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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 September 2015 |
| **Meeting venue:** | Ground Floor, Room G.04, Freyberg Building, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.30pm | New applications (see over for details) |
|  | i 15/CEN/146  ii 15/CEN/147  iii 15/CEN/148  iv 15/CEN/149  v 15/CEN/150  vi 15/CEN/151  vii 15/CEN/153 |
| 4.25pm | General business:   * Noting section of agenda |
| 4.30pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Kate O'Connor | Non-lay (Other) | NTB Co-opt | NTB Co-opt | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 01/07/2015 | 01/07/2018 | Present |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | STH Co-opt | STH Co-opt | Present |

## Welcome

The Chair opened the meeting at 1.00pm and welcomed Committee members, noting that apologies had been received from Dr Cordelia Thomas, Dr Dean Quinn, Dr Angela Ballantyne and Dr Melissa Cragg.

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. Ms Raewyn Idoine and Ms Kate O’Connor confirmed their eligibility, and were co-opted by the Chair as members 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.

## New applications

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| **1** | **Ethics ref:** | **15/CEN/146** |
|  | Title: | Comparison of the blood levels of two forms of fingolimod 0.5 mg tablets in healthy male and female volunteers |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Tolmar Australia Pty Ltd |
|  | Clock Start Date: | 24 September 2015 |

Dr Noelyn Hung, Dr Tak Hung and 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

1. This is a bioequivalence study (generic) that will evaluate the study drug to a reference product (branded drug).

Summary of ethical issues (resolved)

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

1. The Committee noted that the justification for the study and sample size was very clear.
2. The Committee thanked the researchers for their excellent application and clear Participant Information Sheet.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. The Committee queried P.1.1 (page 21) states there is a telephone interview. This information is not in the Participant Information Sheet. The Researcher(s) explained that there is 7-day follow up call. The Committee requested that this is clearly explained in the Participant Information Sheet.
2. The Committee noted a discrepancy between the application and the Participant Information Sheet (5 verses 10 hours for fasting requirements). The Committee noted it states 10 hours in the Participant Information Sheet. The Researcher(s) stated 10 hours was correct.
3. The Committee noted that ethnicity should not be collected on the consent form. The Researcher(s) noted that this had been raised at a prior meeting and explained that they would remove this for the current study and for future applications, adding that ethnicity is collected on a different form. The Committee was satisfied with the response.

Decision

This application was *approved with non-standard conditions* by consensus.

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| **2** | **Ethics ref:** | **15/CEN/147** |
|  | Title: | Assessment of an oral influenza B vaccine tablet (VXA-BYW.10), following a single dose in healthy adults. |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | Quintiles |
|  | Clock Start Date: | 24 September 2015 |

Dr Chris Wynne 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 (resolved)

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

1. The Committee noted Participant Information Sheet was long but covered key information well and was easy to read.
2. The Committee queried how recruiting? The Researcher(s) stated they will recruit through advertising that has been submitted to ethics and use of our own database.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Page 2: the committee noted that the first headings are background information and suggested that this is information is re-headed as such. This is only a suggestion.
2. Page 12: what does the final bullet point on the consent form mean? The Researcher explained that if negligence is involved by the site or individual researcher during an injury then the sponsor may not take responsibility for coverage. This is because the investigator or site is responsible and therefore liable. The Committee noted the researchers were indemnified.
3. The Committee requested Māori contact details are added.

Decision

This application was *approved with non-standard conditions* by consensus.

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| **3** | **Ethics ref:** | **15/CEN/148** |
|  | Title: | AL-335-604 A Study of AL-335, ACH-3102 and Simeprevir in GT1, Treatment-Naïve Hep C Subjects |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Alios BioPharma Inc. |
|  | Clock Start Date: | 24 September 2015 |

Dr Christian Schwabe, Ms Carolyn Harris and Angelica Bernal 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.

1. The Committee asked for the reasons why the study started with an 8 week treatment period, querying whether it was more appropriate to tart with the shorter duration of 4 or 6 weeks, noting that the study aimed to generate safety information. The Researcher(s) explained that the decision to start on the longer duration was a safety consideration. The study question is primarily to determine the safety of the 3 drugs in combination, however there are secondary aims about duration of treatment. In this patient population standard treatment is 12 weeks. There is growing evidence that shorter treatments are just as effective, however other studies indicate that shorter duration can result in unacceptable relapse rates. Therefore we plan to start at 8 weeks and review the data. If the rate of virus clearance is acceptable, within the first week of treatment, we will be comfortable to open the shorter durations. An 8 week start is a conservative and safe starting point.
2. The Committee queried whether the combination has been proven safe in 12 weeks? The Researcher(s) stated no, this combination has not been used before. The Researcher(s) explained the studies and current use of the three study drugs. The Committee accepted the rationale.
3. The Researcher(s) confirmed that participants are seen on a weekly basis. This will allow us to review for drug-drug interactions, adding that they would be reviewing Pharmacokinetics data.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please review for technical terms and explain them briefly (like genotype).
2. For abbreviations, please use whole word and then abbreviate in brackets. Some abbreviations are not fully explained in their first use.
3. Page 2 states no food, water allowed. Please make this clearer – currently could be misunderstood as water not allowed.
4. Remove ‘to avoid problems’ page 1 of 6 on the optional Participant Information Sheet.
5. Pregnant partner Participant Information Sheet – please make it clear this is voluntary.
6. The Committee noted that the health and disability commission do not provide Māori / cultural support for individual studies. The Researcher(s) noted this and explained they were undergoing consultation in order to identify local Māori support contact people.

Decision

This application was *approved with non-standard conditions* by consensus.

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| **4** | **Ethics ref:** | **15/CEN/149** |
|  | Title: | GS-US-339-1631: Study Evaluating Entospletinib Pharmacokinetics in Subjects with Normal and Impaired Hepatic Function |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Gilead Sciences., Australia New Zealand |
|  | Clock Start Date: | 10 September 2015 |

Dr Christian Schwabe, Ms Carolyn Harris and Angelica Bernal 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.

1. The Committee queried how healthy controls are recruited. The Researcher(s) stated primarily from our database. We will match impaired function participants with healthy participants.
2. The Researcher(s) confirmed contact numbers are 24/7.
3. The Researcher(s) confirmed contact details would be added at each locality.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Make it clearer that participants don’t have leukaemia and are not approached to participate because they may have leukaemia.
2. The Committee noted the Participant Information Sheet did not convey ‘what it was like to be in confinement’, adding that it was for 9 days. It is worth explaining briefly what is involved i.e. in a bed, in a ward with other people, TV, WIFI etc. The Researcher(s) explained that potential participants are given this information verbally and will also have a short tour of the ward. The Committee stated that some brief information would be suitable, similar to what is on the website.
3. Page 9 cites US data. The Committee queried if there is any New Zealand data. The Researchers stated not to their knowledge but that the data would be similar to the US. The Committee suggested adding ‘we anticipate that it would be similar in New Zealand’.
4. Amend ‘IRB’ to ‘HDEC’.
5. Page 11 ‘you may not receive any benefit’ but goes on to say you definitely won’t receive any benefit. Remove ‘may’.

Decision

This application was *approved* by consensus.

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| **5** | **Ethics ref:** | **15/CEN/150** |
|  | Title: | Strength versus skill deficits in dysphagia |
|  | Principal Investigator: | Ms Karen Ng |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 September 2015 |

Ms Karen Ng 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 (resolved)

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

1. The Committee noted that with regards to the long term storage of data, this data would be potentially identifiable rather than de-identified (R.2.4). The Committee explained identifiably of data and referred the researchers to the National Ethics Advisory Committee Guidelines for Intervention Studies section 7.2.

Summary of ethical issues (outstanding)

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

1. The Committee stated that it is unacceptable to have someone else consent on behalf of potential participants unable to provide their own informed consent.
2. The Committee noted that the HDC Code of Health and Disability Services Consumers' Rights Regulation 1996 applies to all health research and that a representative is unable to consent for someone on their behalf.
3. Right 7.4 of the HDC Code of Rights states that “Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where –
   * a) It is in the best interests of the consumer; and
   * b) Reasonable steps have been taken to ascertain the views of the consumer; and
   * c) Either, -
     + i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
     + ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.”
4. Further, the Committee noted that Right 9 ensures that these rights extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.
5. The Committee clarified that it is possible (under Right 7.4) if it can be shown that participation is in the best interest of the consumer and they take into account the views of other suitable persons or believe that the consumer would wish to consent if they were able to. In these cases the consent can be provided by the clinician for this individual to participate in the research.
6. The Committee explained that they did not believe that this study meets the best interest measure and, therefore, could not include participants who are unable to consent for themselves.
7. The Committee stated the study could only be approved once it involved participants who can provide consent.
8. The Researcher(s) confirmed they will not enrol any non-consenting participants.
9. The Committee queried whether the post graduate office had been consulted, noting that the dean, research office or head of school may be the appropriate sponsor for the study (a.1.9). Please contact them and see whether they would be considered the sponsor.
10. The Committee asked for more information on the commercialisation of BiSSkiT (r.5.2). The Researcher(s) stated my supervisor has done research and development on BiSSkiT software. The Researcher(s) noted they are not involved in the commercialisation.
11. The Committee noted that for future applications the answer to p.4.1 was given in f.1.2. f.1.2 is about other populations. The Committee added that any stats provided would be better in p.4.1.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Change ‘data will be given a code number’ not ‘you will be given a code number’.
2. Page 5 – please add information about what happens if a participant changes their mind.
3. On the consent form, please remove the yes no boxes unless the statement is truly optional.
4. Please add Māori contact details.
5. Add pictures in Participant Information Sheet (from advertising).
6. The Committee queried what information is collected from GPs? The Researcher(s) stated site of legion and time of stroke, adding that if patient knows this information we will collect it from them – if they are not sure we will contact GP. The Committee requested short statement in Participant Information Sheet on contacting GP.

Decision

This application was *approved* with non-standard conditions by consensus.

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| **6** | **Ethics ref:** | **15/CEN/151** |
|  | Title: | The effect of chiropractic adjustment on mental rotation in children. |
|  | Principal Investigator: | Dr Kelly Holt |
|  | Sponsor: | New Zealand College of Chiropractic |
|  | Clock Start Date: | 10 September 2015 |

Dr Kelly Holt 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

1. The Committee thanked the researcher for their peer review.

Summary of ethical issues (resolved)

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

1. The Committee queried what happens if chiropractor states they do not want to participate in the study after receiving the invitation letter? The Researcher(s) stated study would not proceed with any chiropractors who decline to participate. The Researcher(s) explained that past studies have suggested that support for research among chiropractors is high.
2. Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).
3. (P.4.1) page 20 of application, on benefit for Māori. For future applications please add statistics, if available. (F.1.2) is for statistics concerning other populations
4. (P.4.2) The Committee commended the cultural advisor information, but noted cultural issues must be identified, such as the head being Tapu.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Amend to state that health information is stored for 10 years, and for children, 10 years following turning 16.
2. The Committee noted that the various forms must be headed correctly i.e. Child Assent Form, Parent Consent Form.
3. The Committee noted the current child Participant Information Sheet was too wordy and complex for the lower age brackets. Please have two versions – one for 5-8 and another for 9-12. See <http://ethics.health.govt.nz/guidance-materials/assent-guidance> for guidance.
4. The lower age bracket should be very simple and include pictures.
5. The Committee noted the children don’t need to know about study funding etc. They need to know that it is voluntary and know what happens and why.
6. The Committee noted that child should sign the consent form to facilitate respect for their voluntary participation.
7. Remove tick boxes from consent form unless statement is truly optional.
8. Add cultural support contact details.

Decision

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

* Please provide age appropriate information sheets and assent forms for younger participants and amend the existing information sheets and assent/consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine.

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| **7** | **Ethics ref:** | **15/CEN/153** |
|  | Title: | Investigating whether a targeted nutrient supplement reduces inflammation in people with the Inflammatory Bowel Disease Crohn's disease (CD). |
|  | Principal Investigator: | Ms Bobbi B Laing |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 September 2015 |

Ms Bobbi B Laing 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

1. The Committee noted the cover letter outlining the responses to the Decline decision made at the prior HDEC meeting.

Summary of ethical issues (resolved)

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

1. The Committee asked for a justification of genetic testing, noting that the peer review did not comment on the genetic testing. The Committee discussed the tissue analysis that was planned for the study. The Researcher(s) explained that the participants (with Crohn's disease) express genes that are associated with the disease that affects processing vitamin D. The Researcher(s) added they wanted to look at how the expressions of certain inflammatory genetic markers changed after exposure to the intervention.
2. The Researcher(s) clarified that the genomic sequencing had already been done in a prior study.
3. The Committee explained that proteomic and metabolomic analysis did not require mRNA (used for determining the transcriptome) was thus quite different from genetic analysis. This study did not involve genetic analysis.
4. The Committee queried if allowing the participant to attend any day of the week could confound the results? The Researcher(s) stated that while the participant chose what day they attend i.e. Monday, they will then come on that day for the remaining visits.

Summary of ethical issues (outstanding)

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

1. The Committee asked if participants can choose not to store tissue and still participate. The Researcher(s) confirmed they could.
2. The Committee and the Researcher(s) discussed how the future tissue testing fitted with respect to this current application. The Committee explained that because this testing was undefined and was funding dependent it was appropriate to remove it from this application and instead submit an amendment, once the funds were available and the tests were defined. In order to maintain the ability to have the current participants involved it would be appropriate to have a consent form option to be contacted for further research on their samples, related to the area of this study. Therefore people who were interested could consent to be re-contacted, and subsequently re-consented for further use of tissue.
3. The Committee noted this meant that the Participant Information and Consent Form should have all information about the future testing removed. For example, Participant Information Sheet states tissue held indefinitely, for future research. This is not acceptable – remove.
4. The Committee queried whether the study is sponsored. Please check with the University and see if they are able to act as the sponsor of the study.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. The Committee noted that there is a need for a significant overhaul of the Participant Information Sheet. All references to the future tissue tests need to be removed, and instead have the option for being contacted about more tissue testing added. There must be readability changes, with reference to use of the template PIS/CF. There must be no mention of long term storage beyond the duration of the study.
2. The Committee noted that generally the Participant Information Sheet is difficult to read. Please review the template information sheet and consent from on the HDEC website (<http://ethics.health.govt.nz/>).
3. The Committee queried why a Māori whanau member needs to sign for a Maori participant? The Committee requested that this is removed, instead add a general statement about the option of consulting with Whanau – and that this is an option not a requirement to participate.
4. Reduce repetition of visit procedures by only including what is different between the visits, after the first visit that is explained in full.
5. Page 1 should state study is optional, and that participants can change their mind about involvement at any time that their healthcare is not affected by participation – see HDEC template for guidance.
6. Lots of information on the ingredients. Simplify this information.
7. Review for use of language – ‘test for biomarkers’ instead of ‘using’ biomarkers.
8. The Committee commended the diagram. The Committee suggested adding visits to the diagram.
9. Remove the yes no options from the consent form – only leave them if they are truly optional. As an example, the first bullet with a yes/no is optional.
10. Remove overseas – remove all info about the genetic info.
11. Amend ‘multiregion’ to CEN HDEC.

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*).
* Please confirm in a cover letter the plan to submit an amendment regarding any future testing of tissue.

This following information will be reviewed, and a final decision made on the application, by Dr Patries Herst and Mrs Sandy Gill.

## 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:** | 27 October 2015, 12:00 PM |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington , 6011 |

1. **Problem with Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

The meeting closed at 4.30pm