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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 15 April 2014 |
| **Meeting venue:** | New Zealand Blood Service, 87 Riccarton Road, Riccarton |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 18 March 2014 |
|  | New applications (see over for details) |
| 12.30-12.50  12.50-1.10  1.10-1.30  1.30-1.50  1.50-2.10  2.10-2.30  2.30-2.50 | i 14/STH/41  ii 14/STH/30  iii 14/STH/35  iv 14/STH/36  v 14/STH/37  vi 14/STH/40  vii 14/STH/39 |
| 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 | Apologies |
| 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 | Apologies |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 12.05pm and welcomed Committee members, noting that apologies had been received from Dr Martin Than, Dr Devonie Waaka and Dr Sarah Gunningham.

The Chair noted that fewer than five appointed members of the Committee were present, and that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Mrs Stephanie Pollard confirmed her eligibility, and was co-opted by the Chair as member of the Committee for the duration of the meeting.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 18 March 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/STH/41** **CLOSED** |
|  | Title: | MK-5172 in Combination with MK-8742 with and without Ribavirin(RBV) in HCV Patients who Failed Prior Pegylated Interferon (peg-IFN) and RBV Treatment. |
|  | Principal Investigator: | Dr Alan David Pithie |
|  | Sponsor: | Merck Sharp & Dohme (Australia) Pty Limited |
|  | Clock Start Date: | 03 April 2014 |

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| **2** | **Ethics ref:** | **14/STH/30** |
|  | Title: | LosmApimod To Inhibit p38 MAP kinase as a TherapeUtic target and moDify outcomes after an acute coronary syndromE (LATITUDE)-TIMI 60 |
|  | Principal Investigator: | Prof Ralph Stewart |
|  | Sponsor: | GlaxoSmithKline |
|  | Clock Start Date: | 03 April 2014 |

No member of the research team 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 researcher was unable to attend this meeting. The Chair contacted the researcher subsequent to the meeting to query a couple of points that were not clear to the Committee during the meeting discussion.
* It was not clear when the researchers intend to recruit participants in relation to their cardiac event. The researcher has advised that recruitment will be 12-24hours after the event when they have been transferred to the coronary care unit.
* There are two participant information sheets submitted for this study – 6 pages or 10 pages long - the main study version is 6 pages with a 4 page supplement for reading following participant consent. The Committee discussed whether the additional 4 pages were needed and was satisfied that the necessary aspects for consent were covered in the shortened version and that the 10 page version listed the extra points that may not be important to consent but were useful to know.
* The third participant information sheet is for an optional genetics study that is secondary to the main study.
* The Committee noted that the questions relating to issues for Mâori have been covered well in the application form but have not been translated to the participant information sheet. Please include this consideration for Mâori in the participant information sheet.
* The Committee requested the following changes to the participant information sheets and consent forms:
  + Please clearly state in the title of the genetics study that it is an optional study that is separate to the main study.
  + Please state that any samples use in future research will only be used in studies that have received ethics approval.
* Point 10 on page 10 of the Consent form. Please remove the requirement that the revocation of consent has been done in writing only. Participants may also do this verbally.

Decision

This application was *approved* by consensus with non-standard conditions, subject to the following information being received by the Secretariat.

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

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| **3** | **Ethics ref:** | **14/STH/35** |
|  | Title: | Mk5172-062: MK5172 and MK8742 in HepC patients on opiate substitution therapy. |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Merck Sharp & Dohme (Australia) Pty Limited |
|  | Clock Start Date: | 03 April 2014 |

Prof Gane and Ms Vithika Suri 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.

* The Committee noted that the participant information sheet is long and complex as might be expected and requested some minor changes:
  + The researchers confirmed that a FibroScan will be generally given to participants and in rare cases a liver biopsy would be done. The Committee asked whether the researchers could remove the liver biopsy section entirely noting that it is rarely required. The Committee noted that there will be 10 patients at this site out of a large cohort and to include information because it is relevant in other countries can be confusing for participants.
  + The Committee noted that the exclusion criteria is currently written in negative statements and is quite wordy. The Committee noted that the criteria could be further simplified, categorised and written as positive statements. The Committee noted the same could be done with the side effects. For example, the likelihood of side effects being ‘common’, ‘less common’ and ‘rare’.
  + Under the heading ‘What will happen to my blood and urine samples’. Please specifically state where the samples will be sent as some participants will wish to know where their samples are going. Please also acknowledge that the sending of tissue overseas is a special issue for some Māori and include the following statement: *“You may wish to consult your whanau or hapu group before entering the main study or agreeing to extra research, as some iwi maintain beliefs involving the collective ownership of tissue.”*
  + The researchers confirmed that they do not intend to take photos for this study in New Zealand. Photos may be taken on a case by case basis though. For example, if a patient has a rash. The Committee noted that comprehensive content can make the PIS very long and potentially confusing for participants and in this case they may wonder what the photos are about. The Committee suggested that if it is a requirement to leave this information in that it is included in a more appropriate place in the information sheet.
  + Page 13 under the heading ‘How will my privacy be protected?’ Please remove the words “When possible” in the sentence that refers to health data being sent to the sponsor in a de-identified way. The Committee noted that information sent will always be identified and any oversight would be considered a protocol violation or deviation.
  + Page 5. The Committee queried whether the notification of positive HIV results to local health authorities is correct process. Prof Gane confirmed that HIV not notifiable but Aids is. The Committee asked that the information on page 5 be changed to more accurately reflect the process that would be put in place.
  + The Committee noted that it would be useful from a sponsor perspective if the participant information sheets for both studies were standardised for consistency.
  + The Committee noted that the consent form contains a quite a number of statements and some of these could be grouped together. For example: I have had time to consider whether to take part in the study could be grouped with I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

Decision

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

* Please amend the information sheets and consent form, 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.

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| **4** | **Ethics ref:** | **14/STH/36** **CLOSED** |
|  | Title: | Assessment of single dose of the trial drug REGN1908-1909, in men and women allergic to cats. |
|  | Principal Investigator: | Dr Richard Robson |
|  | Sponsor: | Quintiles Pty Ltd (on behalf of Regeneron Pharmace |
|  | Clock Start Date: | 03 April 2014 |

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| **5** | **Ethics ref:** | **14/STH/37** |
|  | Title: | Vado™ Steerable Sheath Clinical Study |
|  | Principal Investigator: | Dr Ian Crozier |
|  | Sponsor: | Kalila Medical |
|  | Clock Start Date: | 03 April 2014 |

Dr Matt 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 researcher explained that this sheath is advancing on the equipment already used for percutaneous ablation in a variety of arrhythmia problems. What is new about this sheath is that it is able to bend to allow for better contact with tissue inside the heart and this is a key aspect to delivering better therapy. The researchers in this study have experience using other steerable sheaths – the difference between this sheath and others they have used is the way in which it bends.
* The researcher explained that drawing on his experience he estimated that the procedure duration would be shorter as they would be able to accomplish what is needed faster with this steerable sheath.
* The Committee queried what the disadvantages and risks of this new device might be. The researcher said that it may be that the device may not hold shape as well or better than older versions. No danger will be posed if it doesn’t work and the researchers will always be able to remove and replace the sheath with an older sheath during a procedure if this is the case. The Committee asked that this be clearly stated in the participant information sheet and consent form.
* The Committee noted with interest, the answer given at question p.4.2 on the application form that it is a common perception that Māori are over researched and asked where the researchers had drawn this information from. The researcher advised that he would query this with the study’s lead investigator and noted that statistically Māori have been under represented in research. The Committee commended the researchers of a well-answered consultation with Māori section.
* The Committee queried the data safety monitoring committee arrangements and sought clarification on who would have an oversight of safety data and review cumulative data. The assessing of the device will be done by the surgeon - it was noted that there are only 10 patients in this study and this is the only site.
* The Committee asked whether the researchers would discuss any incidental findings with participants if anything significant was found during the testing. The researcher explained that they will do a number of standard screening procedures but not a lot of true diagnostics and any follow up with patients would be as usual.
* The Committee requested the following changes to the participant information sheet:
  + Please revise the study title and introduction and rewrite in lay language.
  + Please remove the pregnancy clause as it is not needed.
  + Please review the document for consistency of font size and type.
* The Committee commended the researchers for clearly identifying complications raised for each procedure in the information sheet.

Decision

This application was *approved* by consensus.

Non-standard conditions for approval: the Committee’s suggestions for the PIS/CF will be reviewed, and a final decision made on the application, by the Secretariat.

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| **6** | **Ethics ref:** | **14/STH/40** |
|  | Title: | Tecemotide versus placebo in participants with unresectable NSCLC. |
|  | Principal Investigator: | Dr Dean Harris |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 03 April 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.

* The Committee noted that there was nothing substantially wrong with application; the protocol is well written and gives a clear indication of what the study involves.
* The key issue for the Committee was that there is some confusion about whether or not tissue will be stored and if so for how long due to discrepancy in information given. At question r.3.11 on the application form it is stated that tissue will be returned to donor, whanau or family member, yet on page 7 of the consent form it is stated that tissue samples will be stored for up to 12 years.
* Please double check the information sheets and consent forms for the storage times and sample destruction bearing in mind the answers given at R.3.1.1 on the application form.
* Please clarify which parts of this study are optional and which are not and that any future unspecified use is subject to ethical approval.
* Please submit a separate information sheet and consent form for the future unspecified research option.
* Please also acknowledge that the sending of tissue overseas is a special issue for some Māori. You may wish to include a statement along the lines of: *“You may wish to consult your whanau or hapu group before entering the main study or agreeing to extra research, as some iwi maintain beliefs involving the collective ownership of tissue.”*
* The Committee requested the following changes to the main participant information sheet and consent form:
* Please include the prohibited medications listed in the protocol.
* Page 6. The Committee noted the statement that it may also be necessary for participants to take medication during or after the research to address side effects or symptoms and that this would be at the expense of the participants. The Committee noted that it would expect that if participants had side effects then they would be treated without cost to themselves. Please provide clarification on the intention of this statement for the Committee.

Decision

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

* Please clarify which parts of this study are optional and which are not and that any future unspecified use is subject to ethical approval. Please submit the requested information sheet and consent form, taking into account the suggestions made by the committee (*Guidelines for the use of Human Tissue for Future Unspecified Research, 2007*).
* Please amend the information sheets and consent form, 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.

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| **7** | **Ethics ref:** | **14/STH/39** |
|  | Title: | Subclinical Congenital Hypothyroidism |
|  | Principal Investigator: | Professor Paul Hofman |
|  | Sponsor: |  |
|  | Clock Start Date: | 03 April 2014 |

Prof Hofman 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 researchers intend to assess whether children who had a slightly elevated TSH (between 10-15 mU/L) have impaired intellect. Despite evidence that the children with levels in this group do not need treatment, several international screening programmes give therapy for TSH levels as low as 7 mU/L. The researchers wish to test this to see whether it is right.
* The Committee queried the appropriateness of phoning people out of the blue with the results from Guthrie Card screening. Prof Hofman acknowledged that this was one of the two main ethical issues in this study. He explained that the data suggests that children with ‘mildly abnormal’ test results go back to “normal” over time. Also, the ‘cut off’ for contacting parents stems from a practical consideration as it would not be possible for staff to contact all parents.
* Prof Hofman acknowledged that when contacting parents, communication of the results will need to be couched in a sensitive way. With this in mind the Committee noted that the use of the word ‘abnormal’ needs to be removed from the participant information sheet and consent form. Prof Hofman’s research nurse will contact make initial contact and call all the people. The Committee was satisfied that someone experienced and suitably trained will contact the parents.
* Prof Hofman confirmed for the Committee that the National Advisory Centre has reviewed the study approved the use of the data from the Guthrie cards.
* The Committee noted the answer given at question p.2.7 on the application form that the researchers intend to meet with families whose children have “abnormal” results and discuss appropriate referrals. Prof Hofman noted the need to not cause anxiety to parents and explained that he and his research team will look at ways to articulate the information with sensitivity. There are potentially 100 families in this study and the researchers will aim to meet with at least 15 percent of these families. The Committee noted that the researchers may need to meet with a high proportion of the study group and wished to feel reassured that the researchers could meet with all families. Prof Hofman noted the practical issues around being able to do this but noted that families will be advised that they can contact the researchers to discuss results if they wish.
* P4.2 says please identify main cultural issues – none. Asking how research affects Maori participants and includes that M consider information and tissue samples they give important as well
* The Committee requested the following changes to the parent participant information sheet and consent form
  + Please reword the title in language that is appropriate for the lay person.
  + Please make clear to parents that they will be asked to do a verbal test.
  + Please revised the language used for consistent tense. Please remove the word ‘subject’ and replace with ‘you’ ‘your child’. Please consider writing the information in a more sensitive way that would be spoken but is appropriate for a lay person
  + Please submit a consent form for parents
  + Parental testing behaviour rating for parents for their children. Please make clear to parents that they do not have to do this.
  + Please include detail around the testing categories under the title ‘What is involved?’
  + Please include the details for the Maori health support contact person.

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 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 Committee discussed the way in which question p.3.2 on the application form is worded. The question asks whether a study will involve potentially vulnerable people who have restricted ability to make decisions about their participation. The Committee noted that the definition of ‘vulnerable’ in the NEAC guidelines is much broader than is suggested in the application form and asked that this be raised at the next Chairs meeting for discussion.
3. The Committee agreed that revocation of consent in writing alone placed an unnecessary burden on participants and that they should be made aware of other options for revoking consent. The Committee asked that in the interests of consistency across committees that this also be raised at the next Chairs meeting for discussion.
4. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | Tuesday, 20 May 2014 |
| **Meeting venue:** | NZ Blood Service, 87 Riccarton Road, Riccarton, Christchurch |

The following members tendered apologies for this meeting.

Ms Raewyn Idoine

Dr Martin Than

The meeting closed at 3.15pm