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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 23 September 2014 |
| **Meeting venue:** | MEDSAFE, Deloitte House, 10 Brandon Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 26 August 2014 |
| 12.30pm | New applications (see over for details) |
| 12.30-12.55  12.55-1.20  1.20-1.45  1.45-2.10  2.10-2.35  2.35-3.00  3.00-3.25 | i 14/CEN/136  ii 14/CEN/145  iii 14/CEN/147  iv 14/CEN/148  v 14/CEN/149  vi 14/CEN/150  vii 14/CEN/153 |
| 3.30pm | General business:   * Noting section |
| 3.45pm | 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 | Apologies |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2015 | Apologies |
| Mrs Gael Donoghue | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Apologies |
| Dr Dean Quinn | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |
| Dr Kay de Vries | Non-lay (observational studies) | 19/05/2014 | 19/05/2017 | Present |
| Ms Kerin Thompson | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 12.30pm and welcomed Committee members, noting that apologies had been received from Mrs Helen Walker, Mr Paul Barnett and Dr Patries Herst.

The Chair noted that fewer than five appointed members of the Committee would be present for review of two studies for review at this meeting for which he has a conflict of interest, and that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Ms Kerin Thompson confirmed her eligibility, and was co-opted by the Chair as member of the Committee for review of 14/CEN/149 and 14/CEN/150.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 26 August 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/CEN/136** |
|  | Title: | RESPECT ESUS |
|  | Principal Investigator: | Dr. Jeremy Lanford |
|  | Sponsor: | Boehringer Ingelheim Pty Limited |
|  | Clock Start Date: | 11 September 2014 |

Dr Jeremy Lanford was present in person for discussion of this application.

Potential conflicts of interest

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 Lanford confirmed that an application has been made to SCOTT for scientific approval. A decision is pending.
* The committee stated the understanding is clear why SCOTT scientific review is required and because of safety concerns the anti-coagulant being trailed is only being used in small amounts.
* The committee noted that a major safety issue was uncontrolled bleeds and was pleased to see that this potential risk was clearly stated in the participant information sheet. Dr Lanford noted that the biggest safety concern about the use of anticoagulants is bleeding inside brain. In previous studies comparing this study drug compared with the anti-coagulant warfarin the outcomes were not much different. Dabigatran has a much shorter half-life. In anti-coagulants with intracranial haemorrhaging no reversal was available but there is no difference in outcome between Warfarin and Dabigatran.
* The committee drew Dr Lanford’s attention to the study exclusion criteria listed at question f.2.1 on page 24 of the application form. If the criteria listed there is not something that may be in the patient’s notes or if the researchers think that the criteria would impact on their health and safety please include them in the participant information sheet. The committee suggested the following criteria listed at f.2.1 may be important to include: history of atrial fibrillation, other specific stroke etiology and history of hypersensitivity or known contraindication to DE or ASA.
* The committee asked Dr Lanford to confirm who the independent data safety monitoring board referred to at r.1.5 on page 14 of the application form is. Dr Lanford advised that formal monitoring arrangements will be overseen by the safety steering committee based in Germany and they will decide whether study should be stopped. Dr Lanford confirmed that the steering committee is independent from the study sponsor and executive. The committee asked that this be made clear in the future.
* The committee advised Dr Landford that, for future reference, question p.4.1 on the application form asks how the proposed research will benefit Māori. It can be useful to include any known statistics about how Māori are represented for example.
* Dr Lanford stated that statistics show Māori and Pacific Islanders have a higher rate of cardio embolic stroke than other groups, it is likely they will have embolic stroke of undetermined source and there is a chance that this study will benefit them. The committee noted that for future reference this kind of information is useful to include at p.4.1.
* The committee advised that for future reference question f.1.2 includes other populations such as Pacific peoples and that it would also be useful to include any known statistics about these population groups and how the research might benefit them.
* The committee asked Dr Lanford for further clarification on how he intended to identify and approach potential participants to the study. Dr Lanford explained that he is a stroke lead medical professional and patients who have had a stroke are referred to him and a stroke nurse. Both he (as a stroke lead medical professional) and a stroke nurse would review patients referred to Dr Lanford after they have experienced a stroke. If someone met the clinical criteria at this point they would discuss the possibility of them taking part in the trial. Dr Landford reassured the committee that he and the nurse would clarify that non-participation would not affect their usual care so that there is no perception or risk of undue influence.
* The committee noted that in terms of participant safety the study medication has come with a foot note about the risk of bleeding. The committee noted that it is mindful of fact that it knows of a death from a similar treatment because the participant was not identified as being on the treatment following a road accident. The committee asked whether participation will be documented in medical notes that are readily accessible to other medical teams. Dr Lanford confirmed that this would be the case in DHB medical records. The committee queried whether participants might wear something that can readily alert medical teams that they are part of the trial such as a medic alert bracelet should an event happen outside of their study locality. Dr Lanford advised that the practice of wearing such bracelets is no longer in effect but he offered to discuss the issue as part of the discussion with potential participants.
* The committee asked whether a member of the research team will take participants through the participant information sheet verbally in addition to participants reading the sheet. Dr Lanford confirmed that this will be the case. The committee was reassured by this noting the power issues inherent in informing patients especially when some participants may have cultural or literacy issues.
* The committee requested the following changes to the participant information sheet and consent form:
  + The committee noted that overall the participant information sheet was comprehensive and well put together but needed some minor changes before it would approve the document.
  + The committee liked that participants are advised to tell the study doctor and staff about any over-the-counter medications they might be taking noting that they can impact on the study drugs used.
  + Page 14: please replace reference to Australian laws with relevant New Zealand laws. Please review the entire document to be sure that the information given is relevant to a New Zealand context.
  + Please include contact details for a Māori support person.
  + Please state that the Central Health and Disability Ethics Committee has ethically approved the study.

Decision

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

* Please amend the New Zealand participant information sheet, 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 secretariat.

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| **2** | **Ethics ref:** | **14/CEN/145** |
|  | Title: | MLN9708 Plus Lenalidomide and Dexamethasone Versus Placebo Plus Lenalidomide and Dexamethasone in Adult Patients With Newly Diagnosed Multiple Myeloma |
|  | Principal Investigator: | Dr Steven Gibbons |
|  | Sponsor: | PPD |
|  | Clock Start Date: | 11 September 2014 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

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.

* This study will look at new type of chemotherapy vs. placebo in patients with newly diagnosed multiple myeloma in addition to background therapy with “len-dex” therapy. The primary objective is to see if the new type of chemotherapy improves progression free survival compared to placebo.
* The main issue of concern for the committee is that the information given in the participant information sheets and consent forms does not give a clear indication of what this research involves, and lacks clarity about the use of any tissue collected. No member of the research team was able to attend the meeting to speak to the committee to clarify this important issue and the committee noted that it would have been ideal if a member of the research team could have attended.
* It was not clear to the committee from the information given in the application form and in the participant information sheets: what will happen to the tissue collected in this study, for what purpose additional samples are being collected and whether tissue will be used for future unspecified research.
* The committee noted that the researchers had answered ‘no’ to question b.4.5 on page 15 of the application form. This question asks whether human tissue collected from study participants will be made available for future research, for instance by being stored in a tissue bank. This answer was at variance with that given at question r.3.11 on page 22 which indicated that tissue taken in this study will be transferred to another tissue bank. The answer given at r.3.1.2 then states that tissue will be destroyed at the end of the study. The information stated in the ‘NZ Master ICF’ suggests that tissue may be used for future unspecified research. There is no obvious future unspecified research information given. The committee noted the requirement that researchers must gain separate consent from participants to collect and use any samples for future unspecified research.
* Page 17 of the main participant information sheet states that additional blood and bone marrow samples collected in the study will be stored at Millennium for up to 15 years from when the study results are reported. It was not clear what these ‘additional’ samples are.
* Page 17 of the main participant information sheet states that *“The samples collected may also be used in the future as part of research related to the development of MLN9708, additional biomarkers relevant to your disease, or response to MLN9708”.*  Any future unspecified research should be optional and consent distinct from that of consent to this proposed research.
* Consent for the biomarker blood samples for genetic testing should also be part of a separate participant information sheet with a title that includes the words ‘optional biomarker research’.
* The answer given at question r.1.13.3 on page 19 of the application form is that ‘yes’, a medical physics expert have has verified that accurate effective doses of ionising radiation have been calculated. However, page 13 of the main participant information sheet states that *“the risk of radiation exposure from these scans is uncertain and has not been determined.”*
* There are two participant information sheets and consent forms submitted with this application. The titles of the forms need to be changed to clearly reflect the study. It was not entirely clear to the committee whether the first form was to identify whether a person has the condition and if so the second form was for consent to the main study. If so the titles on the pre study information sheet and consent form need to be changed to accurately reflect the study. For example, “Pre-study bone marrow sample collection” rather than “Patient information, informed consent and authorisation to access medical records.”
* On page 5 of this information sheet in the second to last paragraph states that *“As long as the record linking your identity to your samples exist, your sample can still be destroyed”* . It is not clear how long the marrow samples will be retained/stored, nor how long the records linking the identity will be kept (as this might prevent samples from being able to be identified should the participant no longer wish for the samples to be retained).
* On page 7 of this consent form please change “subject” to “participant”.
* The committee questioned the relevance of the pregnant partner authorisation participant information sheet. The committee noted that the main participant information sheet has no information for female partners of male participants.

Decision

This application was *declined* by consensus as the Committee did not consider that the study would meet the following ethical standards.

National Ethics Advisory Committee (NEAC) *Ethical Guidelines for Intervention Studies, Free and informed consent, paras 6.7, 6.12 and 6.13, and Features of informed consent Features of informed consent para 6.22*

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| **3** | **Ethics ref:** | **14/CEN/147** |
|  | Title: | The IMPERATIVE-HF trial |
|  | Principal Investigator: | Professor Richard Troughton |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 September 2014 |

Prof Troughton was present by teleconference for discussion of this application.

Potential conflicts of interest

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 asked who the independent data safety monitoring committee that will monitor serious adverse events will be. Prof Troughton explained that this study is funded by the HRC and that any HRC-funded study like this requires a data safety monitoring committee. Prof Mark Richards has established a committee that includes Prof Stewart who has sat on many data safety monitoring committees, Prof Henry Trum from Melbourne and Prof Chris Wright. The researchers will give data to this committee.
* The committee noted that the HRC letter advising that funding for the study was successful stated that the contract must start by 1 October 2014. Prof Troughton confirmed that they had met the conditions and requirements stated by the HRC and once they have ethics approval they can start the study.
* The committee queried the process the researchers intend to take for consenting participants to the study. Prof Troughton advised that the researchers will initially talk about the study with patients and introduce the concept. They will leave the information sheet with the patient so that they can digest the information and then talk about it with family and or friends. The researchers will then talk through the study and can answer any questions.
* The committee commended the researchers on their acknowledgment of Māori and for respecting multi-cultural differences in questions answered in the application form.
* The committee requested the following changes to the participant information sheet and consent form:
  + The committee noted the study exclusion criteria listed at question f.2.1 on page 27 of the application form. The committee noted that where there may be an impact on health and safety that important exclusion criteria are added to the participant information sheet in lay language. Prof Troughton explained from the researchers’ perspective that they wouldn’t approach a patient who met the exclusion criteria and wouldn’t look to consent them to the study. In regard to the committee’s comment about patient safety, that wouldn’t be an issue as they will not look to recruit non-eligible participants. The committee accepted Prof Troughton’s word on this.
  + Page 5 under the heading ‘What happens after the study or if I change my mind?’ Prof Troughton explained that participants can withdraw consent at any time and that there is no influence on standard care if they decide to withdraw. The committee noted that this information was stated under the heading ‘What are my rights?”. Prof Troughton further explained that it is important for the study’s scientific integrity that the researchers keep in touch with the patient to track outcomes; it is important to know that the patient has not come to harm. Prof Troughton agreed to include this information for participants in a follow up statement.
  + The committee noted that the consent form (page 7 of 9) requests consent for retaining blood samples but does not ask for consent for the sample to be taken. The committee suggested that a sentence that states that I agree that my blood sample be taken be included.
  + Page 3 with regard to amount of additional blood to be taken (26 mls) – please put ‘approximately x teaspoons’ to allay concerns that a lot of blood will be taken
  + Page 5: please change “would” be eligible for compensation to “may” be eligible.
  + Page 8: please remove the statements about DNA samples and future unspecified research as this should be covered in the optional consent form for future unspecified research.

The committee requested the following changes to the optional participant information sheet and consent form for future unspecified research:

* + Please make this an optional sheet that is not connected to the main study given that it is a stand-alone option.
  + Page 9: please remove the third, fourth and fifth paragraphs that appear to have been copied from the main consent form.
  + Please include the contact details of all study support people.
  + Page 11: Please include a confidentiality statement that is similar to the one on page 8 in the main consent form.

Decision

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

* Please amend the New Zealand participant information sheet, 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, Mrs Gael Donoghue and Mrs Sandy Gill

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| **4** | **Ethics ref:** | **14/CEN/148** |
|  | Title: | Omega-3 fatty acids and cognition |
|  | Principal Investigator: | Miss Alexia Mengelberg |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 September 2014 |

Miss Alexia Mengelberg and Prof Janet Leathem were present in person for discussion of this application.

Potential conflicts of interest

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 researcher on a very interesting study.
* Participants in this study will be re-formed from another cohort. Prof Leathem explained that another study is being conducted about everyday memory difficulties. 100 people have been seen in that study and they are mostly older people who have agreed to be contacted about future research options.
* The researchers are looking to only recruit participants with mild cognitive impairment and will baseline screen using the Montreal Cognitive Assessment. Miss Mengelberg advised that participants will have to have selected memory impairment and other forms of memory will be normal. Participants with ‘mild cognitive impairment’ are still considered to perform daily activities so this is a selective form of memory impairment.
* The committee queried how the researchers will store data. Miss Mengelberg explained that most of the tests will be completed using pen and paper, and that the files will be stored in locked cabinet. Data will also be stored on her office computer which has a password lock. This is a double blind clinical trial and all participants will be assigned a code number.
* The committee noted that the participants may already be taking a number of supplements given the age group and asked whether there will be any restriction on supplements they may already be taking and whether there will be any wash-out period in the study design. Miss Mengelberg advised that the exclusion criteria listed at f.2.1 of the application form included consumption of fish oil supplements in the last 12 months. The committee asked that this be stated in the participant information sheet.
* The committee asked whether the researchers will go back and make contact with participants should they find out that a participant may require further medical treatment. Miss Mengelberg confirmed that this would be done in consultation with Prof Leathem with results from psychometric tests. The committee asked that this information be stated to participants and suggested wording along the lines that the researchers may contact participants in certain types of situations.
* The committee noted the answer given at question p.4.2 on page 24 of the application form about identification of cultural issues that may arise for Māori. For future reference, the taking of blood is a cultural issue for some iwi. The committee advised that the researcher’s interaction with participants is where the cultural issues come into play.
* The committee noted that the researchers had stated that a formal monitoring arrangement was not necessary and queried the rationale for this. Miss Mengelberg advised that this decision was made because of the nature of product, that is, it is not a prescription medicine and that participants can access the product and it is safe and non-toxic. The committee noted that this emphasises need for exclusion criteria being clearly stated in the participant information sheet.
* The committee queried whether genetic testing is a compulsory part of this study as genetic testing is often an optional part of a study. Miss Mengelberg advised that she would need to give further thought as to whether the testing was optional and noted that it would add a lot to her research to test the APOE4 gene. She noted that there is little information known about the APOE4 gene positive result and its association with dementia. The committee noted the need for clarity about whether this will be a compulsory or optional part of the study. If it is optional, a further and separate information sheet will be needed and if the test is compulsory, this will need to be clearly stated to participants.
* Further information will be needed bearing in mind the implications of a positive result for both the individual and for whanau. A positive result could also have ramifications for health insurance or life insurance, which needs to be made clear to participants.
* The committee asked the researchers to give some thought to the potential for breaking bad news to participants and to advise the committee of the process. It is not currently stated in the study protocol.
* The committee requested the following changes to the participant information sheet and consent form
  + The committee noted that the reason participants have been selected to take part in this study is not clearly stated and that the non-disclosure of this information may be misleading for participants. The committee would be more comfortable it if is clearly stated that they are participating because they have a mild memory problem and does not think that participants knowing this information will detract from the study.
  + Please state that to be eligible to take part in this study participants must also be between 65 and 95 years of age. Please also include the exclusion criteria of allergy to seafood and difficulty with swallowing capsules because of reflux.
  + Please clearly state wash out criteria of 12 months
  + Please include contact details for the study’s Māori support person.
  + Central Committee approval
  + Page 4 in relation to the compensation clause: please change “would” be eligible to “may” be eligible.
  + Please include a footer and version number.

Decision

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

* Please advise the committee whether genetic testing for APOE4 will be a compulsory or optional part of the study. If it is optional, a further and separate information sheet will be needed and if the test is compulsory, this will need to be clearly-------------------------------------------------------------------- stated to participants in the participant information sheet.
* Please give some thought to the potential for breaking bad news to participants and to advise the committee of the process you will take.
* Please amend the New Zealand participant information sheet, 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 all committee members.

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| **5** | **Ethics ref:** | **14/CEN/149** |
|  | Title: | A 52-week, double-blind, randomised, multi-centre, phase III, parallel-group study in patients 12 years and older with asthma, evaluating Symbicort Turbuhaler 160/4.5ug ‘as needed' compared with Pulmi |
|  | Principal Investigator: | Dr Simon Carson |
|  | Sponsor: | AstraZeneca Pty Ltd |
|  | Clock Start Date: | 11 September 2014 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

Dr Quinn declared a potential conflict of interest, and the committee decided that he would not take part in the discussion or decision-making for this application. Mrs Gael Donoghue chaired the discussion for this application.

Summary of ethical issues

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

* One of the main concerns the committee has is that this study is intended to be conducted in a vulnerable group (children). The committee noted that the treatment is not considered standard treatment and it has many side effects and therefore questioned whether it is necessary that children are involved. The committee noted that when using vulnerable groups, they need to be confident that research cannot be done in other groups. The committee would like to see the research team’s justification for using children in this research.
* The committee noted the answer given at question a.7.3 on page 12 of the application form was ‘yes’ that ethics approval for this application was declined approval by an overseas ethics committee. The committee would like the researchers to provide further information on which committee declined the application and why and also whether there have been any changes to the study following the decline decision.
* The committee noted the answer given at question b.2.2 on page 14 of the application that peer review was done by the study’s sponsor. The committee had read the peer review letters and noted a number of recommendations. The committee would like the researchers to clarify whether the recommendations have been acted on.
* The committee noted the answer given at question r.1.6 on page 18 of the application form about data safety monitoring arrangements described in detail the monitoring of conduct and collection but gave little information on overall governance and oversight. Section 6.8 in protocol states that study governance and oversight is “not applicable”. Please clarify this for the committee.
* The committee noted the answer given at question r.1.6 on page 18 of the application form about the criteria for terminating the study. The committee noted the information given about withdrawing individual patients but did not mention what governance and oversight in terms of terminating the study will be. For example, are there any stopping rules in place, who is maintaining oversight of recruitment and adverse events that warrant stopping the study.
* The committee noted the answer given at question r.4.1 on page 21 of the application form that none of the study aspects might produce findings that may be both unexpected and clinically significant for participants. The committee thought a positive pregnancy test could meet the criteria. The committee would like further information about whether the researchers have a process in place for managing and informing participants of clinically significant findings and any follow up that is appropriate.
* The committee discussed the risk that participant safety may be compromised if their GPs are not informed that they are in the study. The committee would like the research team to clarify whether consent to informing GPs is mandatory, particularly as participants will be referred back to their GP for ongoing asthma care once they have completed the study.
* The committee acknowledged that while written withdrawal is useful from a locality point of view that participants are not legally required to withdraw from a study in writing. Withdrawal can be verbal. Please include the verbal notification section used in the other PIS/CFs in the adult participant PIS/CF.
* Please confirm that the contact numbers on the emergency card can be reached 24/7.
* The committee noted that you will send a summary of results to participants at their request. Please confirm whether the summary given to participants will be in lay language.
* Please confirm whether you will use NZ Census information to collect data relevant to New Zealanders. (Question p.4.6 on page 26 of the application form)
* The committee queried the answer given at question f.1.1 on page 27 of the application form as the study does not appear to be set up to reduce inequalities. It may make health outcomes better for this group as well as other New Zealanders. The committee noted this for the research team for future reference only.
* The committee noted that the answer given at question f.2.5 on page 27 of the application form was unfinished. If there is any additional information that you’d like stated, please let the committee know in writing.
* The committee noted the answer given at question p.4.1 on page 26 of the application form. For future reference it would be useful to include any known statistics on Māori and asthma and explain how this research might help change the statistics in future.
* The committee requested the following changes to the participant information sheet and consent form:
  + Please reword study title in lay language.
  + The committee’s understanding of the study is that it will look at using Symbicort on an ‘as needed’ basis without daily maintenance medication. The committee noted that the researchers recognise that the treatment is not standard of care which is why they are doing the study. The committee would like this aspect clearly addressed in more detail in the participant information sheet.
  + Page 10 of the 12-16 year old forms states that the sponsor may stop the study for commercial reasons. The National Ethics Advisory Committee intervention study guidelines state that a study cannot be stopped for commercial interests (para 6.65). Please advise the sponsor of this and please remove this statement from the information sheet.
  + Page 12, paragraph 2: please replace ‘Australia’ with ‘New Zealand’.
  + Page 13: please correct the HDEC email address – [hdecs@moh.govt.nz](mailto:hdecs@moh.govt.nz)
  + Page 14: please remove instruction to sites in the INTERPRETER box before using the information sheet’
  + Pages 14 and 15: the committee noted that Yes/No statements are best used when statements are truly optional. Please look at removing the boxes for statements that are not optional.
  + Page 11: under the heading ‘How will my personal information be used?’ It is stated that personal information will be shared with “government agencies throughout the world”. Please confine this statement to government agencies in countries associated with this research.
  + Page 7: under the heading ‘What are the possible risks and benefits of this study’. The committee noted that the side effects don’t mention that asthma might get worse and that this is a consequence that should be drawn to people’s attention. The committee noted the same for any other allergic reactions that a GP might not know about unless they know their patient is participating in this study.

Decision

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

* Please address each of the requests for clarification and further information in the discussion points listed in the body of this letter.
* Please amend the New Zealand participant information sheet, 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 all committee members.

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| **6** | **Ethics ref:** | **14/CEN/150** |
|  | Title: | Intranasal Oxytocin for the treatment of high frequency episodic and chronic migraine |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: | Trigemina Pty Ltd |
|  | Clock Start Date: | 11 September 2014 |

Dr Dean Quinn was present in person for discussion of this application.

Potential conflicts of interest

The Chair declared a conflict of interest as he is the lead investigator for this study. The committee decided that the Chair would not take part in the decision-making for this study. Mrs Gael Donoghue chaired the meeting for the discussion of this application.

Summary of ethical issues

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

* The committee asked whether SCOTT scientific review for this study is pending and Dr Quinn confirmed that an application has been submitted and a decision is pending.
* The committee noted the answer given at question r.1.4 on the application form about the monitoring arrangements for serious adverse events and asked what the process is for reviewing data and other things like adverse events. By way of background Dr Quinn explained that the study has been running for a year and has now been extended to two sites in Australia and two sites in New Zealand. Serious Adverse Events are looked at closely by the research team and the sponsor has close oversight over these events as they occur because of the size of the study.
* The committee noted the answer given at question p.2.9 on page 22 of the application form that the research team will inform participants of the study results. Dr Quinn confirmed that the summary of results given to participants will be in lay language.
* The committee noted the answer given at question p.4.6 on page 24 of the application form that participant ethnicity status will be collected as part of this study and asked how the researchers intend to collect ethnicity status. Dr Quinn confirmed that the researchers will use standard templates to collect ethnicity data.
* The committee noted the answer given at question f.1.1 on page 24 of the application form that this study might be capable of reducing inequalities between Māori, Pacific peoples and other New Zealanders. Dr Quinn noted that it is difficult to get figures of prevalence of migraine in Māori and Pacific peoples as it may be under diagnosed but noted that if a relatively safe alternative treatment can be offered then this would benefit Māori and Pacific peoples.
* The Committee requested the following changes to the participant information sheet and consent form:
  + The committee commended the researchers on a clearly written participant information sheet. It did note however that it would prefer to see a short study title that is meaningful for participants. Dr Quinn advised that they had requested the same from the sponsor but that the sponsor had wanted the formal title to remain.
  + Page 8: under the heading ‘Could this research project be stopped unexpectedly?’ it is stated that the sponsor may stop the study for commercial reasons. The National Ethics Advisory Committee intervention study guidelines state that a study cannot be stopped for commercial interests (para 6.65). Please advise the sponsor of this and please remove this statement from the information sheet.
  + Page 14: under the heading ‘What if I withdraw from this research project?’ The committee noted that participants are not legally required to withdraw from the study in writing although it is accepted that written withdrawal is preferable.
  + Page 2: under the heading ‘What does participation in this research involve?’ Please replace the word “take” two sprays with “use”.

Decision

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

* Please amend the New Zealand participant information sheet, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

The information will be reviewed, and a final decision made on the application, by the Secretariat.

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| **7** | **Ethics ref:** | **14/CEN/153** |
|  | Title: | CLL14 |
|  | Principal Investigator: | Dr Robert Weinkove |
|  | Sponsor: | Covance New Zealand Limited |
|  | Clock Start Date: | 12 September 2014 |

Dr Weinkove was present by teleconference for discussion of this application.

Potential conflicts of interest

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

Summary of ethical issues

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

* The committee noted that HDEC approval for a trial can be given as long as the researchers have obtained a Universal Trial Number (UTN) for the study. The clinic noted the answer given at question b.4.7 on page 15 of the application form that a trial number will be provided and asked Dr Weinkove to provide the number. Dr Weinkove advised that the trial has been registered and he will provide the relevant information to the committee.
* Dr Weinkove noted an error in title of the study given at question a.1.2 on the application form: “previously treated” should read previously untreated. The committee noted that the participant information sheet and consent form state “previously untreated”.
* The committee noted that the answer to question p.4.1 about how this research might benefit Māori went some way toward answering the question. What was not clear is whether chronic lymphocytic leukaemia (CLL) is of particular concern and therefore whether the study is of benefit to this group. Dr Weinkove explained that the data in New Zealand on the incidence of CLL in Māori is not particularly good. The research team is trying to work on this. The committee noted for future reference that this kind of explanation would be helpful to state in the application form.
* The committee asked how the potential participants and the researchers will come into contact. Dr Weinkove explained that participants with CLL that require treatment are seen by haematologists and their cases will be discussed at a multi-disciplinary meeting. The haematologist will introduce the idea of the trial to patients Dr Weinkove assured the committee that it will be made clear to patients who are considering taking part in the study that non-participation will in no way affect the care they are currently receiving and that they have free choice about whether or not to participate.
* The committee requested the following changes to the participant information sheet and consent form:
  + Page 6: in the interest of clarity for participants, please remove the information about samples being sent and used overseas for further testing and future unspecified research. This information should be stated to participants in the optional consent form for future unspecified research.
  + Page 12: The committee noted that a lymph node biopsy not usual work up for CLL. Prof Weinkove explained that a lymph node biopsy will only be taken if clinically indicated and not routinely as part of the study protocol. The committee asked that this be made clear in the information sheet.
  + Page 18: please put the adverse reaction terms neutropenia, thrombocytopenia, pyrexia into lay language.
  + Page 24 under the headings ‘Will I continue to receive the study drug after the study is over?’ and ‘Will it cost me anything to be in this study?’ Please reword the information in this section to make it appropriate for a New Zealand context.
  + Page 25: please removed the sentence “If this is the case, you will not be covered by ACC and may have to pursue a civil action against the investigators (or institution).”
  + Page 28: please include contact details of the study’s Māori support person.
  + Page 29: please include the words “in my first language” after “I have read it, or it has been read to me”.
  + The committed congratulated the researchers on listing potential side effects in an open and sensitive way. The committee suggested that any important exclusion criteria listed at question f.2.1 on page 28 of the application form be stated in the participant information sheet although it does appreciate that this will form part of the patient notes. Dr Weinkove noted that they are heavily reliant on doctors and specialists and that the process of consent is an ongoing one.
* The committee requested the following changes to the optional information and consent form for collection and bio banking of samples:
  + Page 3: Please change 1 tablespoon to 2 teaspoons for blood samples collected. Dr Weincove said that he will check what is conventionally meant by the volumes stated.
  + Please include a statement that advises that when a sample is sent overseas, unless it is sent in conjunction with a New Zealand Research project, future research is likely to be considered by an overseas ethics committee without New Zealand representation.
  + Please include a statement about the different cultural views that may inform choice about the donation of tissue; for example, for some Māori human tissue contains genetic material that is considered to be collectively owned by whanau, hapu and iwi and that cultural concerns may arise when samples are sent overseas, including how tissue samples are stored and disposed of.

Decision

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

* Please amend the New Zealand participant information sheet, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide the committee with evidence of a universal trial number for this study.

This information will be reviewed, and a final decision made on the application, by Dr Dean Quinn and Dr Cordelia Thomas.

## 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:** | Tuesday, 21 October 2014 |
| **Meeting venue:** | Terrace Conference Centre, 114 The Terrace |

No members tendered apologies for this meeting.

The meeting closed at 3.27pm