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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 26 April 2016 |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 22 March 2016 |
| 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 | i 16/CEN/46  ii 16/CEN/45  iii 16/CEN/47  iv 16/CEN/48  v 16/CEN/51  vi 16/CEN/53 |
| 3.00-3.15pm | General business:   * Noting section of agenda |
| 3.15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 30/07/2015 | 30/07/2018 | Apologies |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | 30/07/2015 | 30/07/2018 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Dr Angela Ballantyne

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 22 March 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/CEN/46** |
|  | Title: | (duplicate) DHP2016 |
|  | Principal Investigator: | Dr Colin Thompson |
|  | Sponsor: |  |
|  | Clock Start Date: | 17 March 2016 |

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

Potential conflicts of interest

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

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

Summary of ethical issues

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

1. The committee noted that it was disappointing to see that some of the comments raised in its decision letter for application 15/CEN/252 dated 10 February 2016 were not taken on board. One example of this was that question p.4.1 on page 19 of the application form and question f.1.2 on page 20 were not adequately answered and stated the same wording as in application 15/CEN/252.
2. The committee noted that the answer given at question O on page 3 of the application form stated that the study will involve ‘one or more participants who will not have given informed consent to participate’ when it has been discussed and agreed with the research team that they will need to consent both participants and staff.

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

1. The committee was pleased to see that the researchers had, as agreed during discussion of 15/CEN/252, submitted participant and staff information sheets with this application. However, the committee noted that the information sheets provided are brief and lacking the information to fully inform participants and staff about what will happen in this study and what they will be required to do. The committee would like to see the specifics of this study outlined in both the participant and staff participant information sheets so that potential participants are able to make a fully informed decision about in this study. In this regard the committee noted that the researchers include information from the protocol and tailor it for participants and for staff.
2. For example the committee noted that under the heading ‘What is the purpose of the study?’ it would be helpful to describe the study for participants. In this case the researcher could briefly describe the need for insulin for diabetic patients and state that there are two different ways used to determine how much insulin each participant gets and note that the only difference in this study with respect to treatment is that some participants will have an extra infusion. Another example is under the heading ‘What will my participation in the study involve?’ the researchers would set out how long participants will be in the study and the frequency and types of tests they will have during this time.
3. The committee noted that the staff information sheet is the same and the participant information sheet and has no specifics about the study. The committee noted that this information sheet needs to be tailored for the nursing staff.
4. In the interests of patient safety, the committee noted that the peer review from John Baker had noted concern about administering Novorapid to inpatients who are unwell and questioned whether the ward nurses would prescribe it and whether ward nurses have the skills to use the “quite complicated” insulin dose calculator. The committee would like further comment from the researchers about whether they anticipate any issues with the nurses using the insulin dose calculator

Decision

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

1. Please amend the information sheets and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies, para 6.22)*
2. Question p.4.1 in the application form is asking if the research addresses an important health issue for Maori and if so how this study might benefit Maori. Please provide any known information/statistics about relevant prevalence and prognosis in Maori to help demonstrate your case and then how the study might benefit Maori. Please do the same for question f.1.2 which asks the same question in regard to other population groups in New Zealand e.g. Pacific peoples, Asian.

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

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| **2** | **Ethics ref:** | **16/CEN/45** |
|  | Title: | DIPG Registry and Repository |
|  | Principal Investigator: | Dr Andrew Dodgshun |
|  | Sponsor: | DIPG Collaborative |
|  | Clock Start Date: | 14 April 2016 |

Ms Kirstie Copeland was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

1. The ultimate goal of this registry is to support research to try to find a cure for patients with DIPG. There is limited data regarding the biology of DIPG due to the very sensitive location of the tumour. Data collected will be de-identified and sent to the registry which is based at Cincinnati Children’s Hospital to help to contribute toward building a bank of knowledge about this type of tumour. The researchers intend to collect information from those who are still alive, collect information about people who have died and also provide information and tissue samples (digitalised slides of images of tumours) for future unspecified research. The researcher confirmed for the committee that tissue samples historically have not been taken as they are in a highly sensitive part of the brain so they would not be sending tissue samples from deceased persons overseas. The researchers will however seek consent to bank biopsy samples done currently for this and future studies.
2. The collection of information from deceased persons. The committee advised the researchers that section 20 of the Human Tissue Act permits the use of tissue collected from a living individual or a body for research that has received the approval of an ethics committee (event though the ethics committee knew that informed consent had not been, and would not be, obtained for the research).
3. The committee noted the answer stated at question r.4.1.1 in the application form about the researchers informing participants of unexpected and clinically significant findings, in particular that should clinically significant information be found as a result of future research, participants and their families will be advised through a face-to-face meeting with the researcher or treating oncologist where possible. The committee queried this noting that such findings may only be known 20 years from now. The researchers confirmed that this would be the case and that it is more about providing information to families. The researchers overseas would need to notify the institution who would try to track down the families.
4. Question p.3.2.1 on page 29 of the application form states that assent will be sought from potential participants and parental consent will always be sought for those under the age of 16 years and may be sought for those who are over the age of 16. The committee acknowledged that given the severity of the illness parents are closely involved but it should be respected that the child/young person can make a decision for themselves about participation.
5. Question p.4.1 on page 29 of the application form: for future reference, the committee advised that the answer to this question should include incidence and prevalence (statistics) of the disorder under study (or treatment indication if a drug trial) in Maori. Some disorders are particularly important for Maori health, while others are relatively rare in Maori and may have less of an impact. If the impact of treatment or prevalence of disease is low or the same as other populations please state this clearly to the Committee. Generally, any available statistics relating to Maori should be provided where possible. The same applies for question f.1.2 which asks the same question in regard to other population groups in New Zealand e.g. Pacific peoples, Asian.

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

1. The committee noted that the PIS/CF has been submitted as a tracked changes version. For future reference, the committee noted that this is not appropriate as it has to approve a version and it is not sure whether the one submitted is the version it should approve.
2. The researchers are asking participants to consent to future unspecified research. In the general information sheet on page 2, where it is mentioned that all research proposals to use the data and tissue samples from the registry must be first approved, please refer participants to the separate and optional information sheet and consent form for future unspecified use of tissue.
3. Main participant information sheet, page 1, under the heading ‘What is DIPG?’: please remove the last sentence in this paragraph as participants will no doubt be aware of the seriousness of the condition.
4. The committee and the researcher discussed whether assent for 7-10 year olds would be helpful in this case noting that there is a fine balance of informing the children and over burdening them. The committee agreed that the 7-10 year old assent is not needed.
5. Main participant information sheet, page 1: ‘Why am I being invited to continued study participation?’, last paragraph. The committee suggested that it might be better to state that if you want to have tissue collected ask your doctor – the researchers’ choice about the kind of language to use.
6. Please set out the contact details more clearly in the participant information sheet and consent forms. For example in the main form, please bold the Health and Disability Commissioner so that people know that it is separate from the researchers’ contact details above.
7. PIS/CF for 11-15 year olds: please include contact number details as the children in this age group may wish to speak to someone with any questions that they have.
8. Information sheet for continued participation upon reaching the adult age of consent: the committee noted that the information stated in the first paragraph on page 1 of this form about 16 being the age that a person is considered adult enough to sign legal contracts is not a legally correct statement as the Minors’ Contract act states that the legal age is 18 years old. Section 36 of the Care of Children Act states a child can make treatment decisions at 16 years of age but that doesn’t mean that they can generally sign contracts. Please change the wording in this sentence to say that at age 16 people are generally able to consent for themselves.
9. Short consent form for translation that is signed by participants and interpreters:

The researchers explained that this is a short form for non-English speaking participants and is a requirement for COG and ANZCHOG studies. The approved document is translated into main ethnic languages and is used as part of the consent process for participants for who English is not a first language. Participants in the study sign the document to indicate that they can fully understand the study in own their own language and have discussed the study. The form is not study specific and is a generic form. The committee queried whether it is useful to submit a generic document for review when an HDEC looks at the study specific documents.

1. The committee noted that the short version could be seen as a short cut to fully informed consent and queried whether the researchers could provide an assurance that participants will understand all of the information in the participant information sheet. One possible way of doing this was discussed: that participants read the full version in their own language and then the short translation form in that order. The researchers explained that in these studies the study clinicians will talk with potential participants about the study and they might understand 80 percent of the study. They are making the signing of the short form a requirement so that they can be assured that people know that they are participating in research.
2. Consent takes place over a number of different intervals/meetings with parents. The committee noted that it might be more helpful to see written documentation and what has come up in terms of questions from participants.
3. For the committee, the issue is the consent provision at the end of the worksheet. The committee queried whether the wording could be revised to read something along the lines of the fact that it is a discussion document only and that the person agrees to consent to the study once they have read the full information sheet and discussed the study with the research clinician. In other words, the committee is seeking assurance that this isn’t the only thing that people sign for consent and that they need to sign consent for the full information sheet as well.
4. In the application reviewed subsequent to this one (16/CEN/47), the researchers explained that the ultimate reassurance for all is that CROs are required to indicate that the full form has been signed. In other words, it is not possible to enrol someone with only the short translation form signed. However, the committee would want to see documented assurance without holding up any research.
5. The researchers explained that the research clinician signs all documents and that the clinicians and participants sign the short consent form and full consent form at the same time. The committee suggested that they make it a preference that the main consent form is signed first. The researchers could put out a note to the treating clinicians that they document this in the consent process that is done as part of a participant’s clinical record and assure the committee that this in fact will happen. The committee was satisfied and agreed that the signing of the short consent form can be done after participants and researchers have gone through all the information in the main participant information sheet.

Decision

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

1. Please amend the information sheets and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies, para 6.22)*

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

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| **3** | **Ethics ref:** | **16/CEN/47** |
|  | Title: | COG AOST1421 |
|  | Principal Investigator: | Dr Mark Winstanley |
|  | Sponsor: | Children's Oncology Group (COG) |
|  | Clock Start Date: | 14 April 2016 |

Dr Scott MacFarlane and Dr Sarah Hunter 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.

1. The committee noted that the researchers had been party to a recent discussion about the abbreviated form for consent/short form for translation used in COG and ANZCHOG studies and heard the committee’s concern the about wording in that form could be read as participants consenting to take part in the study when they have not had the opportunity to take part in a fully-informed consent process.
2. Using this form to indicate that those people know this is research rather

than standard care.

1. The researchers explained that this form is mandated for all COG studies and is used for potential participants who indicate a need for translation of the study information into their first language. The researchers explained that it is a US government requirement that participants sign both the short form and the full information sheet before being enrolled in a study. If participants don’t consider the full information sheet in their first language then the researchers are not allowed to consent them to the study.
2. The committee noted that it intends to send a letter about the way the short form is currently phrased. The way it stands can be interpreted as the participant consenting to participation by signing the short form alone. The committee would need assurance that both the short form for translation and the main participant information sheets are signed to demonstrate that the participant is fully informed.
3. The committee referred to page 2 of the form and noted that it would prefer the wording to read that signed consent was consent to discuss further participation/consider taking part in research. The researchers noted that they could take the committee comment back to the US as they need to meet their requirements. If they say no as it is a requirement the researchers asked whether a letter from the researchers themselves assuring the committee that the short form does not show participant consent to take part in the study would suffice.
4. The researchers explained that the ultimate reassurance for all is that CROs are required to indicate that the full form has been signed. In other words, it is not possible to enrol someone with only the short translation form signed. However, the committee would want to see documented assurance without holding up any research.
5. The researchers explained that the research clinician signs all documents and that the clinicians and participants sign the short consent form and full consent form at the same time. The committee suggested that they make it a preference that the main consent form is signed first. The researchers could put out a note to the treating clinicians that they document this in the consent process that is done as part of a participant’s clinical record and assure the committee that this in fact will happen.
6. The committee thanked the researchers for the cover letter included with this application that gave an overview of the participant information sheets. The committee noted that it would appreciate the same in any future applications.
7. The committee noted the answer stated at question r.1.6 on page 20 of the application form that referred the committee to the study protocol for a description of the study design and the specific criteria for terminating the study. For future reference, the committee noted that it would prefer to see at least the core reason/s for terminating the study stated in this section.
8. The committee noted a Letter of thanks to participants in this clinical trial included with the documentation submitted with this application and agreed that it is a nice gesture. The committee noted that the researchers have called the letter a Koha and explained that the term a ‘Letter of appreciation’ might be more accurate wording as Koha is a reciprocal principle other than saying thank you.
9. Question p.f.1.2 on page 32 of the application form: for future reference, the committee advised that the answer to this question should include incidence and prevalence (statistics) of the disorder under study (or treatment indication if a drug trial) in other non-Maori populations in New Zealand. Generally, any available statistics relating to the other population groups (e.g Pacific peoples, Asian) should be provided where possible. The researchers advised that to the best of their knowledge there is no suggested difference for other groups. The numbers registered on the child cancer registry are not enough to do sub-analyses.

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

1. Main Information Sheet, page 4: the committee noted that there appears to be a typo in the fifth paragraph on this page that talks about a “caretaker” being taught how to give the injections. The committee noted that it presumed the researchers meant “caregiver”.
2. Page 3: the committee complimented the researchers on the diagram used here.
3. Page 6: The committee noted the statement “If you decide to stop participating in the study, your samples for these research study tests can be destroyed by incineration at your request. However, once your samples have been sent to an institution for research purposes they cannot be destroyed. The committee noted that this may be the case but that the statement is inconsistent with what is written in the other information sheets. For example, on the FUR information sheet on page 3 under the heading ‘Can I withdraw permission for my sample to be used for future scientific research?’ it is stated that participants can withdraw their permission at any time. The committee asked the researchers to check the information sheets for consistency.
4. Please bold the contact numbers of people/organisations that participants can call for more information.
5. The committee suggested that the researchers include contact numbers in the participant information sheet for 11-15 year olds as this age group is likely to want more information and may choose to talk to someone.
6. Assent form for children – the committee noted that the side effect of pain is not mentioned in the assent form and queried whether this would be a significant side effect. The researchers confirmed that it would and will include this in the forms.

Decision

This application was *approved* by consensus.

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| **4** | **Ethics ref:** | **16/CEN/48** |
|  | Title: | A rapid non drug treatment for anxiety- the rapid symptom shifting therapy |
|  | Principal Investigator: | Professor Bruce Arroll |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 14 April 2016 |

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

Potential conflicts of interest

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

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

Summary of ethical issues

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

1. The committee noted that it acknowledged the potential benefit of this study is to have a way of dealing with anxiety/depression without drugs and is well worth pursuing. However, the committee agreed that the application did not provide enough information about the study on which to make a decision. In particular the committee agreed that it did not have enough information to know whether this study is safe for participants. Further, the participant information sheet and consent forms submitted with this application did not include enough information for potential participants to make a fully informed decision. The committee agreed on these two grounds to decline this application.
2. The committee noted that it would have been helpful for a member of the research team to attend the meeting to talk to the committee and help address any questions and concerns that the committee has.
3. The committee noted that the peer review submitted from Dr Andrew Jull flagged issues that do not appear to have been addressed as part of this application. The committee would like to see these points addressed in any subsequent application to the committee. The committee would also like to see independent review of the study protocol from someone who is an expert in the field of anxiety/depression and who is not involved in the study him/herself.
4. The committee noted that Dr Henwood’s role is not quite clear. She features on

the participant information sheet but she is not mentioned as a co-investigator in the application.

1. Question p.4.1 in the application form is asking if the research addresses an

important health issue for Maori and if so how this study might benefit Maori. Please provide any known information/statistics about relevant prevalence and prognosis in Maori to help demonstrate your case and then how the study might benefit Maori. Please do the same for question f.1.2 which asks the same question in regard to other population groups in New Zealand e.g. Pacific, Asian, Indian peoples.

1. The committee discussed how the researchers will recruit participants to the study noting that at question p.3.1 in the application form noted that they will be “using emails through the University of Auckland, and newspaper advertising if necessary”. The committee noted that screening for emails and using them without consent would be a breach of the privacy act as private information is being used for another purpose. Also, if the researchers are going to put advertising notices up then the committee would need to see the content.

The committee requested the following changes to the participant information sheet and consent forms when the researchers resubmit the application:

1. The committee acknowledged that the participant information sheet appears to be the same or very similar to a previously submitted information sheet and noted that cutting and pasting from previous sheets when the information does not apply is not acceptable.
2. The committee noted that the researchers might find the PIS/CF pro-forma a helpful reference point for what to include in the participant information. The pro-forma can be found on the HDEC website: <http://ethics.health.govt.nz/>
3. The committee noted that it would be helpful for participants if the researchers could give an overview of what NLP is and say that there two groups in this study and two different forms will be used to see which is more effective. There must be enough information in the PIS for participants to be able to give informed consent.
4. It would also be helpful for participants to know what the randomisation process is and specifically what they will be required to do when they are in the study.
5. The committee noted that there should be acknowledgement that people may feel upset having reflected on their anxiety and that the participant information sheet should spell out what they can do as this is a potential safety issue. Further, the committee would like to see an 0800 24 hour access number stated in the participant information sheet.
6. Please replace your ACC statement with the following: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.  
     
   If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
7. The study contact person details need to be clearly stated and separated out Please also include Maori support person contact details.

Decision

This application was *declined* by consensus as the Committee did not consider that the study would meet the following ethical standards as contained in the *Ethical Guidelines for Intervention Studies*.

Paragraph:

5.4 The study design should be the one best suited to answer the study question, while minimising harm, maximising benefit and meeting other ethical standards.

6.13 Investigators are responsible for designing and conducting studies to maximise the validity and quality of participants’ informed consent. Ethics committees are responsible for checking that proposed study information sheets and consent forms enhance informed consent of this nature.

6.22 Informed consent is essentially a matter of good communication between people. Information should be provided to potential participants in a form and in a way that assists their informed decision-making. For example, the information should as far as possible be provided in lay terms. In general, such information should:

1. explain the study, including:
2. the purpose of the study, including its expected contribution to knowledge and its potential benefits to communities
3. how the study meets the best intervention and equipoise standards
4. the purpose and practical significance of the use of randomisation, blinding or placebos, as relevant
5. the nature and sources of funding of the study, the institutional affiliations of the investigator(s), and who can be contacted to answer questions and how to contact them
6. the study’s status, with a current approval from an ethics committee
7. describe what the study involves, including:
8. what will be done in the study, including how participation in it will differ from not being in the study
9. the time involved in participation (eg, the number and duration of any visits to the research centre, and the expected finishing date of the study)
10. the purpose and expected number of any extra tests to be performed during the study
11. outline potential benefits, risks and compensation, covering:
12. foreseeable risks, side-effects, discomforts and possible direct benefits of study participation, including any risks or benefits to the health of a participant’s family members
13. arrangements for personal compensation for injury, including whether the study is covered by the Accident Compensation Act 2001
14. payments or other forms of reimbursement, if any, provided in recognition of participation
15. the extent of the investigator’s responsibility to ensure that care is provided to participants during the study
16. explain the rights of participants, covering:
17. the voluntary nature of participation, including that they are free to decline to participate or to withdraw from the research at any practicable time, without experiencing any disadvantage
18. the fact that participants have the right to access information about themselves collected as part of the study
19. the fact that participants will be told of any new information about adverse or beneficial effects related to the study that becomes available during the study that may have an impact on their health
20. what provision will be made for the privacy and confidentiality of individuals
21. describe what will happen after the study, covering:
22. whether any study intervention will be available to participants after the study and, if so, under what conditions (including any cost to them)
23. how study data will be stored and for how long, whether the data will be retained for possible future use, who will be responsible for their secure storage and how they will be destroyed
24. whether any biological specimens collected during the research will be destroyed at its conclusion and, if not, details of their storage and possible future use
25. how the study findings will be communicated on completion of the study, including to participants, and in what expected timeframe.

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| **5** | **Ethics ref:** | **16/CEN/51** |
|  | Title: | Comparison of the blood levels of two forms of isotretinoin 10 mg capsules in healthy male volunteers |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas Pharmaceuticals America Ltd |
|  | Clock Start Date: | 14 April 2016 |

Mrs Linda Folland and Dr Tak Hung 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.

1. The committee had no significant ethical concerns about this application and had only a few minor points of note for the researchers.
2. The researchers clarified for the committee the length of the study of 11 days for dosing and blood collection stated in the participant information sheet.
3. Page 4, under the heading ‘Re-dosing’: the committee noted the statement that participants will not be permitted to leave the clinical site during the study and pointed out that legally the researchers cannot confine people. The committee would prefer that the researchers state that they would prefer that participants remain on the site. The researchers explained that once the participants leave they cannot re-join the study and the committee asked that they make this clear to participants in the information sheet.
4. The researchers confirmed that reference to participants receiving four single oral doses at question r.8.1 was incorrectly stated. Participants will receive two doses.
5. Statistics for Maori with acne. The committee noted that any known research statistics on incidence and prevalence in Maori would have been useful to include here at question p.4.1 in the application form. The researchers advised that they had sent further information to the HDEC secretariat as requested. There doesn’t seem to be any higher rates for Maori as opposed to other ethnic groups.
6. Question p.3.1 on page 23 of the application form: The committee noted that the answer stated that volunteers can sign up for the study following the information reading and sought clarification about whether consent is done as a group or individually. The researchers explained that the PIS is read out to a group and then the trial physician meets with potential participant individually and they then have chance to ask questions in private before deciding whether to take part.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **16/CEN/53** |
|  | Title: | A multiple ascending dose study of ACH-0144471 to assess the safety, tolerability, pharmoacokinetics, and pharmacodynamics |
|  | Principal Investigator: | Dr Roderick Ellis-Pegler |
|  | Sponsor: | Clinical Network Services Ltd |
|  | Clock Start Date: | 14 April 2016 |

Ms Margaret Joppa 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.

1. The committee thanked the researchers for the way in which they had addressed the questions at p.4.1 and p.4.2 in the application form. For future reference the committee noted that question f.1.2 asks the same as p.4.1 but for other non-Maori populations in New Zealand (e.g. Pacific peoples and Asian populations).
2. The committee noted the answer stated at question r.1.6 about the criteria for terminating the study on page 15 of the application form and noting that this information could be more strongly stated in the information sheet. If the participant has had a dose then there may be a risk. If they have any adverse events they have a participant card and they have one from the sponsor and this is clearly worded that if they have any side effects then they are provided with contact number for that site.
3. The committee queried how the researchers intend to recruit participants to this study. The researchers advised by advertisement on the radio or newspaper or student newsletters at university, which will include a phone number people can call if they are interested. If participants appear to be eligible when they make contact the researchers will send them a participant information sheet.

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

1. Page 2, b. How is this study set up?: the committee noted the statement that volunteers will be aged between 21 and 55. In this study the participants are 25 years of age and over. Please amend.
2. Page 11, 6. ‘Potential Costs/Reimbursements’: the researchers noted that participants will be given a maximum of 100 dollars per visit and the committee asked that they clearly state that this is the case.
3. Page 14: The committee complimented the researchers on the use of the visuals noting that it offers a helpful overview of what is involved in the study.
4. Please replace the expression “dummy pill” with something along the lines of “pill not containing the active drug”.
5. Page 13: The committee noted that statement that participants will not get any compensation from the sponsor if an injury is caused by the investigators and agreed that this seems unreasonable. The committee asked that the researchers check this with their legal team to ascertain whether it is for the sponsor or is it for the doctor’s indemnity and then express this more clearly in the information sheet.
6. The committee queried whether it is possible to stop the study because of commercial interests. The committee noted that it is unethical to ask people to take risks by entering the study and then suddenly stop it for commercial reasons. Please remove this statement.
7. Optional pregnant partner data release form: the committee noted the statement that “we kindly ask you to sign this consent form to provide information concerning the outcome of your pregnancy” noting that the use of the word outcome was ambiguous. The researchers explained that they simply want to know whether baby was born alive or born with any abnormalities. In the interest of informed consent please state more clearly to the pregnant woman what you mean by outcomes (e.g. miscarriage, born alive) and please note that the mother cannot consent to give health information about the baby before the baby is born. At consent point not relevant as it is for partner. Will be relevant if she does become pregnant. Concerned about being clear to the pregnant woman what information she will divulge and for how long. Please provide a form that the pregnant woman signs before the baby is born and another for her to sign once the baby is born.

Decision

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

1. Please amend the information sheets and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies, para 6.22)*

This information will be reviewed, and a final decision made on the application, by the Chair and 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:

|  |  |
| --- | --- |
| **Meeting date:** | 24 May 2016, 12:00 PM |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington, 6011 |

The following members tendered apologies for this meeting.

Dr Angela Ballantyne

The meeting closed at 3.15pm.