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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 26 November 2013 |
| **Meeting venue:** | Deloitte House, MEDSAFE, Level 6, 10 Brandon Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.10pm  12.30-1.00pm | Confirmation of minutes of meeting of 22 October 2013  Ministry of Social Development |
|  | New applications (see over for details) |
| 1.00-1.20pm  1.20-1.40pm  1.40-2.00pm  2.00-2.20pm  2.20-2.40pm  2.40-3.00pm  3.00-3.20pm  3.20-3.40pm  3.40-4.00pm  4.00-4.20pm  4.20-4.40pm | i 13/CEN/177  ii 13/CEN/175  iii 13/CEN/181  iv 13/CEN/182  v 13/CEN/183  vi 13/CEN/185  vii 13/CEN/186  viii 13/CEN/187  ix 13/CEN/168  x 13/CEN/162  xi 13/CEN/163 |
| 4.40-5.00pm | General business: |
| 5.00pm | 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 |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 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 | Apologies |
| Dr Dean Quinn | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 12.22pm and welcomed Committee members, noting that apologies had been received from Dr Patries Herst.

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 October 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **13/CEN/162** |
|  | Title: | COG ALTE07C1 - Neuropsychological, Social, Emotional, and Behavioural Outcomes in Children with Cancer |
|  | Principal Investigator: | Dr Stephen Laughton |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 14 November 2013 |

Dr Stephen Laughton and Ms Paula Murray 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 noted that this was an observational study spanning ten years. Dr Laughton explained that only 20 New Zealanders would be involved, that there was no end point and that he hoped that it would run for a long time.
* The Committee queried where the funding was coming from. Ms Murray confirmed that the Children’s Oncology Group would fund $1,000 per child. This money would go to the DHB.
* The Committee asked about the peer review process. Dr Laughton confirmed that as this was a collaborative study across North America, the Department of Health and Human Services had reviewed the protocol.
* The Committee noted that the researcher had identified no cultural issues for Māori. The Committee advised that for Māori, anything to do with the head is considered tapu and that in this study, even though the head is not being operated on, the power of the head is still being used.
* The Committee commended the researcher on the PIS for adolescents and young adults, which they considered inclusive, collaborative and empowering to young people. They particularly liked the use of the flow chart.
* The following changes were requested to the PIS and consent form:
  + Please add key inclusion and exclusion criteria, in lay language, to the PIS.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Observational Studies, para 6.11)*.

The response from the researcher will be reviewed, and a final decision made on the application, by Mrs Gael Donoghue and Mrs Sandy Gill.

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| **2** | **Ethics ref:** | **13/CEN/163** |
|  | Title: | COG ACNS0822 |
|  | Principal Investigator: | Dr Stephen Laughton |
|  | Sponsor: | ANZCHOG |
|  | Clock Start Date: | 14 November 2013 |

Dr Stephen Laughton and Ms Paula Murray 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 asked for confirmation of whether Phase II and Phase III were two separate studies. Dr Laughton confirmed that Phase II is a randomisation of three treatment arms - two experimental and the standard treatment. If this is successful, then Phase III of the study will proceed.
* The Committee noted R.1.1 of the application form which states that there is a risk that chemoradiotherapy treatment will not work and asked whether there is the potential that Phase III will not go ahead as the investigative treatment may be more harmful than the standard treatment. Dr Laughton confirmed that this was possible. The Committee queried whether they could approve Phase III given that they would be giving approval for a study that possibly may not proceed.
* Dr Laughton advised that the study would be closed while Phase II data was being analysed. If one of the experimental arms is clearly superior, then Phase III will commence
* The Committee asked what would be the duration between the closure of Phase II and the commencement of Phase III. Dr Laughton explained that this would be up to a year as the researchers would be looking at the one year survival rates and outcomes.
* The Committee asked why only Phase II had been selected for A.2.1.2. Ms Murray explained that Online Forms only lets a researcher select one phase.
* The Committee expressed concern about giving approval for a study that would be dependent on the outcome of another, which may not go ahead or may be changed depending on the data that comes out of Phase II. Dr Laughton explained that if the treatment in Phase II was found to be unsafe, Phase III would not go ahead. The Committee noted that they may be more comfortable with the researcher applying for separate ethics approval for Phase III as more information may need to be included after the conclusion of Phase II, for example, exclusion criteria.
* The Committee noted that the study had received US ethics committee approval and asked whether there were any riders to this approval. Dr Laughton confirmed that this approval covered both phases and that 125 institutions had ethics approval in the US and Canada. Dr Laughton was unsure if there were any provisions to this approval.
* Dr Laughton drew the Committee’s attention to section 4.4.3 of the protocol, in Treatment Arms of Phase III of the Study which states “If neither Arm A nor Arm C is superior to temozolomide, the study will not continue to the phase III portion.”
* The Committee advised that the PIS for future unspecified research needs to include all of the information covered in the *Guidelines for the Use of Human Tissue for Future Unspecified Research*.
* The Committee queried whether SCOTT will be asked to approve both phases of the study and whether they will be approving Phase III without all of the information required to make a decision. Ms Murray confirmed that the application covering both phases went to SCOTT on 12 November.
* The following changes were requested to the PIS and consent form:
  + Please add key inclusion and exclusion criteria, language, to the PIS.
  + Please amend PIS for future unspecified research to include all of the information covered in the *Guidelines for the Use of Human Tissue for Future Unspecified Research*. These can be found at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>

Decision

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

* Please provide confirmation of SCOTT approval *(Ethical Guidelines for Intervention Studies, paras 5.50 – 5.51).*
* Please note this paragraph of the protocol (section 4.4.3, page 37), with particular reference to the last sentence in bold.

If the one-year EFS of either treatment Arm A or treatment Arm C is superior to that of the treatment arm B with temozolomide, the study will continue to the phase III portion. In the phase III portion, patients will be randomized at study enrollment to one of the two following arms for chemoradiotherapy:

Arm B: Temozolomide at 90 mg/m2/dose orally, started in the first week of initiation of RT on a daily basis continuously throughout RT and should continue until the last dose of RT. The 42 days of temozolomide should be given regardless of the end date of RT.

Superior Arm from Phase II of the Study: The treatment arm from Phase II that has a one-year EFS that is superior to temozolomide (either Arm A or Arm C). **If neither Arm A nor Arm C is superior to temozolomide, the study will not continue to the phase III portion.** *(Ethical Guidelines for Intervention Studies, para 5.4).*

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22)*.

The response from the researcher will be reviewed, and a final decision made on the application, by Mrs Helen Walker and Dr Dean Quinn.

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| **3** | **Ethics ref:** | **13/CEN/168** |
|  | Title: | COG ASCT1221 |
|  | Principal Investigator: | Dr Lochie Teague |
|  | Sponsor: | Children’s Oncology Group |
|  | Clock Start Date: | 14 November 2013 |

Dr Lochie Teague and Ms 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.

* The Committee noted that this study is divided into two parts, with the first part being diagnostic testing and the second part comparing differences in two dosing regimens.
* The Committee queried whether participants could withdraw their consent for the use of human tissue as there were discrepancies in answers in the application form (R.3.12 and P.4.2) and the PIS. Ms Hunter confirmed that once the specimens are sent overseas for testing, they can no longer be destroyed. The Committee queried whether a timeframe can be given to participants whereby people can remove their consent. Ms Hunter explained that this was not possible as the specimens were sent overseas straight away. However there is no specified timeframe for the tissue for banking to be sent away so it may still be possible for participants to withdraw their consent.
* The Committee queried whether a participant must take part in Part 1 to be part of Part 2. Ms Hunter confirmed that this was true. The Committee asked that this be added to the PIS.
* The Committee queried whether the medical research testing that will be undertaken is known (page 3 of the PIS). Dr Teague confirmed that this will be for an additional confirmation of the diagnosis.
* The Committee queried the use of yes and no options on the consent form as for some questions participants would not be able to proceed if they answered no to a question. Ms Hunter advised that they had previously been asked to include both yes and no options. Dr Teague explained that if a participant answers no to a question, the researcher will have further discussions with them. The Committee noted that a statement should be added to the consent form that a participant will have to answer yes to every question for the consent form to be valid.
* The Committee noted that that participating adults agreeing to give parental samples will be consenting on behalf of the child and on behalf of themselves. The Committee asked whether a parental sample is required for a child to take part in Part 1 of the study. Dr Teague confirmed that the parental sample is completely optional.
* The Committee noted that not all of the guidelines outlined in the *Guidelines for the Use of Human Tissue for Future Unspecified Research* are covered in the PIS. The guidelines can be found at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>
* The Committee noted that that the key inclusion and exclusion criteria, in lay language should be added to the PIS. Ms Hunter explained that these were not included as they were purely diagnostic criteria. The Committee recommended added wording to the effect of “there are some medical exclusions that might exclude you.”
* The following changes were requested to the PIS and consent form:
  + Please add to the PIS that a participant must take part in Part 1 of the study to take part in Part 2.
  + Please add a statement to the consent form that a participant will have to answer yes to every question for the consent to be valid.
  + Please ensure that all of the *Guidelines for the Use of Human Tissue for Future Unspecified Research* are included in the PIS.
  + Please add the key inclusion and exclusion criteria, in lay language to the PIS.
  + Please add a statement to the PIS that tissue taken and sent overseas is not able to be returned.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22)*.

The response from the researcher will be reviewed, and a final decision made on the application, by Dr Dean Quinn and Mr Paul Barnett.

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| **4** | **Ethics ref:** | **13/CEN/175** |
|  | Title: | BRAin Injury and NeuroAid Supplementation (BRAINS) |
|  | Principal Investigator: | Professor Valery Feigin |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 14 November 2013 |

Dr Alice Theadom 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.

* The Committee asked for clarification on the ingredients of the herbal supplement to be used in the study and for confirmation that the supplement was totally herbal. Dr Theadom confirmed that the only ingredients were the nine listed in protocol.
* The Committee advised that there is a formula with the same name, MLC 601, which has ingredients such as scorpions, leeches and cow bile. The Committee advised that they thought that the herbal supplement to be used in this study is MLC 901 and asked for clarification from researcher that this is what they would be using.
* The Committee noted that page 4 of the PIS states that the herbal supplement is not currently available on the open market, while A.1.6 of the application form states that the supplement is available on the New Zealand open market. Dr Theadom explained that the researchers became aware of this during submission and the PIS had not yet been changed to reflect this.
* The Committee asked that the side effects of the herbal supplement be included in the PIS. While this was dependent on the ingredients, they would most likely be nausea and vomiting.
* The Committee advised that if participants were already taking medicine, it was important that there would be no interactions from the herbal supplement. They advised that it was important that participants are made aware they need to keep taking any prescribed medicines.
* The Committee noted that people who had sustained a brain injury were likely to be vulnerable. Dr Theadom explained that participants would most likely have mild to moderate brain injuries.
* The Committee advised that insure cover should be the equivalent to that provided by ACC. One policy issued by the Federal Insurance Company gives adequate cover but excludes some things, such as personal and adv. injury, while the Vero Liability policy appears to cover ACC aspects. The Committee recommended checking with the insurers that the ACC equivalent is covered under these policies.
* The Committee queried whether the manufacturer is funding the whole study or just the herbal supplement. Dr Theadom confirmed that the manufacturer is funding the whole study. The Committee advised that there needs to be a statement in the PIS that the sponsor is a commercial institution and that the study is being funded for their benefit.
* The following changes were requested to the PIS and consent form:
  + Please amend the PIS to reflect that the herbal supplement is currently available on the open market.
  + Please add a statement to the PIS that the sponsor is a commercial institution and that the study is being conducted for their benefit.

Decision

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

* Please confirm the name of the formula for the herbal supplement to be used in this study *(Ethical Guidelines for Intervention Studies, para 6.7(a))*.
* Please confirm whether the insurance provides coverage that is equivalent to ACC *(Ethical Guidelines for Intervention Studies, paras 8.4 – 8.5)*.
* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22)*.

The response from the researcher will be reviewed and a final decision made on the application, by Mrs Gael Donoghue and Mr Paul Barnett.

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| **5** | **Ethics ref:** | **13/CEN/177 (CLOSED)** |
|  | Title: | “A study comparing how fast the trial drug GS-5816 is cleared from the body, in healthy adults and in adults with severely reduced kidney function” |
|  | Principal Investigator: | Dr Richard Robson |
|  | Sponsor: | Gilead Science, Inc. |
|  | Clock Start Date: | 14 November 2013 |

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| **6** | **Ethics ref:** | **13/CEN/181** |
|  | Title: | An interventional study looking at caregiver education in managing BPSD. |
|  | Principal Investigator: | Dr Bhamini Patel |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 November 2013 |

Dr Bhamini Patel and Dr Bronwyn Copeland 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 noted that it was unclear in the protocol what the new treatment model would be and how it differed to the standard treatment of care. The researcher explained that staff would be given two half days of training, with an emphasis on a functional analysis of behaviour so staff were more aware of why patients behaved in the ways they did. This would then help staff change their approach in how they dealt with patients, with an aim of reducing distress in patients and reduce levels of antipsychotic medication required.
* The Committee asked who made decisions on giving patients antipsychotic medication. The researcher explained that a doctor prescribed the medication but nursing staff would decide on a day-to-day basis on whether to administer the medication.
* The researcher explained that there will be no risk involved for the patient. The study may result in a reduction of antipsychotic medication but this would be a benefit to the patient.
* The Committee noted the researcher’s answer to A.1.6 which states that participants with moderate to severe dementia do not have the ability to make decisions. The Committee advised that patients who cannot legally give consent can still give assent.
* The researcher advised that if a family member does not give consent, this will be respected and that while the intervention will still take place, no data will be collected on their family member. The Committee advised that a statement explaining this needs to be added to the PIS.
* The Committee asked what the process was used for obtaining agreement from staff before starting the project. The researcher explained that there had been a meeting with staff from the facility in which they could discuss any concerns about being involved in the project, what support would be required and feedback was sought on whether staff were keen to participate. At this meeting, staff were also told that their participation was voluntary.
* The Committee queried the peer review process and noted that for future applications, information should be provided on the peer review group, its function and its review process. The researcher explained that the peer review group consisted of consultant psychiatrists and met every two weeks to discuss the purpose and value of proposed projects with colleagues. The Committee queried whether written approval was provided and the researcher confirmed that this had been sent to the HDEC Secretariat.
* The Committee noted that for future applications, when explaining benefits for Māori (P.4.1) this should look at the future benefits to Māori patients in general. Inclusion of whānau and tapu of the head were the main cultural issues that may arise for Māori participating in the study (P.4.2)
* The Committee queried whether changes to antipsychotic medication would be made at a monthly monitoring meeting or on a day-to-day basis. The researcher explained that all DHBs are looking to reduce levels of antipsychotic medication but that this would not be one of the main outcome measures. The researcher advised that the prescribing of regular antipsychotic medication gets reviewed on a monthly basis but the aim is to reduce the use of PRN medication on a daily basis.
* The Committee asked whether staff would be surveyed on their thoughts on the intervention as part of the study. The researcher confirmed that they will not be formally collecting data but that staff would have weekly meetings when the project was finished. The purpose of this would be to gain feedback on how they were finding the new system.
* The Committee asked who would be answering questionnaires. The researcher confirmed that the investigator will go through this with a registered nurse who has been with the patient for five days a week.
* The Committee asked whether the caregiver would provide input on question (g) of the questionnaire which looks at caregiver distress. The researcher confirmed that the caregiver will be answering this question.
* The Committee asked whether the focus of the data collection is on staff experience or patient experience and noted that if there is a focus on staff distress, that they are participants. If staff are not going to be treated as participants, then the questions on staff distress need to be removed. The Committee noted that if staff are giving feedback about the programme, information is being collected but they have not gone through the consent process. The researcher noted that if they are unable to say that staff found the treatment useful, the research will not have much clinical utility in the future. The Committee explained that there could be two separate groups of participants in the same study.
* The Committee expressed concern at asking staff to sign a consent form that would state that the project would only proceed if everybody gives their consent but noted that if staff are going to give feedback that they are participants. The Committee advised that if the outcome measures will only be based on the residents, then consent is not required from staff.
* The Committee noted that if the aim of the study was to change patient behaviour, the most important data would come from the staff who were implementing the changes. The Committee agreed that the protocol would be much stronger if data could be obtained from both staff and patients.
* The Committee noted that more data would be required than just incident reports to give a full picture. The researcher advised that they will use models that focus on the residents, such as dementia care mapping which looks at the interactions between staff and patients.
* The Committee asked for clarification on who would be prescribing the medication. The researcher advised that psychiatrists prescribe the antipsychotic medication and that GPs prescribe the general medication. The Committee advised that all involved in prescribing need to be kept fully informed that when consent has been received from the patient’s family that that the researcher must inform the patient’s GP. This needs to be included in the consent form.
* The Committee advised that data needs to be kept for 10 years (R.2.5).
* The following changes were requested to the PIS/CF:
  + Please provide a simplified PIS for participants with moderate dementia.
  + Please put PIS and consent onto two separate pieces of paper.
  + Please include contact details for the HDEC, Health and Disability Commissioner and Māori cultural support.

Decision

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

* Investigators should develop clear study questions that identify the participant, population, the intervention and the main outcome of interest *(Ethical Guidelines for Intervention Studies, para 5.2)*.

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| **7** | **Ethics ref:** | **13/CEN/182** |
|  | Title: | MK5172-017. Phase II Long Term Safety Follow up |
|  | Principal Investigator: | Mrs Sherryl Hayett |
|  | Sponsor: | Merck Sharp & Dohme |
|  | Clock Start Date: | 14 November 2013 |

Ms Theodora Paraskevopoulos 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.

* The Committee queried whether SCOTT approval was needed for this study. Ms Paraskevopoulos confirmed that this was a long term safety-follow up for patients who had participated in a previous clinical trial.
* The Committee noted that the consent form states that “I have read or had read to me” but the PIS only refers to “read this document carefully”. The Committee noted that there may be varying levels of literacy among participants and that some people will need somebody to take them through the PIS. Ms Paraskevopoulos agreed to amend the PIS to reflect this.
* The Committee noted that the PIS does not include a number that Māori can call for cultural support. Ms Paraskevopoulos agreed to include this.
* The Committee advised that for P.4.1, the Treaty of Waitangi is not a medical benefit. They advised that for future applications, the question is asking what health benefits for Māori in general may come out of the research.
* The Committee commended the researcher’s answer to P.4.2 which acknowledged the cultural issues that are likely to arise for Māori.
* The Committee advised that P.4.1 relates specifically to Māori whereas F.1.2 relates to Māori, Pacific peoples and other New Zealanders. The Committee advised that for future applications, the researcher needs to elaborate on what the actual health benefits will be.
* The Committee queried whether the letter from the Māori Research Committee had been received (P.4.3.1). Ms Paraskevopoulos confirmed that it had and agreed to send this to the HDEC Secretariat.
* The Committee advised that a separate optional PIS and consent form for future research needs to be provided. The researcher advised that they thought this had been sent but they will follow up with the principal investigator.
* The Committee advised that for future applications, the amount of time taken to make a decision on whether to participate should be quantified.
* The Committee asked for clarification on what is considered reasonable for reimbursement of expenses. Ms Paraskevopoulos advised that is normally around $50 and covers travel to the site and parking costs. Ms Paraskevopoulos agreed to put approximate figures in the PIS.
* The following changes were requested to the PIS and consent form:
  + Please insert name and contact details for study staff (page 6 of the PIS).
  + Please provide a separate optional PIS and consent form for future unspecified research.
  + Please include contact details for Māori cultural support.
  + Please amend the PIS to state ““I have read or had read to me”.
  + Please include an approximate figure on the PIS for reimbursement of expenses.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22)*.

The response from the researcher will be reviewed, and a final decision made on the application, by Mrs Sandy Gill and Mrs Gael Donoghue.

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| **8** | **Ethics ref:** | **13/CEN/183** |
|  | Title: | Transfer from Methadone to Buprenorphine |
|  | Principal Investigator: | Dr David Newcombe |
|  | Sponsor: | South EAstern Sydney Local Health District (SESLHD |
|  | Clock Start Date: | 14 November 2013 |

Dr David Newcombe, Associate Professor Nicholas Lintzeris, Dr Susanna Galea, Dr Stefanie Leung and Ms Carina Walters 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 congratulated the researcher on a well put together and thorough application and noted that the purpose of this application was to evaluate a standardised procedure of transferring patients from methadone to suboxone to identify best practice.
* The Committee advised that in order to have informed consent, a summary of inclusion and exclusion criteria for participants should be included in the PIS.
* The Committee asked whether the researchers were intending to store and use tissue for future research. The researchers advised that they would not and agreed to remove this paragraph from the PIS (page 5).
* The Committee asked why participants had one week to decide whether to participate in the study. The researcher explained that this was just to give them enough time to make a decision and so that participants could discuss this with their case worker.
* The Committee queried whether the draft Clinical Transfer Protocol for Methadone will be used. The researcher explained that these were in draft until they had been signed off by the Guidelines Committee, which only occurred last week. They can now be referred to as the National Guidelines and are the final protocol that researchers will be using.
* The Committee queried the use of buprenorphine throughout the application and advised that it needs to be clear that suboxone is buprenorphine plus naloxone.
* The Committee noted that for informed consent, the side effects of buprenorphine need to be included in PIS. The researchers explained that this study is an evaluation of a process of transferring from one drug to another, rather than a trial of a specific drug. This is why their protocol does not include side effect information.
* The researchers advised that when a doctor is transferring a patient from one drug to another, it is assumed that they would inform patients of the side effects. The Committee noted that it cannot be assumed that all doctors will give this information.
* The Committee discussed adding a statement to the consent form about side effects but were concerned that this may confuse the process if this was mentioned. The Committee noted that if research is focused on a process, it is misleading to put information in a consent form that it is not part of the trial and that informed consent should only focus on the risks and benefits of participating in research, rather than normal clinical practice.
* The Committee agreed that the after subaxone is first mentioned in the PIS, the statement “the side effects of which your medical practitioner will have explained to you” should be added.
* The Committee asked if evidence of Māori consultation had been received. The researcher confirmed that it had just been received from Helen Wihongi at Auckland District Health Board. The researcher agreed to send this to the HDEC Secretariat.
* The Committee queried whether pregnant or breastfeeding women would not be part of the study because they would not be on methadone or because they would not normally be transferred to another drug. The researchers confirmed that pregnant and breastfeeding women would not be part of the population pool as they would not be transferred to another drug.
* The Committee asked whether people would be invited to transfer from methadone to buprenorphine. The researchers confirmed that they will not be asking for people to transfer and that the study would consist of people who had already made the decision to transfer.
* The following changes were requested to the PIS and consent form:
  + Please add key inclusion and exclusion criteria, in lay language, to the PIS.
  + Please state that this study has received approval from the Central Health and Disability Ethics Committee on page 5 of the PIS.
  + Please amend the ACC statement on page 4 of the PIS from “you would be eligible for compensation to “you may be eligible for ACC compensation.”
  + Please remove the paragraph on tissue samples being stored (page 5).
  + Please add “the side effects of which your medical practitioner will have explained to you” after suboxone is first mentioned on the PIS.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22)*.

The response from the researcher will be reviewed, and a final decision made on the application, by Mr Paul Barnett and Dr Dean Quinn.

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| **9** | **Ethics ref:** | **13/CEN/185** |
|  | Title: | The ASCOLT Study |
|  | Principal Investigator: | Dr Mark Jeffery |
|  | Sponsor: | THE UNIVERSITY OF SYDNEY |
|  | Clock Start Date: | 14 November 2013 |

No researchers were 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.

* The Committee noted that the reference to the Injury Prevention, Rehabilitation and Compensation Act on pages 9 and 10 of the PIS needs to be amended to the Accident Compensation Act.
* The Committee queried the form for withdrawal of participation which gives participants the option of withdrawing from study treatment but agreeing to continue the study follow-up. The Committee noted that the form does not seem to allow for wanting to withdraw from the study completely.
* The Committee noted there was some confusion over the number of participants in the study. A.1.5 and A.2.1 state that there will be 2660 participants, while A.6.3.2 states that there will be 1220 participants.
* The Committee noted that the researcher had answered in P.4.2 that there were no cultural issues for Māori, but that cultural issues for Māori had been noted in the PIS. The Committee advised that for future applications, the information provided in the PIS should also be included in the application form.
* The Committee noted that no issues for Pacific peoples had been identified in F.1.1.
* The Committee noted that the answer to P.4.3.1 stated that “each participating site will consult with its Māori Committee for approval and recommendations”, whereas the PIS only states that the location will be Christchurch.
* The Committee advised that the evidence of peer review should be provided on NHMRC Clinical Trials Centre letterhead.
* The Committee advised that for future applications, the researcher should provide a quantity of time (P.3.1) as “as long as necessary” may mean different things to different people.
* The following changes were requested to the PIS and consent form:
  + Please provide two separate PIS and CFs for the optional donation of blood samples and tumour tissue and for optional future unspecified research.
  + Please include exclusion criteria of use of PPIs, aspirin, NSAIDS, anticoagulants and Cox-2 inhibitors on the PIS.
  + Please state that this has study been approved by the Central Health and Disability Ethics Committee (page 10 of the PIS).

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention* *Studies, para 6.22)*.
* Please provide evidence of peer review on NHMRC Clinical Trials Centre letterhead *(Ethical Guidelines for Intervention Studies, para 5.11).*

The response from the researcher will be reviewed, and a final decision made on the application, by Mr Paul Barnett and Mrs Gael Donoghue.

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| **10** | **Ethics ref:** | **13/CEN/186** |
|  | Title: | A study of PF-04950615 versus placebo for the reduction of cardiovascular events (B1481022) |
|  | Principal Investigator: | Dr John Baker |
|  | Sponsor: | Pfizer Australia and New Zealand |
|  | Clock Start Date: | 14 November 2013 |

Dr John Baker, Ms Rhonda Litchfield and Mrs Catherine Howie 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 acknowledged a well put together application.
* The Committee noted that if a participant has low cholesterol, they will be dosed monthly and asked for clarification on how this will be handled with blinding. Dr Baker confirmed that those on the placebo will also have their dosage reduced. He noted that the first dose will be halved, then the dose will move from 75mg weekly to 75mg monthly.
* The Committee asked for clarification on time needed for the screening visit as page 3 of the PIS implies that this is site specific. Mrs Howie agreed that this would not normally be site specific and confirmed that the correct time of approximately two hours will be added to the PIS.
* The Committee noted that the PIS refers to subjects and advised that this is people are normally referred to as participants in New Zealand.
* The Committee advised that the PIS should include details of how much space will be need in the fridge for storing the study drug. Mrs Howie confirmed this will be clarified.
* The Committee asked how participants will keep drug safe from children given that it needs to be stored in a fridge. Mrs Howie confirmed participants would have a special bag and a tamper free box for the drug, which is mentioned in PIS.
* The Committee noted that section 9, page 11 of the PIS states that it is the responsibility of the participant to inform their GP that that they are participating in the study. Mrs Howie confirmed that is mandatory for the researcher to inform participants’ GPs and that this statement will be removed.
* The Committee asked for clarification on the retention of data. While the application states that data will be retained for 15 years, it is not clear when the 15 years is from. Mrs Howie will confirm this.
* The Committee noted that the compensation section on page 2 of the pharmacogenomic consent was well written and queried whether this was taken from a template. Mrs Howie confirmed that this was provided by Pfizer.
* The Committee noted that the insurance cover should be equivalent to ACC cover. The AIG Certificate of Insurance describes the cover as being medical malpractice cover which would not be equivalent to ACC cover. The Committee recommended confirming with Pfizer as to whether this study actually gives ACC equivalent cover.
* The Committee asked for future applications that for R.5.4.1 please clarify time, rather than take as much time as needed. Dr Baker advised that this would usually be done verbally and that usually people would come back within a week.
* The Committee asked for clarification of what constituted reasonable travel expenses. Mrs Howie confirmed that this is for petrol vouchers to cover mileage and parking.
* The Committee commended the researchers on their understanding of Māori cultural issues.
* The following changes were requested to the PIS and consent form:
  + Please provide key inclusion and exclusion criteria, in lay language, on the PIS.
  + Please change “additional” to “optional” on the title of the pharmacogenomic consent form.
  + Please add time allowed for the screening visit to the PIS.
  + Please add details on how much fridge space will be required for storing the study drug to the PIS.
  + Please remove the reference to “informing your primary health care provider” on page 11 of the PIS.
  + On page 14 of the PIS, under future research statement, please add by signing this “optional” consent form.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention* *Studies, para 6.22)*.
* Please confirm whether the insurance provides coverage that is equivalent to ACC *(Ethical Guidelines for Intervention Studies, paras 8.4 – 8.5)*.

The response from the researcher will be reviewed, and a final decision made on the application, by Dr Dean Quinn and Mrs Sandy Gill.

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| **11** | **Ethics ref:** | **13/CEN/187** |
|  | Title: | A Study Comparing GDC-0199 and Rituximab to Bendamustine and Rituximab in Patients with Relapsed/Refractory Chronic Lymphocytic Leukaemia. |
|  | Principal Investigator: | Dr Andrew Butler |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 14 November 2013 |

No researchers were 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.

* The Committee noted that this was a Phase III study and that SCOTT approval was required.
* The Committee asked for clarification on why the clinical trial registry number was pending.
* The Committee asked for the name of the radiologist, licensed under the Radiation Protection Act 1965, with responsibility for the supervision of ionising radiation to participants in the study (R.1.13.2)
* The Committee noted that the question on how the study may benefit Māori (P.4.1) had not been adequately answered and recommended that for future applications, a description on how the study would benefit Māori in general was required.
* The Committee did not feel that that main PIS covered issues for Māori with sending tissue overseas. The Committee recommended that the last four lines of the information provided for P.4.2 be added to the PIS. This also needs to be added to the PIS for future unspecified research.
* The Committee asked for clarification on page 8 of the consent form for future unspecified research, which states that “tissue samples will be stored indefinitely”, while the application form states 15 years.
* The Committee noted that not all of the guidelines outlined in the *Guidelines for the Use of Human Tissue for Future Unspecified Research* are covered in the PIS. The Committee recommended paying particular attention to section 8. The guidelines can be found at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>
* The insurance certificates refer to AbbVie Limited and AbbVie Inc., while the application form refers to AbbVie Pty Ltd. Please clarify who is responsible for the study and who the insurance covers.
* The following changes were requested to the PIS and consent form:
  + Please complete the contact details for further information on page 5 of the optional future unspecified research PIS.
  + The optional consent form for future unspecified research is currently labelled PIS. Please amend this to optional consent form.
  + Please add the key inclusion and exclusion criteria, in lay language, to the PIS.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention* *Studies, para 6.22)*.
* Please confirm who is responsible for the study and who the insurance will cover *(Ethical Guidelines for Intervention Studies, paras 8.4 – 8.5)*.

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

## 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:** | 30 January 2014, 12:00PM |
| **Meeting venue:** | Deloitte House, MEDSAFE, Level 6, 10 Brandon Street, Wellington, 6011 |

No members tendered apologies for this meeting.

1. **Other business**

* Moira Wilson of the Ministry of Social Development (MSD) attended the meeting to discuss what ethics approval would be required for researchers seeking to use the linked data from the MSD predictive risk modelling system (PRM).
* Ms Wilson explained that on the recommendation of NEAC, they are looking to make the data from the PRM available to other researchers and that this data will be made available through Statistics New Zealand.
* Ms Wilson asked whether there would be any way of providing the protections of the *Standard Operating Procedures for Health and Disability Ethics Committees* without researchers having to bring a study to HDEC for approval every time they want to obtain information from the PRM.
* The Committee expressed concern about whether the Central HDEC could make that decision or whether it should it be considered by HDEC chairs and/or NEAC.
* The Committee agreed that their view was that each individual research request would need to come back on a case by case basis as each study would deal with vulnerable people.
* Ms Wilson agreed that the option of researchers getting ethics approval before gaining the data from Statistics New Zealand could be added to the process.
* The Committee noted that when people join a GP, they sign a form saying that data can be used for research purposes. Ms Wilson advised that the PRM will bring together a range of data which may not have undergone the same process.
* The Committee noted that there was a much larger risk involved with using all elements of data and that there was the risk of further stigmatising people who are already stigmatised.
* Ms Wilson agreed that MSD will develop a protocol of how the system will work and the rules that researchers will follow to get access to data. Ms Wilson agreed to circulate this protocol to the Committee when it is completed.

The meeting closed at 5.00pm.