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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 20 May 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 15 April 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 | i 14/STH/57  ii 14/STH/50  iii 14/STH/51  iv 14/STH/53  v 14/STH/54  vi 14/STH/48 |
|  | General business:   * Noting section of agenda |
| 2.45pm | 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 | Apologies |
| 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 | 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 | 01/07/2014 | 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 | Present |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Ms Raewyn Idoine, Ms Gwen Neave and Dr Martin Than.

The Chair noted that fewer than two lay members of the Committee were present, and that it would be necessary to co-opt a member of another HDECs in accordance with the SOPs. Mrs Susan Buckland confirmed her eligibility, and was co-opted by the Chair as a 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 15 April 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/STH/57** |
|  | Title: | A study to evaluate GS-9620 for the treatment of virally-suppressed subjects with chronic HBV. |
|  | Principal Investigator: | Prof Ed Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 08 May 2014 |

Prof Gane and Ms Kerry Walker 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 Waaka declared a potential conflict of interest but the Committee deemed that this was not a significant conflict of interest and did not require Dr Waaka to leave the room during discussion.

Summary of ethical issues

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

* The current standard of care for chronic HBV is life-long therapy. The idea of TLR is to replicate what happens in cells to stimulate interferon and allow the body to clear antigens and work against infection. Studies in animals have had promising results.
* The Committee asked whether the findings of the phase I study showed any significant side effects. Prof Gane advised that he conducted the phase I study and no significant side effects were found. The phase I study showed the drug was effective but a longer time is needed to achieve viral eradication. The Committee noted that the previous results would indicate the drug is quite promising.
* The Committee agreed that there are no major ethical issues of note in this application and congratulated the researchers on a well written application.
* The Committee noted that the application form stated that blood samples will be sent overseas but that there was no mention made in the main participant information sheet or the optional pharmacokinetic sub study participant information sheet about this. Prof Gane acknowledged that this was an omission on the researchers’ part and they will update the documents with this information.
* The Committee questioned the amount of information in the optional pharmacogenomics sub study participant information sheet about long term storage and also whether the researchers will be looking at other markers and was satisfied that the information sheet clearly states that samples will be stored for up to 15 years for this purpose.
* The Committee noted a few minor grammatical issues in the main participant information sheet and asked the researchers to review with that in mind. For example, the second paragraph on page one stated that the purpose of the form is: “to give you information you about the study”.
* The Committee congratulated the researchers on a very detailed scientific peer review report.
* The Committee discussed whether it would ask the researchers to include a standardised statement about contraception that specifically states that men and women of child bearing age need to use two forms of contraception while on this study. Some of the Committee members were satisfied that the information given in the information sheet addressed the issue of contraception well and that the standardised statement was not necessary in this case. It was agreed that clarification would be sought about whether the HDEC standardised statement should be mandatory for all applications or should be considered on a case-by-case basis. No changes are required for approval of the current application.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **14/STH/50** |
|  | Title: | Pacritinib in patients with thrombocytopaenia in Myelofibrosis |
|  | Principal Investigator: | Dr Peter Ganly |
|  | Sponsor: | Ockham Oncology |
|  | Clock Start Date: | 08 May 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 objective of this study is to compare the efficacy of two different dose schedules. 352 patients will be enrolled at 100 treatment sites.
* The study is looking only at supportive care at this stage. Nothing that is disease altering.
* The Committee noted that the researchers had stated that participation in this study would not incur additional costs for participants, but at the same time the researchers noted that some things such as CT scans that would need to be covered by participant. The Committee noted that this should be New Zealand specific.
* The Committee thought it was reasonable that there should be no additional costs for participants beyond standard of care and recommended that costs for any study procedures above and beyond standard care should be picked up by the company.
* The Committee noted that there is no information in the participant information sheets to remind participants that taking part in this study might affect their personal insurance and recommended that the researchers include a sentence stating that participants might like to contact their insurer to check that taking part in the study would not affect their insurance before consenting to the study.
* The Committee discussed whether it would ask the researchers to include a standardised statement about contraception that specifically states that men and women of child bearing age need to use two forms of contraception while on this study. Some of the Committee members were satisfied that the information given in the information sheet addressed the issue of contraception well but it was agreed that clarification would be sought about whether the standardised statement is mandatory for all applications or should be considered on a case-by-case basis. No changes are required for approval of the current application.
* The Committee requested the following changes to the participant information sheet
  + Question r.3.11 of the application form states that tissue will be disposed of at the end of the study, or if participants withdraw consent for its use in this study. However there is no cultural statement about the collection and storage of tissue samples in the participant information sheet. The Committee recommended that the researchers include a statement that addresses Maori cultural issues associated with ongoing storage in tissue banks, tissue being sent overseas and the use within genetic studies.
  + The Committee requested the following changes to the participant information sheet: The Committee noted that it might be reassuring for participants if a statement assuring that their personal information will be treated confidentially and with respect was stated upfront on page 13 (Use and Release of Information about You). The Committee suggested the following introductory sentence: “Your personal information will be respected and treated confidentially as follows:”.
  + The Committee noted that the participant information sheet was lengthy and acknowledged that while there may be constraints in shortening the form that the researchers consider doing so if possible. The researchers may wish to consider using the current standard consent form that can be found on the HDEC website: <http://ethics.health.govt.nz>.
  + The Committee noted that some of the information in the document was repetitive and also that some of the language used did not seem appropriate, e.g. ‘termination visit’ and suggested that the researchers review the document with this in mind.

Decision

This application was *approved* by consensus.

Non-standard approval conditions:

* Please amend the participant information sheet, 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/51** |
|  | Title: | Efficacy, safety and immunogenicity of BI 695501 versus adalimumabin patients with active rheumatoid arthritis. |
|  | Principal Investigator: | Dr Nigel Gilchrist |
|  | Sponsor: | Quintiles pty Limited |
|  | Clock Start Date: | 08 May 2014 |

No member of the research team was present for discussion of this application. The researchers were advised of the Committee’s decision as soon as it came to hand.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

Dr Waaka and Mrs Frank-Alexander declared potential conflicts of interest but the Committee deemed that they were not significant conflicts of interest and did not require Dr Waaka or Mrs Frank-Alexander to leave the room during discussion.

Summary of ethical issues

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

* The Committee commended the researchers on a well written application.
* The Committee noted that the researchers have sought SCOTT approval for this study and was satisfied that the scientific robustness would be assessed by this review body. The researchers have also indicated that an independent safety monitoring committee is in place.
* The Committee discussed previous tests in humans and whether any safety issues were identified. The first-in-human study was in healthy volunteers who were given adalimumabin or the study drug, the safety profile was very good and no significant differences between the two drugs were found in terms of safety. One of the principal issues with long term use is immune suppression. Long term side effects are to be expected but are anticipated to be the same as adalimumabin.
* The Committee confirmed the ways in which participants will be recruited and was satisfied that there were no ethical issues in the methods stated in the application form.
* The Committee requested the following changes to the participant information sheet:
  + The Committee acknowledged the small number of participants being recruited to the study in New Zealand but noted that if possible to change the sheet given the small number that a more succinct statement about why the participant is invited to the study the better. The Committee noted the sentence on page two of the information sheet that states “You are being invited to take part in this study because you have moderate to severe RA and have active disease despite treatment with other anti-rheumatic medicines.” would be helpful to state upfront.
  + Please include contact details for the study’s Maori support person.
  + The Committee noted on page three of the participant information sheet, the screening period requirement that a positive tuberculosis test will be reported if required by law. The Committee questioned whether this is required by law in New Zealand. It was confirmed that it is. The Committee requested that the words “in your country” be removed from this statement.
* It was not clear to the Committee whether all participants in the study would have continued access to the drug after this intervention study. The participant information sheet states that there was no guarantee and that participants may be able to continue in an open label study. However, the Committee also noted that this drug has not been proven as superior so this is fine.

Decision

This application was *approved* by consensus.

Non-standard approval conditions:

* Please amend the participant information sheet, 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/53** |
|  | Title: | Darifenacin bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 08 May 2014 |

Dr Noelyn Hung, Dr Tak Hung and Mrs Linda Folland 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 has read and understood the two bioequivalence protocols submitted for review and the recorded conversation below covers issues identified in both 14/STH/53 and 14/STH/54.
* The Committee queried the amount of money that will be offered to reserved participants who will be expected to come in and fast overnight and do preparation but not take the drug. They will also have alcohol restrictions for two days prior and not be able to take medications for two weeks prior. Mrs Folland acknowledged the preparation involved but explained that they always run a fine line of not offering too much incentive for people to take part.
* The researchers confirmed for the Committee that there may be cross-over in the two studies (fasting and fed conditions). There will be a stand down period of 60 days between studies and the researchers will be recruiting concurrently for the two studies so it would be unlikely for the same volunteer to participate in both studies.
* The Committee queried the researchers’ procedure for obtaining informed consent. The researchers explained that they hold information sessions to talk about consent and participants can either give consent at the end of the session or take time to decide. The researchers further clarified that not all participants have a private consultation with a physician or a researcher where they have the opportunity to ask further questions. The Committee advised that it would be worth having a private consultation where the participants sign the consent form at that time, rather than during the public information session.
* The Committee agreed that it was not convinced by the researchers’ argument that participants sign the consent form first and then talk details later noting that mass consenting is not the best way to gain consent. The Committee was not concerned about the researchers holding public information and questioning sessions to discuss the study but rather that all participants are not seen individually to ask questions if needed at the point of signing consent.
* The Committee asked that the researchers give every person a private conversation with a qualified member of the research team where the consent form is signed. This ensures that the researcher has checked with **each** participant to ensure he/she has understood the consent form, is happy with the information provided, and has had all of his/her questions (including those the participant may not have been comfortable raising in a more public forum) answered prior to signing the form.
* The Committee noted the scientific peer reviewer’s disclosure that he was involved in a 2010 BE clozapine study in patients performed by Zenith Technology and asked whether this was his last contact with Zenith. The researchers confirmed that he continues as a paid consultant for Zenith. The Committee noted that it is not concerned about the relationship for this level of study but in future higher risk studies that it would expect to see someone more independent to carry out scientific review.
* The Committee noted the answer given at question p.4.1 on the application form that the researchers expected to involve Maori to the extent that they are currently represented in Dunedin (7-9%) and asked what specific methods they had in place to achieve this. The researchers advised that this is a blanket statement as they can’t select participants but rather try to involve them if they can. The researchers are monitoring and reporting to Hine Forsythe. The researchers advised that participant numbers were variable – from five percent to 20 percent so when averaged out the numbers are not too far from 7-9 percent.
* The Committee noted that an internal data safety monitoring committee is in place for this study and agreed that this is appropriate given that the study is low risk.
* The Committee requested the following changes to the participant information sheet:
  + Page four, Risks: The Committee noted that rare but serious side effects should always be included in the participant information sheet and for healthy volunteer studies in particular. Mrs Folland acknowledged that they are always looking for ways to make the information as clear as possible but may have oversimplified in this case and will detail the side effects as requested.
  + The Committee noted the statement on page six of the information sheet about discontinuation in the study. While it is a fine statement the researchers cannot enforce it as they must give patients autonomy. The researchers explained that it was included in the interests of patient safety. The Committee requested that the researchers change the statement to state that “it is recommended that you are monitored for your own safety until a doctor has cleared you”.
  + Page eight, Blood Samples Collection: The Committee advised that the taking of tissue is a sensitive issue for some Māori. Please include a statement recognising the fact that some Māori have specific issues regarding consent. For example: *“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated should be discussed with your whānau, hapu and iwi as appropriate. However it is acknowledged that individuals have the right to choose”* or, *“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 noted that the participant information sheet was lengthy and questioned whether a shorter and clearer document might be more reassuring for participants. The Committee agreed however that a review was not needed and that the information is appropriate for the audience it is intended to reach.
  + The Committee noted that the information sheet did not make mention about whether this drug can affect sperm and whether male participants can father a child while on the drug or for a certain time after. The researchers confirmed that the information sheet does state that people cannot participate if they are planning on starting a family within 60 days of being on this trial. The Committee was satisfied with this but note that they had noticed the information from a female point of view but not from a male point of view.

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*).
* Please give every person a private conversation with a qualified member of the research team where the consent form is signed. This ensures that the researcher has checked with **each** participant to ensure he/she has understood the consent form, is happy with the information provided, and has had all of his/her questions (including those the participant may not have been comfortable raising in a more public forum) answered prior to signing the form (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This information will be reviewed, and a final decision made on the application, by Dr Waaka and Mrs Frank-Alexander.

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| **5** | **Ethics ref:** | **14/STH/54** |
|  | Title: | Darifenacin bioequivalence study conducted under fed conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 08 May 2014 |

Dr Noelyn Hung, Dr Tak Hung and Mrs Linda Folland 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.

* Please see the discussion recorded for 13/STH/53 as it also relates to issues identified in this study.

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*).
* Please give every person a private conversation with a qualified member of the research team where the consent form is signed. This ensures that the researcher has checked with **each** participant to ensure he/she has understood the consent form, is happy with the information provided, and has had all of his/her questions (including those the participant may not have been comfortable raising in a more public forum) answered prior to signing the form (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This information will be reviewed, and a final decision made on the application, by Dr Waaka and Mrs Frank-Alexander

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| **6** | **Ethics ref:** | **14/STH/48** |
|  | Title: | PROTECT-ICD Trial |
|  | Principal Investigator: | Dr Martin Stiles |
|  | Sponsor: | Westmead Hospital |
|  | Clock Start Date: | 08 May 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 did not identify any outstanding ethical issues for this study and noted that it is a worthwhile study.
* The Committee noted that the scientific issues have been well-reviewed and any specific issues noted were responded to by the researchers.
* The Committee noted that there is some uncertainty about the benefit risk ratio but if participants are sufficiently informed they can choose whether or not to take part.
* The Committee noted that there is a lot of information in the participant information sheet for a vulnerable group of patients to consider. The Committee agreed however that the patients will have time to think about the information and also that there will be relatives and friends around who can support the patient.
* The Committee clarified that inpatients in hospital under the care of cardiologists will be recruited.

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 discussed whether it would ask researchers to include a standardised statement about contraception that specifically states that men and women of child bearing age need to use two forms of contraception while on this study. Some of the Committee members were satisfied that the information given in the studies reviewed at this meeting addressed the issue of contraception well but it was agreed that clarification would be sought about whether the standardised statement is mandatory.
3. The Committee was unable to access the internet and it was asked that this be addressed given that some members need to be able to access the members’ portal. The Secretariat will contact the NZ Blood Service to see whether this issue can be remedied.
4. Committee members wish to be able to access parking space for the duration of the meeting and cannot currently do so at the NZ Blood Service as their protocol is that parking is for donors only and parking in the immediate area is for either 60 minutes or 120 minutes. The Secretariat will contact the NZ Blood Service to see whether this issue can be remedied. If not, the Secretariat will look at alternative venues.
5. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 17 June 2014 |
| **Meeting venue:** | NZ Blood Service, 87 Riccarton Road, Riccarton, Christchurch |

The following members tendered apologies for this meeting.

Mrs Angelika Frank-Alexander

The meeting closed at 2.00pm.