworth |
|  | Sponsor: |  |
|  | Clock Start Date: | 08 August 2013 |

Dr Jeremy Skipworth 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 follow up to a national study that was started more than a decade ago. The prior study showed there was no increase of homicide committed by that the study population (people who had mental illness).
* The follow up study aims to determine the relationships between mental illness, homicide and parole.
* This study is to assess whether this group of people have appropriate access to rehabilitation and healthcare when in prison and consequently whether they have equal options for parole and access back into the community.
* Participants did not consent to take part in prior study.
* Dr Skipworth confirmed there was no interview element of this study.
* The Committee noted consent will not be sought for ‘participants’, noting there are no interviews or actual study participation.
* The study will view outcome data of parole applications for the participant groups, and further outcomes such as being sent back to prison.
* The Committee stated the Maori consultation was robust.
* Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **13/STH/90** |
|  | Title: | DEXA Analysis of Delta TT acetabular cups and HMAX stem. |
|  | Principal Investigator: | Mr William Farrington |
|  | Sponsor: | Lima Orthopaedics |
|  | Clock Start Date: | 08 August 2013 |

Mr William Farrington 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 clinical study to assess patients who have hip replacements for osteoarthritis.
* The study will look at primary hip replacements.
* The study will observe the bone density of where the artificial replacement is, and how this changes over time. Mr Farrington noted that few studies have looked ‘behind the socket’.
* There are 4-5 different hips for different patient requirements. The sockets for this study will be predominantly for patients between 55 and 70 years old.
* Participants are public patients. There will be no extra cost for participants.
* The Committee queried whether the study was for the primary benefit of the sponsor. Mr Farrington clarified that the study was not for the primary benefit, and that participants would have access to ACC.
* The hip replacement is being paid for by the DHB. Committee queried who would fund any potential complications. Dr Farrington clarified the DHB will fund complications.
* The DEXA scan is being paid for by the sponsor who manufactures the acetabular components.
* The Committee asked if there was a difference in cost between component providers. Mr Farrington responded that the cost of this company’s component is the same as 3 other companies who could provide components to the DHB.
* Please provide evidence of recent peer review, noting peer review submitted was from 2011 and was only valid for 12 months.
* Secretariat will forward information relating to what is required for peer review.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please include options outside of study participation to ensure the participants are fully informed of their options,
* Please review the PIS/CF and remove any Australian references e.g. HREC Secretariat pg. 6,
* Please make it clear to participants that the Southern Health and Disability Ethics Committee has reviewed the study, and include contact details (0800 4 ETHICS or hdecs@moh.govt.nz),
* Committee suggested reviewing the PIS/CF template, found at (<http://ethics.health.govt.nz/system/files/documents/pages/PISCF-templates-June3013.doc>), and making changes to formatting. Please proof read for completeness.

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*).
* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).

This following information will be reviewed, and a final decision made on the application, by Dr Mathew Zacharias and Ms Raewyn Idoine.

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| **4** | **Ethics ref:** | **13/STH/91** |
|  | Title: | Investigating Idelalisib with Bendamustine and Rituximab in previously treated Chronic Lymphocytic Leukemia |
|  | Principal Investigator: | Dr David Simpson |
|  | Sponsor: | PPD Global Ltd (NZ Branch) |
|  | Clock Start Date: | 08 August 2013 |

Dr David Simpson 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.

* Interventional study to assess safety and time to progression of disease of a combination of Idelalisib, Bendamustine and Rituximab to treat Chronic Lymphocytic Leukemia.
* Patients are randomized to receive study drug or placebo.
* Participants can stay on longer than the trial period of 48 weeks as long as there are no signs of toxicity.
* The Committee noted that if participants stop a standard treatment drug they are able to stay on the study drug.
* The Committee noted that this is access to a drug that is not available to New Zealand patients, as it is FDA approved but not Medsafe approved.
* Please clarify if researchers will be involved in standard care treatment.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please simplify the side effects section, for example refer to information if it has already been stated to avoid repetition,
* Please review formatting to ensure it is consistent throughout the document and to make it easier to read. For guidance on how to format for participant accessibility please see <http://ethics.health.govt.nz/system/files/documents/pages/PISCF-templates-June3013.doc>),
* Please add tick boxes to the Consent Form. Please see above link for example,
* Please include a pregnancy clause into the Consent Form. This can be the same as in the Patient Information Sheet,
* Note you do not need the interpreter box.

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*).
* Please clarify if the researchers are the potential participants doctor or health provider and whether there is a potential conflict of interest, if so how this will be addressed (*Ethical Guidelines for Intervention Studies* *para 6.3*).

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

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| **5** | **Ethics ref:** | **13/STH/92** |
|  | Title: | A Randomized, Open-Label Study Comparing the Combination of YONDELIS® andDOXIL®/CAELYX® With DOXIL®/CAELYX® Monotherapy for the Treatment of Advanced-Relapsed Epithelial Ovarian, Primary Peritoneal |
|  | Principal Investigator: | Dr Anne O'Donnell |
|  | Sponsor: | inVentiv Health Clinical |
|  | Clock Start Date: | 08 August 2013 |

Dr Anne O'Donnell 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 if the sponsor would place limits on publication, noting that the investigator will hold ‘all rights for all data’. Committee would be unable to approve this application unless the investigator will publish both positive and negative information as per (*Ethical Guidelines for Intervention Studies* *para 7.19*).
* The Committee noted the peer review was independent.
* The Committee noted there may be a cultural bias against Maori as there are no culturally appropriate methods to dispose of tissue which may prevent Maori from participating.
* The Committee queried if the researchers are the potential participants doctor or health provider and whether there is a potential conflict of interest, and if so how this will be addressed.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please address discrepancies between the section headings of the PIS and CF,
* Please review formatting to ensure it is consistent throughout the document and to make it easier to read. For guidance on how to format for participant accessibility please see <http://ethics.health.govt.nz/system/files/documents/pages/PISCF-templates-June3013.doc>),
* Please ensure the emergency contact number is explicitly stated and is available to contact 24 hours a day 7 days a week,
* Please quantify the risks numerically, rather than ‘most common’. I.e. how many fatalities out of 8 thousand,
* Add the statement from R.4.1.1 of the application to the PIS/CF to ensure participants are aware of the consequences for having a positive BRCA 1/2 test.

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*).
* Please clarify if the researchers are the potential participants doctor or health provider and whether there is a potential conflict of interest, if so how this will be addressed (*Ethical Guidelines for Intervention Studies* *para 6.3*).
* Please clarify for the Committee what publication restrictions will be in place for the study (*Ethical Guidelines for Intervention Studies* *para 7.19*).

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

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| **6** | **Ethics ref:** | **13/STH/93** |
|  | Title: | Long-term impact of brain injury |
|  | Principal Investigator: | Professor Valery Feigin |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 08 August 2013 |

Professor Valery Feigin 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:

* Study is to propose further monitoring for an on-going study.
* Study will seek full consent from participants.
* Study has low risk with high potential benefits.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please proof read,
* Please include what information and or questions will be asked of teachers,
* Please seek explicit consent to send data overseas,
* Please make it clear that health data pertaining to the child participants will be retained by the researcher for ten years after the child has attained the age of 16,
* Please clarify that it can be your own neurologist who can assist in accessing test results under ‘what are my rights’ in the parent or legal guardian PIS.

Decision

This application was *approved* by consensus.

Please email an updated PIS/CF to [HDECS@moh.govt.nz](mailto:HDECS@moh.govt.nz) for completeness.

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| **7** | **Ethics ref:** | **13/STH/94** |
|  | Title: | Cervical and Breast Screening for Women with Intellectual Disability |
|  | Principal Investigator: | Dr Brigit Mirfin-Veitch |
|  | Sponsor: | Frozen Funds Charitable Trust |
|  | Clock Start Date: | 08 August 2013 |

Dr Anna Paris 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.

* Study aims to gather data from a series of face to face interviews with women who have intellectual disabilities.
* This is primarily in response to a Ministry of Health report focusing women with intellectual disabilities that identified that this population group does not get sufficient access to screening for breast cancer or cervical smear tests. This study aims to identify barriers for this population group to access these services
* Study results will inform future practice to address the low percentage of uptake of these services for this population.
* Committee queried the sample size and study power. Researcher clarified that the ability to argue for a saturation point is difficult, as the women involved have very different health needs. The total will be up to 20 women, with 6 being key informant interviewers, or people conducting the screening.
* Committee queried rationale for excluding women who have had neither breast screening nor cervical smear. Researcher stated it was potentially more informing by asking the women who had had the tests, to hear their experiences and reasons. The study will generate useful information that will be disseminated to services to highlight that these services are not being accessed.
* Committee noted important information could be missed by not including the participant group who have not had either test. For instance, it may be an issue relating to the caregivers rather than the individuals or the women themselves may not be aware of the tests.
* Committee queried the composition of the peer review body that reviewed the study.

Decision

This application was *approved* by consensus.

Please email the composition of the peer review body to [HDECS@moh.govt.nz](mailto:HDECS@moh.govt.nz) for completeness.

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| **8** | **Ethics ref:** | **13/STH/95** |
|  | Title: | Suicide in Older New Zealanders |
|  | Principal Investigator: | Dr Gary Cheung |
|  | Sponsor: |  |
|  | Clock Start Date: | 07 August 2013 |

Gary Cheung 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.

* There is little suicide data on older people in New Zealand. The results would aide in suicide prevention, which is difficult to start without having statistics on this demographic.
* Regarding P.4.2, the Committee suggests talking with Maori university research ethics Committee members for guidance on cultural issues that may be raised during the study, noting there are more cultural issues than data de-identification.
* Committee queried the possible stigmatization from study publication for families. Researcher stated there are 250 people in the sample size. No individual data would be published.
* Committee queried whether any specific (particular) reporting would be published. Researcher confirmed families will be unable to identify a case, as data will be aggregate.
* Committee suggested any ‘unusual’ suicide methods would be group as ‘other’ to ensure potentially identifying information is not published.
* Committee queried what would occur if a GP refused to release confidential information. Researcher explained that GPs will be approached by phone, though at the end of the day of the GP is not comfortable releasing information then it is their choice. There will be no means taken to force the GP to release information.
* Committee suggested going through Primary Health Organisations to assist with data being released to ensure the study is representative of New Zealand as a whole.
* Committee queried if researchers would extract acute medical services, as older people may be admitted as an acute medical condition. Researcher clarified that he hopes GP electronic notes will include acute medical data and hospital admissions. Committee suggests you include accessing this broad range of data in your protocol for completeness.

Decision

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

* Please submit details (CV’s) of co-investigators for this study.
* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Please provide a letter or email from the Coroner approving release of reports.

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

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| **9** | **Ethics ref:** | **13/STH/97** |
|  | Title: | Evaluation of the IASD System II |
|  | Principal Investigator: | Professor Robert Doughty |
|  | Sponsor: | DC Devices, Inc. |
|  | Clock Start Date: | 08 August 2013 |

Professor Robert Doughty 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.

* Single arm interventional study to assess an implanted device which aims to reduce blood pressure in participants.
* The Committee noted the protocol was well designed.
* The study is an international study. Study aims to recruit 30 participants in New Zealand.
* The Committee queried whether researchers would be involved in patient care.
* The Committee requested clarification of measures in place to manage a potential conflict of interest in recruiting participants if researchers may be providing patient care.
* The Committee requested clarification about whether the researchers were using public or private facilities for screening and recruitment.
* Please provide more information on how frequently the study is being assessed by the DSMC.
* The Committee noted that there was no evidence of independent peer review. The Committee requested evidence of independent peer review (by appropriate experts who are parties free of conflict of interest in regards to sponsors and the researchers and or investigators).
* The Committee queried what measures were in place for removing the device in the future, as well as clarification about what long term follow up for participants was in place, in particular if there are any health problems.
* The Committee queried whether it was appropriate for participants to have the choice that their GP will not know of study involvement. Please clarify if these participants will these participants be enrolled in the study.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please be specific about the number of patients who have had the device implanted, and over what time period,
* Please make it clear to participants the risks involved with the anti-coagulants which are required to take part,
* Please include information about any SAE that have occurred in relation to this device, and if it was not specifically related to the device please explain this clearly,
* Please include a lay study title.

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*).
* Please clarify if the researchers are the potential participants doctor or health provider and whether there is a potential conflict of interest, if so how this will be addressed (*Ethical Guidelines for Intervention Studies* *para 6.3*).
* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Explain what plans are in place for long term follow up of participants.
* Provide information on how often the DSMC will review the study.
* Clarify whether participants who choose not to notify their GP will be enrolled in the study.

This following information will be reviewed, and a final decision made on the application, by Dr Devonie Waaka and Ms Raewyn Idoine.

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| **10** | **Ethics ref:** | **13/STH/100** |
|  | Title: | NORIBOGAINE THERAPY FOR RELIEF OF OPIOID WITHDRAWAL, PHASE IB (NITROW PIB) |
|  | Principal Investigator: | Professor Paul Glue |
|  | Sponsor: | DemeRx Inc |
|  | Clock Start Date: | 08 August 2013 |

Professor Glue 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. Nicola Swain declared a potential conflict of interest. The Committee decided to allow Dr Swain to remain in the meeting room and take a full part in the discussion and decision relating to that item of business.

Summary of ethical issues

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

* The study is the third in the series of three studies looking at use of a drug called NORIBOGAINE to treat opiate withdrawal symptoms from methadone.
* This study is informed by confirmed toxicology reports from past studies.
* Study will see whether the estimate dose of 120 – 240ml a day will prevent opiate withdrawal symptoms.
* Population group are healthy. Up to 70% will have hepatitis C due to the target population group.
* Patients are followed up for three months after completing the treatment.
* The study has an independent DSMC
* The committee queried what plan was in place if a participant started using opiates again. Professor Glue explained that if participants indicate they want to use opiates again they will be referred to the methadone treatment programme.
* Committee queried the amount of blood being drawn, 670ml over ~9 days. Professor Glue responded that there were no concerns that participants would become anaemic. The researcher added there was an intensive screening process as well as extensive follow up, participants are seen twice daily and closely monitored.
* Committee queried the QTC effect monitoring in place. Professor Glue stated that there is 24 hour Holter monitoring and this data being analysed by a US group who are specialists in this area.
* There is a GE healthcare state of the art monitor for this study. Regular assessment will be undertaken. Assistance will be on hand if any individuals had dangerous QTC readings.
* The Committee queried if there had been a relationship formed with Otago District Health Board to deal with any major problems. Professor Glue clarified that ODHB was fully aware of the study being conducted and could assist with any problems.
* Committee queried whether the 19 cases of death reported in the literature following the use of ibogaine, and whether this had any impact on the study of noribogaine.
* Professor Glue stated the reasons for death were health related, though it can be difficult to distinguish between disease, study drug and other factors. Professor Glue noted these instances were in non-clinical settings such as lay detox centres and the instances where study drug resulted in death had far higher doses than that proposed in this study.
* The Committee commended the peer review, noting the study was also going to SCOTT.
* The Committee was satisfied that the compensation was in vouchers rather than money.
* The Committee queried the specific nature of reasons vouchers were being offered, in particular for ‘criminal expenses’. The researcher stated they were not expecting any unusual claims however were trying to cover all possibilities.
* The Committee requested that in future applications questions P.4.1 and P.4.2 are answered more comprehensively.
* Committee queried whether there are there any issues with drawing this quantity of blood. Professor Glue explained that if venous access was not possible the participants would be excluded.
* The Committee queried whether participants who tested positive for cannabis would be excluded. Researcher clarified that intermittent cannabis use would not result in exclusion.
* The Committee asked if heavy cannabis users would have issues with the long stay in treatment. Professor Glue clarified the distinction between testing for THC and THC acid would allow researchers to know how heavy the users were, which would inform study inclusion criteria. If there was a concern that a participant was a heavy user they would be excluded.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please review formatting to ensure it is consistent throughout the documents and to make it easier to read. For guidance on how to format for participant accessibility please see <http://ethics.health.govt.nz/system/files/documents/pages/PISCF-templates-June3013.doc>).

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 paid respect to Ken Copland, the chair of the Lower South Ethics Committee, who passed away. The secretariat is to arrange a card for the family on behalf of the Southern Ethics Committee.
3. The Committee queried whether there were reporting abilities for Protocol deviations and violations, requesting information to better inform continued ethical approval for applications.
4. Committee discussed how best to address recruitment to studies, noting it is appropriate that participants should be given a time to talk, and also to give their decision, to an independent body.
5. Committee requested that Maori consultation was raised at the chairs meeting, as applications are often avoiding or not answering the question sufficiently.
6. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 17 September 2013, 12:00 PM |
| **Meeting venue:** | Heartland Hotel Cotswold, 88-96 Papanui Road, Christchurch |

The following members tendered apologies for this meeting.

* Ms Gwen Neave for September
* Angelika Frank-Alexander for September and October
* Martin tentative apologies for September October.

Secretariat to look into seconding members to ensure Committee composition is appropriate and quorate.

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 3.15pm