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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 16 December 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 18 November 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/STH/183  ii 14/STH/192  iii 14/STH/202  iv 14/STH/204  v 14/STH/205  vi 14/STH/208  vii 14/STH/210  viii 14/STH/211  ix 14/STH/212  x 14/STH/213  xi 14/STH/214  xii 14/STH/216 |
| 4.30pm | General business:   * Noting section of agenda |
| 4.45pm | 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 | Present |
| Mrs Angelika Frank-Alexander | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Apologies |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Nicola Swain | Non-lay (observational 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 | Apologies |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 01/09/2014 | 01/09/2015 | Present |
| Dr Fiona McCrimmon | Lay (the law) | 01/09/2014 | 01/09/2015 | Apologies |

## Welcome

The Chair opened the meeting at 12.15pm and welcomed Committee members, noting that apologies had been received from Mrs Angelika Frank Alexander, Dr Devonie Waaka and Dr Fiona McCrimmon.

The Chair noted that fewer than two appointed lay 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 Helen Walker confirmed her eligibility, and was co-opted by the Chair as member of the Committee for the duration of the meeting.

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 November 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/STH/202** |
|  | Title: | GS-US-367-1169:Phase 2 Study of GS-9857 and Sofosbuvir + GS-5816 in Subjects with Chronic Non-Genotype 1 HCV Infection |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 04 December 2014 |

Prof Gane and Ms 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 Study

* This study is a progression of a few studies done where the researchers were looking at new drugs to shorten treatment times. Both this study and another study for review at this meeting (14/STH/204) will look to shorten the treatment even further by combining drugs. The researchers are hoping that the shortened treatment will offer the same level of efficacy and improve compliance. The comments below relate to both studies (14/STH/202 and 14/STH/204).
* The committee did not have any major ethical concerns about either study but did note some points in the participant information sheets and consent forms that it would like addressed before it will give ethical approval.

The committee requested the following changes to the participant information sheets and consent forms:

(Main Study PIS/CF)

* Please consider a briefer lay study title.
* The committee noted a couple of typos on page 1 of the main participant information sheet and consent form. Please include a space between ‘ANDINFORMED’ in the title. Please include the word ‘read’ in the third sentence in the third paragraph. It currently reads “Please take time to information carefully”.
* The committee noted that the first sentence on page one of the information sheet may not read as the most encouraging start for participants. The committee asked that this sentence be removed.
* Please state that the Southern Health and Disability Ethics Committee have given ethical approval for the study.
* Page 2, paragraph 5: currently states that cohort one will enrol 90 genotype 1 infected patients. Please change genotype to non-genotype.
* Page 11: The committee asked that the researchers revisit the subheadings and include a subheading to state “risks of procedures during the study” to separate these out from serious adverse events.
* Page 13: Please include the subheading ‘Contraception Requirements’ before ‘Men only’ and ‘Women only’
* The committee noted the information that women of childbearing potential should not rely on hormone-containing contraceptives as a form of birth control during the study. The researchers clarified that this is because of a lack of study drug interaction rather than a toxicity issue. Because of a change in metabolism brought on by taking oral contraception, a person may not be protected from pregnancy. The committee asked that a sentence be included in lay terms about why oral contraceptives cannot be used as a reliable method in this study.
* The committee noted the statement in the ‘Men only’ section that hormonal birth control may be more effective when taken for at least three months and queried whether this might reflect old thinking as hormonal birth control can work immediately or within the first week. The researchers agreed and advised that they would query this.
* Page 19: the committee complimented the researchers on flowchart pertaining to questions that participants might have noting that it is a useful visual for participants to refer to.
* The committee noted that the study application states that participants won’t have access to the medicine used after the trial but that this is not mentioned in the participant information sheet. The researchers explained that the study medicine is not lifelong treatment and that it is hoped that the medicine will be shown to be curative. The researchers explained that most of the recent studies trialling the combination of these two drugs showed a response rate of 95%. Relapse is an issue and while they don’t know what it will be, an estimate is between 2-5%. Participants who relapse will need to wait for other treatment options to be developed. The committee suggested that the researchers could note that the study drug will not be available after the trial in the ‘Possible Benefits’ section. The researchers advised that they are happy to elaborate.
* The researchers confirmed that a liver biopsy is strictly optional and explained that the Fibroscan section must be included in patient information as it is a global study. The researchers confirmed that Fibroscan is now standard of care here in New Zealand and is valid in 99% of cases but may not be in few cases where conditions such as obesity would mean a liver biopsy is required. The researchers will state that a Fibroscan will be performed in New Zealand.

(Optional Pharmacokinetic PIS/CF)

* Page 4: The committee noted that the form states that participants will be reimbursed for their time but that the amount they will be reimbursed is not stated. The researchers noted that the reimbursement rate is yet to be finalised but they will advise the committee of the amount when known and will include it in the information sheet.
* The committee queried how long the samples will be stored and the researchers advised that analyses will be performed within a couple of months for this study. The samples will be kept for no longer than 10-15 years for further analyses. The committee queried whether data gained on samples within one year would be the same as data gained on samples stored after longer duration. The researchers advised that they would query this and advise the committee.

(Optional Pharmacogenetic PIS/CF)

* The committee complimented the researchers noting that this is one of best descriptions of pharmacogenomics and biomarker research testing that it has seen to date. The committee’s only comment on this form was in regard to some inconsistency in the headings used on the consent form. The committee asked that the researchers change the ‘consent for biomarker research testing’ to pharmacogenomics testing in the interest of consistency.
* Please add a brief description of the term pharmacogenomics

(Optional archive sample PIS/CF)

* The committee was concerned that it is not clear as to whether consent is being sought for future genetic or non-genetic testing. The researchers noted that the study protocol is vague on how the samples will be used and will seek clarification and advise the committee. The researchers will also clarify how samples will be used in the information sheet and consent form once known.

Decision

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

* Please amend the participant information sheets and consent forms, 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 Sarah Gunningham.

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| **2** | **Ethics ref:** | **14/STH/204** |
|  | Title: | GS-US-367-1168:Phase 2 Study of GS-9857 and Sofosbuvir + GS5816 in Subjects with Chronic Genotype 1 HCV Infection |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 04 December 2014 |

Prof Gane and Ms 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.

* Please see the discussion recorded for 14/STH/202.

Decision

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

* Please amend the participant information sheets and consent forms, 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 Sarah Gunningham.

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| **3** | **Ethics ref:** | **14/STH/205** |
|  | Title: | The HUMBA (Healthy mUMs and BAbies) Demonstration Trial |
|  | Principal Investigator: | Professor Lesley McCowan |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 04 December 2014 |

Prof McCowan and Ms Rennae Taylor 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 Study

* This study is a random controlled trial in obese pregnant women who will be randomised to receive dietary advice by a community healthcare professional or standard nutritional and physical activity advice from the Ministry of Health. Participants will also be randomised to receive a probiotic or placebo. The aim of the study is to see whether either or both of these interventions may be effective in glucose metabolism or losing weight. If successful it may offer long term improvement to the health of both babies and mothers.
* The researcher noted that in the region where they are based 86% of women are clinically obese when they become pregnant, which poses health risks to both mother and child.
* The committee noted that this is a worthwhile study.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

* There are no outstanding ethical issues.
* The committee noted some minor points in regard to the information stated in the participant information sheet and consent form but approval is not conditional on the changes being made.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

* There are no outstanding ethical issues.

The committee requested the following changes to the participant information sheet and consent form:

* Page 2: The committee suggested that the researchers may wish to explain the term ‘Placebo’ when it states that women may be allocated to a placebo arm in the study. For example, the term ‘sugar pill’ could be used.
* The committee suggested that the researchers may wish to use the word ‘bacteria’ rather than ‘bug’. The researchers explained that following consultation with the PI community that the term ‘bugs’ was suggested. The committee noted that ‘bugs’ imply other things and bacteria might be a more appropriate term in this case.
* The committee noted that the researchers state that there are no known major side effects of taking probiotics but that a possible minor side effect is a minor GI upset. The committee asked that the researcher’s state that participants may experience minor, digestive upsets such as gas and or bloating from the probiotics instead of stating that there are no side effects.
* The committee queried why the researchers intend to store the samples indefinitely. The researchers explained that no end point was specified as they are waiting for additional funding. The committee noted that the guidelines of future unspecified research while not providing a specific timeframe themselves does state that a time should be specified and recommended that this is something the researchers need to explore. The participants should know how long samples will be stored for and where.

Decision

This application was *approved* by consensus.

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| **4** | **Ethics ref:** | **14/STH/183** **CLOSED** |
|  | Title: | A Single-Dose Study to Assess the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of Odanacatib in Adolescents and Young Adults Treated withGlucocorticoids. |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | MSD - Merck Sharp & Dohme (Australia) Pty Limited |
|  | Clock Start Date: | 04 December 2014 |

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.

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| **5** | **Ethics ref:** | **14/STH/192** |
|  | Title: | COG ANBL1232: Response and Biology Based Risk factors Guiding Therapy in Non-high Risk Neuroblastoma |
|  | Principal Investigator: | Dr Rob Corbett |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 04 December 2014 |

Ms Kirstie Copeland 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 study

* This study will look at response and biology based risk factors guiding therapy in children under three years of age who have non-high risk Neuroblastoma to determine which children need treatment and what the best treatment is. The researchers are looking to treat more effectively. Every child who participates in this study needs to be enrolled in a bio study first to determine genetics.
* Participants will be grouped into three groups depending on age, tumour stage and biological and genomic features. Group A (L1) will be observed only to see whether the tumour goes away but will receive surgery if the tumour starts to get bigger. Group B (L2) will be observed for up to three years. Chemotherapy and surgery will be treatment options should there be any growth in the tumour. Group C will be participants 18 months or less in age with more than one tumour will begin chemotherapy straight away.
* The committee noted that researchers will look to recruit 30 participants in NZ between two sites and asked how common this illness is in children. Ms Copeland noted that it isn’t common – up to 3 cases each year in Christchurch. The recruitment period may be long but the treatment itself is not.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows:

* The committee recognised the importance of such a study but noted that a parent of a child might have difficulties agreeing to their child being observed and asked the researchers to explain what standard care would be for these children. Ms Copeland noted that current treatment is sometimes chemotherapy and other times surgery. She emphasised that participants will be extremely carefully monitored and any increase in tumour size they can be moved to a treatment option. In this study they are looking to avoid unnecessary treatment and the side effects it brings.
* The committee noted that it is helpful to rationalise dealing with this group of patients as such research could potentially save young children from having to have unnecessary treatment.
* The committee noted that it had difficulty understanding the aims of the study from the participant information sheets and had to read the application for clarification. It suggested that the researchers may wish to explain all three groups’ involvement in one overarching leaflet. Ms Copeland noted combining may overload participants with too much information and that participants are not randomised but are put into a group for clinical reasons. The informed consent process will be detailed and parents will have time to read the information and to discuss it with their doctor. The committee was satisfied with this response.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

* There are no outstanding ethical issues.

The committee requested the following changes to the participant information sheets and consent forms:

* The committee noted that the participant information sheet noted that information will be kept for 10 years after participants reach 16 years of age. It noted that legally it should be kept for 10 years after the youngest child in the study has reached 16 years of age.

(Attachment 1)

* Please remove and reword terms such as ‘IV’ and ‘subcut’ and ‘labs’.

(Consent forms for all groups)

* The committee noted that it recommends that the interpreter box is replaced with the following statement: *“I have read, or have read to me in my first language, and I understand the Participant Information Sheet. I have had the opportunity to ask questions and I am satisfied with the answers I have received.”*

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **14/STH/208** |
|  | Title: | LATE EFFECTS OF PREMATURITY |
|  | Principal Investigator: | Dr Stephanie Moor |
|  | Sponsor: |  |
|  | Clock Start Date: | 03 December 2014 |

Dr Moor was 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.

* The researchers in this study are part of a team that is looking at very premature babies (born at 24-30 weeks) over their lifespan to 16 years of age. At the same time the researchers are also studying a control group of participants who were not born prematurely. The study aims to look at brain development, physical development over their lifespan. This is a new cohort as babies born very prematurely prior to the 1990s didn’t often survive. The researchers are hoping to understand subtle issues better and help this group of young people to better manage what is going on for them.
* There is some evidence that there may be an increase in neuro psychological issues for this group. The researchers are not sure what they will find but perhaps more anxiety and peer-related social difficulties. Want to take a fine grain look and give tips to help manage this better.
* The committee had no major ethical concerns about this study and complimented the researchers on an extremely worthwhile study and also the fact that they are making attempts to help fix what they find. The team looks experienced and able to help in this area and participants could benefit from being in this study.
* The committee discussed some of the difficulties that the researchers are having noting that this impacted on some aspects of the study such as the ability to provide lunch for their participants. The committee suggested that the researchers may wish to contact some local businesses to explain what the study involves and to ask whether they would be interested in supporting the study by providing lunches. The committee was not concerned that this approach would be unethical.

The committee requested the following changes to the participant information sheets and consent forms:

* The committee noted that the information sheets are well written, concise and to the point. The only request the committee had was that some of the terms be explained in language that seems less scary. For example: ‘Neurological exam’.

(Teacher information sheet)

* Please include a sentence that states that both the young person and their parent or guardian have consented to the teacher providing information about the young person.
* Questionnaires – Dr Moor noted for the committee that the burden of completing questionnaires won’t be high as the questionnaires are completed electronically and there is the option to skip questions that are not relevant. The researchers will put the questionnaires online and ‘road test’ them in a control population to iron out any glitches.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **14/STH/216** **CLOSED** |
|  | Title: | A study to see how the trial drug Orbactiv affects blood clotting tests, following single doses in healthy adults. |
|  | Principal Investigator: | Dr Richard Robson |
|  | Sponsor: | The Medicines Company |
|  | Clock Start Date: | 03 December 2014 |

Dr Robson was 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.

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| **8** | **Ethics ref:** | **14/STH/210** **CLOSED** |
|  | Title: | Tiotropium inhalation powder bioavailability study |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Cipla Limited |
|  | Clock Start Date: | 03 December 2014 |

Dr Noelyn Hung, Dr Tak Hung and Ms 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.

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| **9** | **Ethics ref:** | **14/STH/211** |
|  | Title: | Desvenlafaxine bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 03 December 2014 |

Dr Noelyn Hung, Dr Tak Hung and Ms 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 study

* The committee noted that this is first of four Desvenlafaxine bioequivalence studies under different conditions for review at this meeting and agreed to discuss all four at the same time.
* This study aims to evaluate the bioequivalence of the test drug, an extended release formulation, in fasting and fed conditions on higher strength 100mg and fasting only on 50mg. The same studies were done a couple of years’ ago and the researchers are now testing for another company. The formulation is approved in Australia and Portugal and a safety profile is well established.
* The researchers confirmed that the new formulation to be studied will go to Medsafe for an abbreviated review process.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

* The committee noted information stated in the participant information sheet that advises participants that if they feel nauseated to the extent that they might vomit that they should lie on their back because lying on the right side will increase absorption of the drug may make symptoms worse and lying on the left side may slow absorption of the drug and affect the results of the study. This is not something that the committee has seen in other studies. The researchers noted that this is a regulatory authority recommendation. If need be, they are pragmatic and do allow participants to move. The researchers offered to provide the committee with the regulatory guidance.

The committee requested the following changes to the participant information sheet and consent form:

* Frequency of possible adverse reactions in the information sheet it was suggested that they give the approximate frequency i.e. 1:100 rather than common percentage.
* Please bold the contraception requirements as this is important information.
* Page 6 under the heading a) Pre dosing: please bold the words “required to stay at the clinic.”
* Please make earlier mention of fasting requirements as it is useful to participants to clearly state this up front.
* Page 2: pregnancy exclusion criteria at (xii): please state up front earlier in the information sheet that that it is okay for female participants to take oral contraceptives.

The committee noted that it will meet in Dunedin in 2015 and suggested that it might meet at the Zenith facility and take the opportunity to have a tour through the facility. The researchers were open to this.

Decision

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

* Please amend the participant information sheets and consent forms, 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 Mathew Zacharias.

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| **10** | **Ethics ref:** | **14/STH/212** |
|  | Title: | Desvenlafaxine bioequivalence study conducted under fed conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 03 December 2014 |

Dr Noelyn Hung, Dr Tak Hung and Ms 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 (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

* The committee queried the requirement that participants consume a standardised FDA breakfast that includes bacon noting that this requirement potentially discriminates against some groups of people taking part. The researchers acknowledged this point but must follow these requirements to the letter of the law and they cannot vary the breakfast. Some who cannot eat bacon could take part in the fasting condition study.
* Please see the discussion recorded for 14/STH/211.

Decision

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

* Please amend the participant information sheets and consent forms, 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 Mathew Zacharias.

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| **11** | **Ethics ref:** | **14/STH/213** |
|  | Title: | Desvenlafaxine bioequivalence study conducted under fasting conditions and at steady state |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 03 December 2014 |

Dr Noelyn Hung, Dr Tak Hung and Ms 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 (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

* There are no outstanding ethical issues. Please see the discussion recorded for 14/STH/211

The committee requested the following changes to the participant information sheet and consent forms:

* The committee questioned the safety of participants receiving the dose and then being free to go home after 30 minutes. There may be some issues that arise with giving a 100mg dose to someone who has never had the study drug before. Previous studies have required participants to stay at the facility for some hours so that researchers can observe them.
* The researchers advised that they could give the dose at night and ask participants to stay overnight so that they can be observed. Taxis can also be provided to take people home the next day. If any adverse effects happen, their internal data safety monitoring committee will capture this information and stop the study if necessary. The committee asked that this information be clearly stated in the participant information sheet and consent form.

Decision

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

* Please amend the participant information sheets and consent forms, 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 Mathew Zacharias.

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| **12** | **Ethics ref:** | **14/STH/214** |
|  | Title: | Desvenlafaxine 50 mg bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 03 December 2014 |

Dr Noelyn Hung, Dr Tak Hung and Ms 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 (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

* There are no outstanding ethical issues. Please see discussion recorded for application 14/STH/211

Decision

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

* Please amend the participant information sheets and consent forms, 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 Mathew Zacharias.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. A/Prof Harrison-Woolrych has accepted a work opportunity offshore for six months starting April 2015. The committee will look at co-opting a member from another committee during this time.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 17 February 2015, 08:00 AM |
| **Meeting venue:** | Sudima Hotel - Christchurch Airport, 550 Memorial Drive, Christchurch |

The following members tendered apologies for this meeting.

* Dr Mathew Zacharias

The meeting closed at 3.40pm.