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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 19 August 2014 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Avenue, Christchurch |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 15 July 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/STH/103  ii 14/STH/104  iii 14/STH/107  iv 14/STH/109 **CLOSED**  v 14/STH/110  vi 14/STH/112 **CLOSED**  vii 14/STH/113 **CLOSED**  viii 14/STH/115 |
| 3.30pm | General business:   * Noting section of agenda |
| 4.00pm | 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 | 01/07/2015 | Present |
| 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 | Apologies |
| Dr Nicola Swain | Non-lay (observational studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr MARTIN THAN | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | 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.

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 15 July 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/STH/103** |
|  | Title: | DARE-C II |
|  | Principal Investigator: | Professor Edward/EJG Gane |
|  | Sponsor: | University of New South Wales |
|  | Clock Start Date: | 07 August 2014 |

Prof Gane and Angelle Lockie were present via 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.

* Professor Gane introduced the study. The population group in this study will comprise people who cannot have treatment with interferon because of the psychological side effects. This is a short course of treatment and the assumption is that the immune response will cure vast majority of this group.
* Many of the people in this population are HIV co-infected. Prof Gane noted the increase in the number of cases they are seeing. Five years ago they may have seen 2-3 cases per year in this group and they are now seeing over 12 cases per year and half will be HIV co-infected. This is a difficult population to treat and the treatment offered in this study could be an easy treatment to offer this group.
* The Committee queried the specific reasons for this study and Prof Gane explained that their primary goal is to look at the drug’s ability to clear Hepatitis C at the time of recent infection; its efficacy and safety. The secondary goal is to include immunological and genetic predictors of a good response. Prof Gane noted that they are hopeful they will see 100% response. Given extra immune activation they may see this. It may be difficult to look at baseline indicators if everyone responds.
* The committee noted the requirement that participants must consent to have their tissue from this study used for future unspecified research. Prof Gane confirmed that participants not prepared to consent to this would not be eligible to take part in this study. All samples will be kept at the Kirby institute in Australia. Because there are only three participants in this study the committee was satisfied that this was appropriate and did not press that the consent for future unspecified research be optional.
* The Committee requested the following changes to the participant information sheet and consent form.
  + Please include a lay title above the protocol title
  + The committee suggested that the research team revise the information to make the document less dense with fewer pages.
  + Please include the details of the person to contact in event of an emergency on the patient card. In the interest of patient safety this is key as the emergency contact person can take clinical responsibility to inform ED staff of any crucial safety information on a 24/7 basis.
* The committee queried whether the researchers have an original scientific peer review document that they could provide. Prof Gane confirmed that they do and that he would send a copy to the HDEC secretariat.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **14/STH/104** |
|  | Title: | Efficacy and Safety of MEDI-551 in Subjects with Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorders |
|  | Principal Investigator: | Dr Deborah Fleur Mason |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 07 August 2014 |

Dr Deborah Mason 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.

* This study is a commercial interventional drug trial in patients with Neuromyelitis Optica or Neuromyelitis Optica Spectrum disorders. Both conditions are rare and the researchers want to look at MEDI-551 in delaying the onset of the condition. The study will be conducted in two parts. In the first part participants will be randomised to get either the study drug or placebo in a 3 to 1 ratio. Participants will then have the option be part of an open label study with all participants receiving active drug. The Committee did not have any issues with the study design.
* The Committee noted that it is interesting that participants will not be paid for taking part in part one of the study. There is usually some form of reimbursement for participation in a placebo-controlled trial, however they can take part in the open label study and this may be the incentive for them to enter the study.
* The participant information sheet and consent form was not clear about whether patients will stay in after receiving IV infusions and if so for how long. The researcher clarified that this is an outpatient type of infusion and participants are required to stay for two hours after the infusion. The Committee asked that the researchers clarify this in the participant information sheet.
* The Committee queried the rate of infusion reactions with the study drug noting that there has been a move away from pre-medication treatment with fully humanised monoclonal antibodies but that pre-medication was routinely administered in this study. The researcher noted that earlier studies had shown no problems but because there have been infusion reactions with the standard rituximab they want to prevent this possibility.
* The researcher confirmed that the study drug has never been used in New Zealand and that an application is currently before SCOTT.
* The Committee queried why participants are being asked to separately consent to having an MRI. The researcher explained that a standard protocol is in place for studies because the scan is not done as part of a clinical need. Participants also need to be aware that there may be incidental findings that they are not currently aware of.
* The committee noted that the open label study consent sheet does not have a space for the patient to enter their name and sign and asked that this be included.
* The Committee noted that the main information sheet and consent form is wordy and repetitive in parts but did not suggest changes given the number of patients (3-4) who will be recruited in New Zealand. The Committee did request however that the following changes be made to the information sheet and consent form:
  + Please include the following statement on the consent form for men and women of child bearing age:
    - *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.*
  + Please include the details of the person to contact in event of an emergency on the patient card. In the interest of patient safety this is key as the emergency contact person can take clinical responsibility to inform ED staff of any crucial safety information on a 24/7 basis. Please ask participants to call the emergency contact as well as 111 so that the emergency contact can inform ED staff of important safety information.

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **14/STH/107** |
|  | Title: | Preparation in Capsule Endoscopy Study |
|  | Principal Investigator: | Dr Gary Lim |
|  | Sponsor: |  |
|  | Clock Start Date: | 07 August 2014 |

No member of the research team was 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.

* Capsule endoscopy is a procedure that’s already used in routine clinical practice. It can be a somewhat hit and miss procedure because small bowel content may cause an imperfect view. The committee thought that the equipoise requirement is just breaking and that the study is justified as it is a fairly low risk study.
* The Committee noted a downside for the patient is that they will get a bowel preparation and that the information provided to participants in the information sheet may not emphasise how unpleasant that could be and may not encompass some of the side effects. The committee noted however that the protocol notes that up to 15% opt not to have the procedure because it can be unpleasant - this study uses a half dose that has been shown to be as effective.
* Two different preparations are being used to see whether one is superior and the treatments are not experimental.
* The Committee agreed that the peer review from an expert body in Australia is adequate as there is minimal risk of harm in this study.
* The Committee suggested that the researchers may wish to consider defining what a capsule endoscopy and bowel preparation are at the start of the participant information sheet.
* The Committee noted the answer given at p.4.3 on the application form indicated a disregard for Māori who may be involved in this study. The Health Research Council’s guidelines for researchers on health research involving Māori state that consultation is a vital step for research that may involve Māori as participants or when the topic is of particular relevance to Māori health. The guidelines state that it is important to note that a researcher’s perceptions of priorities for Māori health may differ substantially from those of particular Māori communities and that consultation is done to address this potential issue as well as any potential issues relating to the study design and methodology. Please ensure that consultation with a Māori research body is done before the study begins and advise the Committee of this.

Decision

This application was *approved* by consensus.

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| **4** | **Ethics ref:** | **14/STH/109** **CLOSED** |
|  | Title: | Study of MK + Ipilimumab for advanced Melanoma |
|  | Principal Investigator: | Dr Bernie Fitzharris |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited |
|  | Clock Start Date: | 07 August 2014 |

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| **5** | **Ethics ref:** | **14/STH/110** |
|  | Title: | ENZARAD |
|  | Principal Investigator: | Dr Stephen Williams |
|  | Sponsor: | Canterbury District Health Board |
|  | Clock Start Date: | 07 August 2014 |

No member of the research team was 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.

* This study will look at high risk localised prostate cancer and evaluate a new treatment combination in this patient group and see whether there are any benefits in the reduction of metastatic disease. The Committee noted that it is a standard phase III design and did not have any issues in this regard.
* The Committee emphasised for future reference that more attention needs to be given to the application form. The answers given in this application form did not always answer questions as they were asked. For example, the questions about the description and justification of study. The risks of the study drug and radiation were not well described in the application but were covered in the participant information sheet.
* The Committee discussed the funding arrangement for this study and how this may affect participants’ access to compensation in the event that it is needed. There is no compensation available from the funder but compensation may be covered by ACC and this is clearly stated in the application form.
* The Committee requested the following changes to the participant information sheet and consent form:
  + The Committee noted that the researchers had stated that there were no cultural issues identified but that consultation with Māori is being carried out. The Committee suggests that researchers might wish to consider that the collection, use and storage of tissue will be an issue for some Māori and to reflect this in the participant information sheet and consent form.
  + Page 1 of 16: Please include a lay title. Second sentence in the first paragraph “This study may be suitable for you because…” could be a shocking statement if the patient does not already know this. The committee suggested a rewording of this sentence.
  + Page 2 of 16: The Committee noted that information stated in the ‘Purpose of this study’ is confusing and wordy. Please clearly differentiate what standard treatment is from what the study treatment will be.
  + Page 2 of 16: the use of the term medical castration. It was noted that this is the term used in discussion with patients as it can be the easiest way of explaining effects.
  + Page 3 of 16: The information given under the heading ‘Study Assessments’ states that assessments are summarised in a table and makes reference to asterisks but no table or asterisks appear in the form.
  + Page 5 of 16: please move the information about a participant’s right to withdraw to the page 1 of the form.
  + Page 7 of 16: The risks section discusses not only the risks of the study treatment, but also of the standard treatment participants would receive even if they did not participate. Please either remove information about the risks of standard treatment or clearly identify in the risks section which drugs/therapies are standard therapy.
  + Page 8 of 16: The last paragraph on this page mentions tracking a pregnancy should a participant father a child. The Committee noted that the participants should be advised that they should take precautions to not father a child while participating in this study.
  + Page 14 of 16: please remove the ‘Request for Interpreter’ box.
* The Committed suggested that the researchers may wish to use the HDEC participant information sheet/consent form pro forma that can be found on the HDEC website <http://ethics.health.govt.nz>

Decision

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

* Please amend the participant information sheet, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

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| **6** | **Ethics ref:** | **14/STH/112** **CLOSED** |
|  | Title: | Demonstrating proof-of-concept for a continuous positive airway pressure (CPAP) breathing therapy mask |
|  | Principal Investigator: | Doctor Andrew Veale |
|  | Sponsor: | AUT Enterprises Limited |
|  | Clock Start Date: | 07 August 2014 |

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| **7** | **Ethics ref:** | **14/STH/113** **CLOSED** |
|  | Title: | A study of how the body processes and clears Maxigesic® IV, following single doses in healthy adults. |
|  | Principal Investigator: | Dr Richard Robson |
|  | Sponsor: | AFT Pharmaceuticals Ltd |
|  | Clock Start Date: | 07 August 2014 |

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| **8** | **Ethics ref:** | **14/STH/115** |
|  | Title: | The Anorexia Nervosa Genetics Initiative (New Zealand) |
|  | Principal Investigator: | Professor Martin Kennedy |
|  | Sponsor: |  |
|  | Clock Start Date: | 07 August 2014 |

Prof Martin Kennedy and Dr Jenny Jordan 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.

* Prof Kennedy gave a brief introduction to the study. It is part of an international consortium that is using large cohorts to identify genes underlying complex disorders. A group in the States is running the consortium and trying to recruit as many people as possible to power the study. This is one arm of a much bigger study.
* It is known that there is an underlying gene disorder to anorexia nervosa but it is not known what the genes are.
* The New Zealand researchers will play an active role in recruitment, data analyses and dissemination of information. The tissue analyses will be done in the USA.
* The Committee acknowledged that this is a worthwhile study but noted the need for further extensive information about the study processes, a timeline process in place, and changes to participant information from the researchers before it will approve the study.
* The Committee queried how the researchers intend to recruit participants. They intend to take a broad approach disseminate knowledge that there is a website to go to through an online survey, newspaper advertising that directs people to the website, and flyers to eating disorder groups. They do not intend to recruit actively ill people.
* The Committee noted that the researchers do not need a consent form for an online survey as people have implied consent by completing the survey. The website does need to state the contact details of people that participants can contact, however.
* Participants under 16 will need parental consent to do the online survey. 14-15 year olds can have their parents to sign on behalf and the website can give a contact phone number for parents.
* Dr Jordan confirmed that participants who meet the criteria for anorexia nervosa (DSM5) qualify for second part of the study. Dr Jordan will be responsible for initial contact by phone or email to complete a diagnosis.
* The Committee emphasised the need to know the consenting process for 14-15 year olds and 16 year olds and over. One of the tenants of the New Zealand ethics process is that a conversation needs to be had face to face and the forms signed in person. The Committee suggested that this could be done by skype but that it will need to see the process outlined clearly. The Committee noted it is also important that 14 and 15 year olds give assent so that they show they are invested as well.
* The Committee noted that the researchers can send the blood kits after the participants have consented to the study and they need to have the signed form in their possession before any study related procedures can take place.
* Bloods collected will be assessed for the DNA and will be shipped unseparated to the Otago laboratory. The security of the specimen was discussed and the Committee suggested that the researchers look at system and sample issues from a logistical perspective and consider whether the study should be done in main centres only. If a more dispersed model is chosen the researchers will really need to look at the logistics.
* The researchers will recruit people with anorexia nervosa but anticipate that they will need to do a study with a control group. The Committee noted the need for the control groups to be age and sex matched and also geographically and ethnically. This could be submitted as an amendment to the study rather than as a new application.
* The Committee noted that question r.3.11 was not answered. The researchers are seeking indefinite storage. An application for a new tissue bank will be needed for the samples that are intended for storage at Otago University and a copy of the guidelines for an application for a new tissue bank are included with this decision letter. The samples may be able to be stored in an existing tissue bank and the Committee suggested the researchers talk to colleagues about this possibility.
* Incidental findings will go to a medical geneticist first and they will decide whether the findings should be pursued with the participant. The hospital board would likely pay for this. The Committee asked that this information be included in the timeline they have requested.
* The Committee requested the following changes to the participant information sheet.
  + Please revise and simplify the information and include bullet points for readability.
* The Committee requested the following changes to the consent document:
  + Please use the word ‘blood’ consistently instead of alternating with the word tissue.
  + Please include a yes/no option for people who may change their minds about wanting to know of any incidental findings (e.g should a family member develop an illness).
  + Page 7 of 8, final two points please replace “properly” approved with “ethically” approved.
* The Committee requested the following changes to the study advertisement:
  + Please clearly state that participants may be contacted about a further study if they meet the inclusion criteria
  + Please place the ANGI email address on one line.
  + Please remove reference to New Zealand’s quota in the study being 300 participants.

Decision

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

* If you intend to store tissue at Otago University in a new tissue bank you will need to make a separate application to the HDECs to establish the tissue bank. Please refer to the attached guidelines (*Chapter 13 of the Standard Operating Procedures for Health and Disability Ethics Committees*). Alternatively, should you decide to store the samples in an existing tissue bank, please advise the Committee that you intend to do so.
* Please provide further extensive information about the study processes, including a timeline (*Ethical Guidelines for Observational Studies* *para 6.11*).
* Please amend the participant information sheet and consent forms, taking into account the suggestions made by the committee (*Ethical Guidelines for Observational Studies* *section 5, Design of Study and Protocol*).

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

## 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:** | 16 September 2014, 12:00 PM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Avenue, Christchurch |

The following members tendered apologies for this meeting.

No apologies were tendered.

The meeting closed at 3.30pm