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

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.10pm | Confirmation of minutes of meeting of 18 February 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/STH/20  ii 14/STH/22  iii 14/STH/24  iv 14/STH/25  v 14/STH/26 |
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| 1.55pm | General business:  Noting section of agenda |
| 2.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** |  |  |
| 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 Dr Sarah Gunningham.

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 February 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/STH/20** |  |
|  | Title: | Developing a blood test for Parkinson's Disease. |  |
|  | Principal Investigator: | Dr Nick Cutfield |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 06 March 2014 |  |

Dr Nick Cutfield 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.

* Dr Cutfield explained that Parkinson’s disease (PD) is a common neurodegenerative disorder characterised by tremors, slowness and stiffness of movements. There are also changes in sleep, thinking and moods but these are relatively neglected by researchers as the motor movements are easier to treat, either with tablets or neurosurgery.
* Dr Cutfield explained that none of the current treatments change what is happening inside the brain cell and that nothing has yet been proven to slow damage in the brain cell. He noted that by the time a patient is diagnosed there is already significant damage in the parts of the brain, which makes it difficult to slow the progression.
* Dr Cutfield explained that if an accurate diagnosis can be found earlier, then it may be possible to slow the progression of the disease. A blood test could be developed to be a predictive blood test, which would be used as part of GP screening. The purpose of this study is to see whether MicroRNA can be used as the basis of a blood test to diagnose PD.
* Dr Cutfield advised that the study will group participants with PD into sub-groups – those with impaired memory and thought processes, those who develop fluctuations in movements and those without sleep and memory problems.
* The Committee were concerned about not testing the control group but agreed that this was dealt with by the use of sub-groups for those with PD.
* Dr Cutfield advised that most studies involving PD require a fairly detailed clinical description and that all of the proposed tests for participants are standard tests.
* The Committee noted that the plan was to have 30 participants per group and asked how the researcher would ensure that these numbers were even, for example, would participants give consent before testing or would there be pre-testing screening before the consent process. Dr Cutfield advised that it was relatively easy to identify those with motor skill issues and that the Montreal tool would be used to identify those with cognitive issues. He noted that there was likely to be a recruitment bias as those who do not have cognitive problems tend to be motivated to take part in studies and therefore it is likely they would be easy to recruit.
* The Committee queried the response to R.3.2 which stated that brain slices would be used in the study and asked whether this was a separate piece of research to the MicroRNA study. Dr Cutfield explained that the study could not be submitted for funding unless there is a mechanistic element to the study.
* The Committee queried the answer to B.4.5.2 which states that “we would not be storing blood with the aim of being a tissue bank.” Dr Cutfield explained that developments during the course of the study might allow another type of test to be added to the analysis. The Committee advised that the protocol could be amended but the Committee would need to be notified.
* Dr Cutfield explained that other researchers might want access to the samples and they did not want to go back to participants and get consent again. The Committee advised that participants could consent to future unspecified research to allow for this. This future research would still need ethical approval but participants would not be re-contacted for consent. Participants are able to withdraw consent to the future unspecified research at any stage.
* The Committee asked whether Dr Liana Machado, Dr John Reynolds and Dr Ping Liu would be involved in the study as they had been identified in the PIS. Dr Cutfield advised that they are not ready to be part of this trial. The Committee advised that their names should be removed from the PIS.
* The Committee noted that while peer review had been provided, it was only half a line. They acknowledged that this is the Department of Medicine format but encouraged the researcher to provide more detail in future ethics applications.
* The Committee advised that data needs to be kept for ten years, rather than five years.
* The Committee recommended looking at the template PIS/CF on the HDEC website (<http://ethics.health.govt.nz/home>) and discussing any queries with Dr Nicola Swain, a committee member based in Dunedin.
* The following changes were requested to the PIS and consent form:
  + Please include page numbers.
  + Please proof read for spelling, grammar, missing apostrophes, capital letters, incorrect words and consistency, e.g., degrees are included after some people’s names but not others.
  + Please reduce paragraph spacing and keep text separate from the footer.
  + Please amend the PIS from “in a way we believe is ethical” to “in studies that have been approved by an appropriate Ethics Committee” (page 3 under future research).

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observational Studies, para 6.10).*

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

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| **2** | **Ethics ref:** | **14/STH/22** |  |
|  | Title: | Smoking status and cognition in patients with HD |  |
|  | Principal Investigator: | Dr Chris Kenedi |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 06 March 2014 |  |

Dr Ailsa McGregor and Dr Gregory Fincuane 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.

* Dr McGregor explained that preclinical studies suggest that varenicline may improve ataxia and motor function in patients with Huntington’s disease (HD). This is a safety and tolerability study of varenicline in three patients with HD who smoke.
* The Committee queried whether three participants would give a fair assessment. Dr McGregor explained that her initial plan was to submit the pilot study for ethical review but that a colleague had suggested taking a small number to see if they could tolerate the dose of varenicline and do what was asked for them. Dr McGregor acknowledged that this was not a large enough number to get statistical information but it will give researchers a broad idea of the types of problems participants may encounter in the pilot study.
* The Committee noted that they found it difficult to determine the purpose of the study from the PIS/CF. They asked whether the primary aim was to test tolerability of varenicline or if taking varenicline affects cognitive testing. Dr McGregor confirmed that the primary aim was to test the tolerability but it would also see whether the patients on varenicline could perform the cognitive tests required for a larger study.
* Dr McGregor advised that the tests to determine cognitive function had been used in patients with schizophrenia, mental health disorders and methamphetamine users. She explained that the results of this test would allow researchers to map participants on a continuum of cognitive impairment.
* The Committee queried whether there was any data on people who continue to smoke while taking varenicline and what the risks of doubling up on nicotine would be. Dr McGregor advised that she was unsure of the literature but that a colleague had indicated that a number of patients who take it continue to smoke. The Committee recommended that the researchers review the literature on this.
* The Committee noted that there was no consultation with Māori. Dr McGregor explained that this had not taken place because there would only be three participants and she did not know what the ethnicity of participants would be. The Committee advised that consultation should ideally take place before a study starts, particularly given the high smoking rates in Māori.
* The following changes were requested to the PIS and consent form:
  + Please include varenicline in the PIS title as participants will be receiving it.
  + Please include side effects of varenicline, information on whether participants should continue to smoke while on the study and what will happen after the study.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies, para 6.22).* The Committee recommends looking at the template PIS/CF available on the HDEC website (<http://ethics.health.govt.nz/home>).

This information will be reviewed, and a final decision made on the application, by Dr Nicola Swain and Ms Gwen Neave.

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| **3** | **Ethics ref:** | **14/STH/24** |  |
|  | Title: | A new nucleotide analog to suppress HCV infection |  |
|  | Principal Investigator: | Prof Ed Gane |  |
|  | Sponsor: | Clinical Network Services Ltd |  |
|  | Clock Start Date: | 06 March 2014 |  |

Professor Ed Gane and Ms Margaret Joppa 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.

Dr Devonie Waaka declared a potential conflict of interest, and 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.

* Professor Gane explained that this is a study to determine the safety and efficacy for a new oral antivirus drug to treat the hepatitis C virus. He explained that a similar drug, sofosubuvir in combination with ribavirin, has recently been approved as the standard care in the USA and Europe but this has not yet been approved in New Zealand or Australia.
* Professor Gane advised that this will be a first in man study done in two parts. The first part will be single ascending doses followed by multiple ascending doses for healthy volunteers. The second part is a proof of concept phase with a range of multiple doses given to participants with the hepatitis C virus. Professor Gane explained that participants would not be exposed to multiple ascending doses until the single ascending dose results have been checked for safety.
* The Committee asked for confirmation on data safety monitoring. Professor Gane explained that he would teleconference with the operations manager and coordinator of the study site to discuss safety data, laboratory data and safety events. There would be stopping rules for each group, for example an adverse event or laboratory abnormality in more than one patient. There would also be built in stopping rules for cases where a dose was found to be effective at a lower level.
* The Committee queried how many sites would be involved in the study. Professor Gane advised that there would be one site for healthy volunteers and up to eight sites in New Zealand and Australia for the second part of the study.
* The Committee asked whether there were any side effects from the study drug. Professor Gane advised that the drug should have the same side effect profile as sofosbuvir which has no known side effects.
* The Committee acknowledged that participants with the hepatitis C virus would be eligible to be enrolled in future trials. Professor Gane confirmed that all 32 patients would be offered the option of going onto Phase 2 later in the year.
* The Committee commended the researcher on the Māori consultation.
* The following changes were requested to the PIS and consent form:
  + Please include that there is a potential risk of allergic reaction to the drug.
  + Please include the numerical option for the 0800 STUDIES number on both PIS.
  + Please amend the first sentence on ethical approval on page 2 of the PIS to “This study has received ethical approval from the Southern Health and Disability Ethics Committee.”
  + Please simplify the groupings for the section on how the study is set up (page 2 of the PIS).
  + Please clarify that there are no known side effects in humans because this is a first in humans study (page 8 of the PIS).
  + Please include the statement “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” in the PIS/CF.

Decision

This application was *approved* by consensus subject to the following non-standard approval conditions being met.

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies, para 6.22).*

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| **4** | **Ethics ref:** | **14/STH/25** **(CLOSED)** |  |
|  | Title: | MK-8228-001: MK8228 vs. Placebo in Prevention of CMV infection in HSCT Recipients |  |
|  | Principal Investigator: | Dr Andrew Butler |  |
|  | Sponsor: | MSD - Merck Sharp & Dohme (Australia) Pty Limited |  |
|  | Clock Start Date: | 06 March 2014 |  |

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| **5** | **Ethics ref:** | **14/STH/26** |  |
|  | Title: | HINT 2 |  |
|  | Principal Investigator: | Dr Kathryn Williamson |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 06 March 2014 |  |

Dr Kate Williamson and Professor Frank Bloomfield 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.

* This study will investigate blood sugar levels in preterm babies. The researchers have worked with bioengineers in Christchurch who have developed a computer modelling programme to predict levels of insulin for babies and when further blood sugar tests should be taken. This will help improve glucose control and reduce levels of hypoglycaemia in babies. Professor Bloomfield explained that the algorithm requires increased blood testing and there are risks for babies involved with this such as developmental issues. Neurodevelopmental outcomes will be measured in two year olds to monitor this.
* Professor Bloomfield confirmed that the 46 babies in each group was based on power calculations
* The Committee noted the feedback from the grant application which queried the accuracy of the continuous glucose monitoring system. Professor Bloomfield confirmed that the software that comes with glucose monitors is not accurate at low levels but that the bioengineers had addressed this by developing their own algorithms and that the glucose monitor software would not be used.
* The Committee commended the researchers for their acknowledgement of the potential conflict of interest.
* The Committee asked how the computer programme had been validated. Professor Bloomfield confirmed that this had been validated against virtual and real patients in the Christchurch Hospital neonatal and intensive care units. He noted that there have been several publications in bioengineering literature, two of which were on the paediatric population.
* The Committee asked for clarification on the difference between groups 1 and 2. Professor Bloomfield explained that group 1 will have a computer determining the dose of insulin and the timing of when the next blood sample is to be taken. These decisions will be checked by a clinician to ensure that they make clinical sense. For group 2, the computer will determine the timing of the next blood sample and the clinician will decide the dose of insulin as per standard practice. This will help determine whether it is the computer model or the more frequent testing that has an impact on blood sugar levels.
* The following changes were requested to the PIS and consent form:
  + Please include page numbers.
  + Please change the first sentence in the PIS from “you baby” to “your baby”.
  + Please include a statement in the PIS that the use of blood samples may be viewed as a cultural issue for Māori and they may want to consult with others about this.
  + At present the consent form looks cramped. Please look at the template PIS/CF on the HDEC website (http://ethics.health.govt.nz/home) to determine whether all options on the consent form need to be there.
  + Please remove the options for translators on the consent form as these are no longer required and replace with the statement “If you need an interpreter please tell us.”
  + Please include that professional Māori translators will be made available to families where appropriate in the consent form.

Decision

This application was *approved* by consensus subject to the following non-standard approval conditions being met.

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies, para 6.22).*

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee agreed that the HDEC Secretariat would draft a standard paragraph on future unspecified research which could be included in participant information sheets. Dr Devonie Waaka agreed to send wording that had been approved in previous studies to the HDEC Secretariat.
3. The Committee agreed that the HDEC Secretariat would provide a draft document on Data Safety Monitoring Board Standards, with information on what level of monitoring would be expected based on the type of study. This will be brought to the next Southern meeting for review, before going to the next HDEC Chairs’ meeting for approval.
4. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 15 April 2014, 12:00 PM |
| **Meeting venue:** | New Zealand Blood Service, 87 Riccarton Road, Riccarton |

The following members tendered apologies for this meeting.

Dr Sarah Gunningham

The meeting closed at 2.00pm.