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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 March 2014 |
| **Meeting venue:** | Deloitte House, MEDSAFE, Level 6, 10 Brandon Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 25 March 2014 |
|  | New applications (see over for details) |
| 12.30pm  3.00pm | i 14/CEN/34  ii 14/CEN/36  iii 14/CEN/39  iv 14/CEN/40  v 14/CEN/41  vi 14/CEN/42  vii 14/CEN/43 |
|  |  |
| 3.40pm | General business:   * Noting section of agenda |
| 4.10pm | 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 |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2014 | Present |
| Mrs Gael Donoghue | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2014 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members.

The Committee welcomed Peter Galagher who is from the University of Otago, Wellington and Hansa Patel and Tati Cocker who are students studying for a PGDip Clinical research degree from Victoria University.

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 25 February 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/CEN/34** |
|  | Title: | Gut Health and Glucose Tolerance |
|  | Principal Investigator: | Miss Renee Wilson |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 March 2014 |

Renee Wilson (CI) and Jenny Willis (PHD Supervisor) 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 commended the project.
* The Committee described the study noting there were secondary study questions. The Committee queried whether all study questions were going to and able to be addressed in this study. The Researchers clarified that the study could answer all of the study questions posed.
* The Committee queried whether tissue would be sent overseas (B.4.5). The Researchers explained samples will be kept in New Zealand, adding that at this stage there is no intention to send samples overseas.
* R.4.1.1 talks about ‘frank diabetes’. Please clarify what this means. The Researcher explained that frank means ‘overt’ diabetes.
* (B.1.1) ‘metabolites in the headspace above stool samples’- please clarify. The Researchers explained that the collected faecal samples have a solid phase and a gaseous phase. The gaseous aspect is referred to the headspace and it can be used to measure volatile compounds.
* Committee queried if funding has been applied for. Researchers confirmed an application had been made to Diabetes New Zealand, University of Otago while also seeking other sources of funding.
* The Committee queried if the study would not proceed until funding was secured. The Researchers confirmed.
* (P.2.1) Please clarify the actual period of time participants are given to decide whether or not to participate. Researchers explained that if the potential participants did not respond to initial contact they would not be followed up, estimating 4 weeks of no response being considered as not interested.
* The Committee queried if recruitment would occur in Palmerston North. The Researchers explained there was a need for fresh samples and in order to get enough samples Palmerston North will be a site, as well as Christchurch.
* The Committee queried if Palmerston North participants would be assessed in Palmerston North or in Christchurch. Researchers confirmed there were appropriate localities to be assessed in Palmerston North.
* (F.1.2) The Committee noted this question refers to all populations, not exclusively to Maori. The Committee noted for future applications the study team need to consider how the study intervention might impact other populations, such as Pacific Islanders. The Researchers acknowledged that there is a prevalence of diabetes in Pacific Islanders, and accepted the point.
* The Committee asked if the Researchers wanted to store the faecal samples. The Researchers explained they did want to store samples. The Researchers confirmed the samples would only be used for diabetes and gut research.
* The Committee discussed storing the tissue and decided it was appropriate to have a separate, optional, consent form for storage of samples.
* (A.6.2) Please clarify the sample size for the study. The Researchers responded that it was hard to calculate the power of the study, noting this research had not been done before. The likelihood would be roughly 100 participants. The Committee queried if this was a pilot study. The Researcher stated they would consider the study a pilot study.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Pg.2 currently references to ‘GI’ digestion. Please explain abbreviations for lay participants.
* Pg.2 first sentence ‘what will my participation in study involve’. The Committee suggests rewording to clarify, for instance to read, ‘you will be invited into the study because you are either a healthy participant, because you have been diagnosed with type 2 diabetes or you have been diagnosed with pre-diabetes’. This will clarify the three categories and make it explicit why the participant has been approached.
* Please include exclusion criteria, and if possible, inclusion criteria. This information should be provided to the participant early in the process. please add f2.1 pg.23 in application form
* Please add p3.1 pg21 To explain more clearly the time frame of whether or not to participate.
* Pg.3 the legislation refers to ACC. The title of the legislation is called the ‘Accident Compensation Act’. Please amend.
* Pg.2 remove reference to Southern Ethics Committee and refer to the Central Health and Disability Ethics Committee.
* Please make it explicit that samples will not be destroyed.
* Give participants the option to opt out of having their study samples stored after the research.
* The Committee decided that in order to store the samples the Researchers will need to submit a new, optional, PIS relating to future unspecified research. The HDEC recommends the Researchers view Guidelines for Use of Tissue for Future Unspecified Research (found on quick links at <http://ethics.health.govt.nz/home>).

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* 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 following information will be reviewed, and a final decision made on the application, by Mr Paul Barnett and Mrs Gael Donoghue.

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| **2** | **Ethics ref:** | **14/CEN/36** |
|  | Title: | Healthy Relationships |
|  | Principal Investigator: | Dr Christine Wilson |
|  | Sponsor: | Kidpower, Teenpower, Fullpower Trust (NZ) |
|  | Clock Start Date: | 13 March 2014 |

Dr Christine Wilson (CI) 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.

* Dr Wilson explained that the earlier research in America focused on whether participants could recognise a risky situation and how they would respond to a risky situation. This research indicated they often did not realise they were in a risky situation.
* This study aims to increase the participant’s ability to recognise risky scenarios.
* Please explain the ‘pre-assessment’. Dr Wilson explained this was to set baseline measures for participants to see how participants initially responded to certain scenario stories and how well they understood the situation the main character was in. It would allow the investigators to determine whether the programme had increased their ability to recognize unsafe situations.
* The Committee queried if the participants are to take the role of the victim or perpetrator? Dr Wilson confirmed it was victim.
* Dr Wilson explained the pre-screening will look at differences in responses. The responses will be rated on a 3 point scale – didn’t understand, partial understanding, and complete understanding. This is so we can measure the differences between the responses of different individuals and the three different groups.
* The Committee queried if the same scenario will be used for the pre- and post- tests. Dr Wilson explained there would be two scenarios, one would be fixed (identical for both pre- and post-tests) one would be random.
* Committee confirmed that the control group was in place to see if participants would not simply learn expectations relating to the specific scenarios.
* The Committee queried whether the pre-screening testing was to assess the different levels of disability of participants. Dr Wilson noted there was no test to determine ‘level of disability’.
* Please explain the measures in place to ensure scenarios will be safe for participants, noting there was a chance of further harm resulting from a scenario triggering emotions associated with a previous traumatic event. Dr Wilson explained there was a possibility that some of the scenarios may trigger such responses but that the researchers are well versed in recognising and dealing with these situations. Dr Wilson added that there are referral measures in place as well as the option to withdraw for participants and explained the protocols in place.
* The Committee asked what would happen if a participant is withdrawn and refuses to talk to the study personal – how you will ensure their safety. What are the safety procedures in place? Dr Wilson explained that if someone withdraws due to personal reasons it would not be appropriate for the teacher or study personal to follow up without the participants consent or interest. If a participant came back then the referral processes are in place.
* Dr Wilson explained the CEO would be the first point of referral if there was a definite issue that could escalate.
* Committee queried the reason for having a control group? Dr Wilson explained that the control group is hypothesised to not show improvement in recognition of unsafe situations over time. If the control group did show improvements over time, this would affect the outcomes of this research project and lead to further research questions.
* Is the control group mentally impaired? Dr Wilson confirmed.
* The Committee queried why the Researcher felt they did not have to consult with Maori. Dr Wilson explained that Maori consultation was typically only sought when working with Kaupapa Maori. The Committee noted that due to the potential for Maori participants being involved consultation is appropriate. The Committee suggested seeking consultation with the company’s internal Maori Advisory group.
* The Committee noted the study involved working with the head which is tapu and a cultural issue.
* The Committee queried whether intellectually disabled people would feel pressured into agreeing to participate for fear of becoming isolated from the group. Dr Wilson noted that the project is often run as a group, though approaching participants is generally done individually to avoid such coercion. Dr Wilson noted the participants often self-select for participation in the study but that there was a need to recognise if coercion is occurring..
* The Committee queried how the scenarios are selected. Dr Wilson explained the participants choose the scenarios (from a pool of 40 scenarios) during the actual programme Pre- and post test scenarios were selected by the researchers one is random and one is consistent across the pre- and post-test and is the same for all participants. The programme scenarios will be shown to the whole group, allowing for discussion amongst participants. The test scenarios will be done separately, with just individual participants and the Researcher.
* The Committee queried if there was a diverse number of types of scenarios. Dr Wilson explained the scenarios take into account different disabilities and ethnicities and focus on real life situations, including encounters with members of the public (in public places) and personal relationships.
* 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).
* For future reference (F.1.1) and (F.1.2) needs to give better account of potential cultural issues for all ethnicities, not only Maori.
* The Committee confirmed the research could only be done with participants who will be able to give informed consent.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please include the health and disability advocacy group contact number (http://www.hdc.org.nz/)
* Please include Maori contact numbers.
* The Committee strongly suggests revising the PIS after viewing the HDEC template, found at <http://ethics.health.govt.nz/home> because the PIS had some information missing which may impact informed consent. For instance – why have these particular participants been approached to participate? Please clarify for participants. Also include more information about the actual programme, for instance what will be involved for me? All information about procedures, time commitments etc.
* The Committee suggested a picture diagram, noting the participant population may benefit from this.

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

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| **3** | **Ethics ref:** | **14/CEN/39** |
|  | Title: | An Australian-lead, investigator-initiated, multi-centre, prospective, randomised, parallel group, double-blind, placebo-controlled trial to establish the effect(s) of routine administration of fluoxe |
|  | Principal Investigator: | Dr John Gommans |
|  | Sponsor: | Royal Perth Hospital |
|  | Clock Start Date: | 13 March 2014 |

Dr John Gommans (CI)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.

* Committee commended the studies goals.
* The Committee noted that the study drug had been widely used for the past 20 years.
* This application will explore whether the study drug can improve recovery from recent stroke.
* The timing of administering the study drug is important as it is hypothesised to only be effective for freshly injured brain (before day 15).
* Recruitment needs to occur within the first 2 weeks.
* Committee confirmed blood samples will be destroyed.
* The Committee queried if it is possible to run the study only with people who are able to give informed consent. Dr Gommans explained that to some extent they could conduct the study in New Zealand however we may exclude people who lose specialised damage relating to communication.
* The Committee asked why this was significant, noting that if participants who consented showed physical improvements in the brain this could be extrapolated to the more vulnerable patient population.
* Dr Gommans explained that the brain works in a number of different ways, and that if people with significant communication difficulties are excluded it will miss a significant patient population who have unique brain trauma.
* The Committee noted the uncertainty about the legality of non-consensual studies and to suggest that the Researcher seeks formal legal advice (para 15 Standard Operating Procedures for Ethics Committees).
* The Committee noted the Guidelines for Interventional Research state there is an ethical obligation not to research on vulnerable participants when the study could reasonably be run on a more competent research population. They were satisfied with the researchers response.
* (P.4.2) The Committee noted there are cultural issues associated with taking samples and dealing with the head. The Dr Gommans noted this.
* Dr Gommans confirmed the Australian funder would cover the treatment costs in New Zealand.
* The Committee queried if participants would be reimbursed. Dr Gommans confirmed all expenses would be covered by the funder.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please include the exclusion and inclusion criteria.
* Insert information on Central Health and Disability Ethics Committee.
* Alter Multi-region HDECS to Central HDEC.
* Please include Maori contact numbers.
* Please make it explicit that participants will be reimbursed.
* Committee noted the ACC section is very good.
* Please add F.2.1 Pg.27 and 28 in application form re Inclusion/Exclusion criteria.

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 following information will be reviewed, and a final decision made on the application, by Mrs Gael Donoghue and Mrs Helen Walker.

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| **4** | **Ethics ref:** | **14/CEN/40** |
|  | Title: | Non-Suicidal Self-Injury in Rangatahi Māori |
|  | Principal Investigator: | Miss Tahlia Kingi |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 13 March 2014 |

Miss Tahlia Kingi (CI), Dr Lynne Russell and were present in person for discussion of this application.

Potential conflicts of interest

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

No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

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

* The study will include Rangatahi who self-harm, as well as Rangatahi who don’t in order to gain a definition and understanding on what young Maori consider self-harm.
* The study also seeks to understand what is considered ‘good support’ by Rangatahi and what would help Whanau support at risk Rangatahi.
* 12-18 year olds in the application, though the protocol discusses a section for ‘over 19 year olds’.
* The Committee queried what the over 19s role was in the study. The Researchers responded that the over 19s are Whanau, social workers and those who work with Rangatahi. The Committee confirmed this is not the young people themselves. This will be a focus group to get their perspective on at risk Rangatahi.
* Please explain how potential participants will be identified? The study population will be identified from high schools, community groups. The Researchers explained existing community groups and Kura Kaupapa that have been meeting over the last couple of years would also be used. Any Rangatahi Maori that are part of the youth and wellbeing study (12/CEN/85) will be referred to our research, which is separate from the youth and wellbeing study. The Committee noted that it is important to ensure that any approach to rangatahi is a careful one that does not in any way identify them to their peers or others and ensures confidentiality and safety.
* The Committee queried what mechanisms are in place to check participants are safe before they leave the Hui, adding the Hui may raise issues for the very vulnerable participant population. The Committee requested information on external support persons/agencies the researchers have in place that Rangatahi can be referred to if a need arises as a situation may occur where long term support/therapy is required for a participant following their disclosures at hui.
* The Researchers explained that the study team would be present at every Hui who have a substantial amount of experience with identifying and working with youth and Maori suicide.
* Researchers explained there are further processes, though sometimes it comes down to a ‘gut feeling’, adding it was hard to articulate. The Research team feels that the processes in place will be ‘best practice’, steeped in Tikanga. The Committee reminded the researchers of the need for vigilance as this could be a safety risk area for participants and needed to be carefully monitored.
* The Researchers explained that contact will be made with the support person and the Rangatahi the following day to ensure the participants are safe.
* The Committee asked if the research team had considered urban Maori. The Researchers explained they would be mindful of this and the fact that while a Rangatahi may identify as Maori, they may not have an in-depth understanding of Tikanga Maori..
* The Committee queried whether Whakama would be accounted for – particularly relating to the participant population. The Researchers confirmed this was taken on-board but was an oversight in not including it in the application for ethics.
* Pg.10 of protocol – Please explain how mental health issues will be identified alongside the self-harming issue. For example, the Committee noted that if a participant has bi-polar the information discussed at the Hui may trigger the participant to experience an episode of the highs or lows that can present with bi-polar. The Researchers explained the identification of mental illness is not a research goal. The Committee felt the lack of identification of mental health issues while not a component of the research, is an important factor in participants ability to cope with discussing and revealing information that creates an emotional reaction and can create a risk for the participants . This is a safety issue for participants and needs to be taken into account.
* The Committee queried the safety mechanism in place ensure the support person is not someone who poses a risk to them, emotional, physical or otherwise. The Researchers explained that the Rangitahi identify who they want to bring as support, though there is no formal measure in place to assess or risk – adding this issue would be true of all studies involving assent or support.
* The Committee noted that researchers need to ensure that the support person is a safe one and that the Rangatahi are not being pressured into having any particular support person by a person or whanau member who believes it is their right to be the support person. This is an important safety issue for the participants.
* The Committee noted the participant population will include self-harmers, and these participants may have family issues which creates a conflict in having a family member as a support person.
* The Committee queried the need for a support person was a mandatory requirement. The Researchers confirmed yes – support is required to participate.
* The Committee suggested documenting the confirmation of confidentiality by those attending the Hui.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* ‘If you are Rangatahi between 12-18 years with Maori ancestry or if you ‘think of yourself as Maori’. Please clarify what this means. The Researchers explained this referred to self-identification as Maori. The Committee suggests removing the section “or if you think of yourself as Maori”.
* The Researcher suggested including clear wording for participants to choose an appropriate person to come as a support person, noting it did not have to be whanau but could also be a person over 16? who the participant trusted. The Committee agreed that this would be a good measure to ensure the participants are able to be open, honest and safe when participating in hui.
* Ensure the Central Health and Disability Ethics Committee details are included.

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 Observation Studies para 6.11).
* Clarification of safety measures in place, taking into account the concerns raised by the Committee (Ethical Guidelines for Observation Studies para 5.5).

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

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| **5** | **Ethics ref:** | **14/CEN/41** |
|  | Title: | The transition from acute to chronic post-surgical pain - a prospective, randomised controlled trial |
|  | Principal Investigator: | Mr Campbell MacLachlan |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 March 2014 |

Mr Campbell MacLachlan (CI) 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 study will assess whether acute pain that transitions to chronic pain can be prevented by a combination of drugs, compared to the current standard treatment (no treatment) and whether certain personalities are more likely to transit from acute to chronic pain than others
* 150 participants will be recruited.
* How common is it to be in persistent pain after surgery. Mr MacLachlan explained the figures are unknown but the study aimed to generate further data.
* Mr Maclachlan confirmed this study would focus on hip and knee replacements.
* Please explain how screening of health information will occur in order to identify potential participants and to ensure they are not on medication that will exclude their participation.
* Mc Maclachlan explained one of the questionnaires asked about their current medication. The Committee noted the questionnaire actually asked if they had mental illness which is not explicit enough. Please ensure questionnaires seek all relevant information to ensure patient safety – particularly to identify exclusion criteria with regards to use of other antidepressants, including St Johns Wort.
* (P.2.7) Please clarify how often the participants who are randomised to the treatment wing will be seen in person and the level of follow up involved. Mr Mclachlan responded they will come in periodically until they are on the maximum dose of the study drug. The drug is escalated up to the full dose. Once at the full dose they will not be contacted for 3 months.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The Committee suggests revising the PIS after viewing the HDEC template, found at <http://ethics.health.govt.nz/home>
* 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).
* Include information on how is data confidentiality maintained
* Pg.2 – please remove bullet points as this is not helpful for potential participants.
* Please include information about ACC coverage.
* Include information about consulting with family and friends about study participation.
* Include potential risks for participants.
* Include exclusion and inclusion criteria for participants. Please add re Inclusion/Exclusion criteria f2.1 pg 21 of application.
* Please ensure any requirements for participants and what is expected of them is explicit in the PIS (for instance any additional trips to clinic).
* Include the Central Health and Disability Ethics Committee contact information.
* R.1.1 – this shows all of the side effects of the study drugs – please include this information in the PIS.
* Please ensure the publication results are anonymous and that this is made clear to participants.
* Include Maori support numbers and HDC contact numbers.

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 following information will be reviewed, and a final decision made on the application, by Dr Patries Herst and Mr Paul Barnett.

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| **6** | **Ethics ref:** | **14/CEN/42** |
|  | Title: | ORBIT 4 |
|  | Principal Investigator: | Dr Conor O'Dochartaigh |
|  | Sponsor: | Clinical Network Services |
|  | Clock Start Date: | 13 March 2014 |

Dr Conor O'Dochartaigh and Ms Catherine Howie 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 queried if there was tissue stored for future unspecified research. The Researchers confirmed they are asking the participants to allow tissue to be retained to look at bio-markers and research relating to the study.
* Please provide separate Optional PIS and CF for future unspecified research.
* Noted PIS is very long.
* Is the sponsor going to pay for potential side effects from the study drug? Researchers confirmed the sponsor would cover these costs.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please include the main exclusion criteria.
* Pg.4 has a duplicate sentence – please remove.
* Pg.1 – what does my participation involve? This section talks about the disease. Please review, for instance: introduction, then information on disease, then what will study involve for me.
* Pg.10 – 5th paragraph. Please include ‘if you don’t want blood samples taken then you cannot participate’.
* Pg.11 – reference the optional sheet then include the bulk of the information on a separate, optional, PIS.
* Pg.12 - under benefits – second paragraph. Take the second sentence of this paragraph out, as this refers to compensation in the event of injury, not benefits.
* Pg.13 - please reword the sentence “Otherwise, you might have unexpected expenses from being in this study”, as this indicates participants may incur a cost.
* Add main exclusion criteria add f.2.1 pg 28. in brief lay language(as there is a lot of medical language) and to note age and pregnancy are in the PIS.

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* 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 following information will be reviewed, and a final decision made on the application, by Mrs Helen Walker and Dr Patries Herst.

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| **7** | **Ethics ref:** | **14/CEN/43** |
|  | Title: | Alios BioPharma ALS-8176-503 |
|  | Principal Investigator: | Dr Thorsten Stanley |
|  | Sponsor: | inVentiv Health Clinical Australia Pty Ltd |
|  | Clock Start Date: | 13 March 2014 |

Dr Thorsten Stanley and Marina Dzhelali were present in person for discussion of this application.

Potential conflicts of interest

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

No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

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

* The Committee commended the Northern A Committee’s review of the application.
* Have Researchers applied for SCOTT? The Researchers stated the study had been submitted.
* The Committee noted the differences between the amended protocol and the original protocol (which was declined).
* The Committee confirmed the younger cohort would only be opened after safety information analysis was conducted on the older cohort.
* The Committee noted that the protocol only requires 2 older cohort participants to be analysed, after which the next younger cohort would start treatment (pg.24). The Committee noted there could be 2 12 month old infants in the older cohort and a 2 month old in the next younger cohort.
* Please justify how two infants would be sufficient as safety data. The Researchers explained the sponsor had provided answers to the scientific Committee’s queries.
* The Committee noted the difference between 12 months and 2 months – while the sentinel data may be there, it needs to be clear to the Committee that adequate measures and safety data is available minimise risk. Currently this is not clear.
* The Researcher acknowledged it was not clear when enrolment of the next younger cohort could be commenced.
* The Researchers stated they felt it made sense to only start the next younger cohort once all the older information had been analysed, rather than just 2 participants. The Committee agreed. Please get sponsor to clarify.
* (R.5.4.1) Please explain how potential conflicts will be mitigated, noting the Researcher or recruiter may be the treating paediatrician. The Researcher noted there were a number of paediatricians at the hospital and the CI was only on call one day a week. The Researcher further explained he was prepared to delegate treatment responsibilities out if he was enrolling a participant into the study.
* Please explain the costs and reimbursement, for instance would babysitting be able to be reimbursed? Please include further information on what reimbursement is available. Researchers explained the contact was not finalised with the sponsor, but would clarify the level of reimbursement. The Researchers added that babysitting would be reimbursed.
* Please provide information about the mother agreeing to provide medical history and health information, as the PIS is currently about the child participating. The consent for obtaining the mother’s medical information could be included in the current PCF.
* The Committee queried whether both parents needed to consent. The Researchers explained it was just one parent, adding usually it was the mother. The Committee suggested removing the option for both to sign.
* Pg.4 application – for future applications please include a time frame of consent, or an average period of treatment.
* P.4.1 – in future applications – please give a brief overview about impact of intervention, not citing a piece of research. Some information, statistics. A paragraph summary – the potential benefits if the intervention works what impact it will make.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Include dosing information - a relative explanation relating to the dosing levels in the study for instance ‘less than 3 times’.
* Please include exclusion and inclusion criteria.
* Pg.6 please amend to ‘in the nose’ not ‘on the nose’.
* Include information on how data will be kept confidential.
* PIS – single dose ascending - page 3. – refers to “ 5 subjects” – 3rd paragraph down, last sentence – please amend to “infant”.

Decision

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

* The committee is unclear about the study design and therefore is unable to judge whether the risk for the younger cohort is sufficiently minimised. (Ethical Guidelines for Intervention Studies para 5.4, page 11).
* 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 following information will be reviewed, and a final decision made on the application, by Dean and Paul.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee discussed the response received relating to population level data linking and child welfare from MoH. The Committee noted the requested audit, as a condition of HDEC approval, had been met for the year.
3. The Committee discussed the issue of non-consensual trials, clarifying HDEC’s role – to focus on the ethics of the studies. It is reasonable for HDEC to suggest, when there is a reasonable doubt of the legality of the actions described in the study, that the Researcher seeks further legal advice.
4. The Committee noted there are no Maori contact details on the template HDEC PIS/CF and requested this is amended as soon as possible.
5. The Committee noted there should also be information on the inclusion and exclusion criteria on the template PIS.
6. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 22 April 2014, 12:00 PM |
| **Meeting venue:** | Terrace Conference Centre, 114 The Terrace, Wellington, 6011 |

The following members tendered apologies for this meeting.

* Dr Patries Herst.

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 4.15pm