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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 21 October 2014 |
| **Meeting venue:** | Terrace Conference Centre, 114 The Terrace, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.10pm | Confirmation of minutes of meeting of 23 September 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/CEN/157  ii 14/CEN/162  iii 14/CEN/163  iv 14/CEN/166  v 14/CEN/168  vi 14/CEN/169  vii 14/CEN/171  viii 14/CEN/172  ix 14/CEN/173  x 14/CEN/174  xi 14/CEN/175 |
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| 4.25pm | General business:   * Noting section of agenda |
| 4.31pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| 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 |

## Welcome

The Chair opened the meeting at 12.21pm 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 23 September 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/CEN/157** |
|  | Title: | SJMB12 - Medulloblastoma |
|  | Principal Investigator: | Dr Stephen Laughton |
|  | Sponsor: | St Jude Children's Research Hospital |
|  | Clock Start Date: | 02 October 2014 |

Dr Stephen Laughton, Dr Sarah Hunter and Dr Karen Tsui 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 they found the titles of the PIS confusing as it was often not easy to differentiate between the various forms. Dr Hunter agreed that they will look at changing the labelling of the documents for the next study.
* The Committee noted the length of the PIS and asked if this could be reduced by taking out the optional sub-studies which will not be available in New Zealand. Dr Hunter advised that the studies not available in New Zealand have already been removed. She explained that they are bound by the requirements of the sponsor, New Zealand and ADHB requirements. The Committee recommended appending a brief two page overview of the study to the front of the PIS. Dr Hunter agreed to talk to the study team as it would have to be approved locally. The Committee also recommended reformatting the PIS to reduce the number of pages with white space.
* The Committee asked for clarification on the level of detail of researchers’ discussions of the PIS with participants and parents. Dr Laughton confirmed that he spends a lot of time going through the PIS with potential participants and they are given time to go away and think about the study before coming back to ask any questions. He explained that the nature of this study means that consent does not have to be obtained before the biopsy is taken. Dr Laughton advised that in paediatric oncology studies, the paediatric oncologists take the consent and they often have a neurological specialist to answer questions.
* The Committee asked for clarification on incidental findings for genetic testing (page 3 of the Information Sheet for Parental Blood Sample) as they believed the statements were inconsistent as results will not be sent to participants of their doctor.
* The Committee asked for clarification on the optional research testing part of the Consent Form for Pre-Screen (page 2) as they did not think this was optional. Dr advised that she did not think this statement was relevant to New Zealand participants but agreed to confirm this with the sponsor.
* The Committee noted that in order to withdraw from the study, participants need to complete a form and post it to St Judes. They advised that under the Code of Health and Disability Services Consumers' Rights, withdrawal does not need to be done in writing. Dr Hunter agreed that participants could inform the researchers of their withdrawal and the researchers would fax the withdrawal to St Judes. The reference to “decision in writing” (page 4 of the Information Sheet for Parental Blood Sample”) also needs to be removed
* The Committee noted that the reference to US legislation was confusing (page 4 of the Information Sheet for Parental Blood Sample). Dr Hunter explained that this was required by the sponsor. The Committee recommended moving the statement in bold that New Zealand has no equivalent law, to the beginning of the paragraph.
* The Committee asked if all of the participants would be based in Auckland as they were concerned that the number for participants to call with any questions was an Auckland number and would be a toll call for those outside the area. Dr Hunter advised that Starship takes patients from all of the North Island, with the exception of Wellington. She said that the Christchurch Paediatric Oncology catchment area is not running this trial but the study team have agreed that potential participants from this area can access the treatment. Dr Hunter agreed to see if the ADHB has an 0800 number that participants can call.
* The Committee requested the following changes to the PIS and consent form:
  + Information Sheet for Parental Blood Sample – Please amend “will not be given to you or your doctor” to “will not be given to you or your child’s doctor” (page 2).
  + Information Sheet Aged 7-11 Years – Please change “you and your family can choose” to “you or your family can choose”.

Decision

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

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

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

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| **2** | **Ethics ref:** | **14/CEN/162** |
|  | Title: | ABX203-002: ABX203 therapeutic vaccine in HBeAg negative patients with chronic hepatitis B |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Abivax SA |
|  | Clock Start Date: | 09 October 2014 |

Professor Edward Gane 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 advised that they found the PIS confusing in relation to treatment groups and recommended the use of a diagram to explain the groups.
* The Committee noted that they found the application more informative than the PIS. They said it was not clear in the PIS what the drug was and why it was being given as a nasal spray.
* The Committee advised that for future applications, P.4.1 is looking for statistics, if available, of the prevalence of the condition being studied in Māori.
* The Committee requested the following changes to the PIS and consent form:
  + Please provide a separate PIS and consent form for future unspecified research. Please refer to the *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes* at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> for information that should be provided.
  + Please remove the reference to participant’s responsibility to inform their local doctor of their participation in the project (page 6 of the PIS).
  + Please remove the Australian paragraph on complaints and compensation (page 11 of the PIS).
  + Please note that HIV is not a notifiable disease so study doctors are not required by law to notify government health authorities (page 9 of the PIS).
  + Please include a history of substance abuse as an exclusion criteria in the PIS as this may not be part of a patient’s clinical records.
  + Please ensure that contact details are correct as Dr Helen Wihongi is currently listed as the contact person for Māori (page 13 of the PIS).

Decision

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

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

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

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| **3** | **Ethics ref:** | **14/CEN/163** |
|  | Title: | Managing gout in the community |
|  | Principal Investigator: | Professor Lisa Stamp |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 October 2014 |

Professor Lisa Stamp 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.

* Professor Stamp explained that there are several parts to the study. When a patient comes to the clinic with gout they will receive current best practice for the treatment of gout. Patients will then be asked whether they would like to take part in the study which will involve the collection of additional data, quality of life questionnaires and the collection of blood samples to assess drug concentrations. The research nurse will go through the informed consent process and collect the additional data. There will also be a retrospective audit on the management of gout at the clinic in 2012 and a prospective audit on whether the patients are being treated according to best practice guidelines.
* The Committee recommended removing the reference to a retrospective audit and instead making the two audits a clinical records audit.
* The Committee noted that HDEC approval is not required for audits but gave approval for the audit aspect of this study.
* The Committee asked for clarification on what would happen to blood samples as it was currently unclear in the PIS. Professor Stamp advised that they will be held in Christchurch but a statement is included on the consent form for the samples to be sent overseas for testing if necessary.
* The Committee advised that a separate PIS and consent form should be provided for the future unspecified research. Please refer to the *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes* at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> for advice on what information is required.
* The Committee referred the researcher to section 13 of the *Standard Operating Procedures for Health and Disability Ethics Committees* on tissue banks. They recommended paying close attention to the governance arrangements and the management of tissue.
* The Committee noted that no registered health professional would be giving treatment R.1.7 and asked why no had been selected given that Dr Judd would be involved. Professor Stamp explained that the treatment of gout would be occurring regardless of whether the participant agreed to take part in the study.
* The Committee advised for future applications that P.4.1 is looking for statistics for gout relating to Māori, while some examples of cultural issues for P.4.2 would be the collection of blood and the concept of whakama for those who have gout and their families.
* The Committee advised for future applications that F.1.2 is looking for statistics of the prevalence of gout in Māori, Pacific people and other New Zealand populations.
* The Committee requested the following changes to the PIS and consent form:
  + Please amend the Injury Prevention Rehabilitation and Compensation Act to the Accident Compensation Act 2001 (page 2 of the PIS).
  + Please include Māori cultural support contact numbers.
  + Please include that this study has received ethical approval from the Central Health and Disability Ethics Committee.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide an optional participant information sheet and consent form for future unspecified research *(Ethical Guidelines for Intervention Studies, para 6.22).*

The further information received will be reviewed, and a final decision made on the application, by Dr Kay de Vries and Mr Paul Barnett.

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| **4** | **Ethics ref:** | **14/CEN/166** |
|  | Title: | Ibrutinib in Combination with Obinutuzumab versus Chlorambucil in Combination with Obinutuzumab in participants with Treatment-naive Chronic Lymphocytic Leukaemia or Small Lymphocytic Lymphoma |
|  | Principal Investigator: | Dr Gillian Corbett |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 09 October 2014 |

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 this study is to evaluate ibrutinib in combination with obinutuzumab compared with chlorambucil in combination with obinutuzumab, which has been considered the gold standard for a number of years.
* The Committee noted that participants will need to match all of the inclusion criteria and none of the exclusion criteria in order to take part in this study.
* The Committee noted that all of the side effects have been acknowledged in the PIS.
* The Committee asked for clarification on the last two bullet points of page 24 of the PIS and asked if they should be removed and included on the consent form for future research.
* The Committee noted that if participants were randomised to the study drug, there were was substantial risk of harm without benefit as they would not be receiving standard treatment. They asked that a sentence be added to the PIS that if participants are randomised to the study drug, they will not be receiving standard care.
* The Committee noted that the PIS was complicated and technical. They recommended including a flowchart for participants which clearly outlines what will happen in each treatment arm.
* The Committee noted that for future applications the answer to R.3.7 that leftover samples will be destroyed was not accurate as some samples will be bio banked.
* The Committee noted that the answers to P.3.1 and P.3.2 in relation to vulnerable people were contradictory.
* The Committee advised that P.4.1 should have included statistics on the prevalence of CLL or SLL in Māori, while F.1.2 should also have included statistics for Māori, Pacific people and other New Zealand populations.
* The Committee were concerned with the wording around alternatives to participation (pages 10 and 11 of the PIS). They suggested removing all of the bullet points except for “you may be eligible for other cancer research studies” and adding a sentence to the effect of “you will be treated by your clinician in the usual way as your condition requires”.
* The Committee requested the following changes to the PIS and consent form:
  + Please include a lay definition of 17p deletion (page 1 of the PIS).
  + Please include as exclusion criteria (3) history of malignancies, (6) use of prednisone, (9) system infection, (13) major surgery within four weeks of the first dose, (15) clinically significant cardiovascular disease, (16) inability to swallow capsules, and (17) concurrent use of warfarin (numbers refer to the exclusion criteria listed on the protocol).
  + Please remove the words “according to national provisions” (page 11 of the PIS).
  + Please include whether participants will be informed of any incidental findings as per R.4.1.1 of the application.
  + Please remove the references to tissue being sold (page 12 of the PIS).
  + Please add “Central” to this study has received ethical approval from the Health and Disability Ethics Committee (page 21 of the PIS).
  + Please delete bullet point “I am aware that the proposed study…” as this is covered in the optional consent form (page 24).
  + Please include the word “optional” in the title of the consent for additional blood sample storage and testing for future research (page 25).

Decision

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

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

The further information received will be reviewed, and a final decision made on the application, by Mrs Gael Donoghue and Dr Cordelia Thomas.

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| **5** | **Ethics ref:** | **14/CEN/168** |
|  | Title: | SWITCH: Short Intravenous Study for Cellulitis |
|  | Principal Investigator: | Dr Mark Birch |
|  | Sponsor: | Barwon Health |
|  | Clock Start Date: | 09 October 2014 |

Dr Mark Birch 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.

* Dr Birch confirmed that ethical approval had now been given at the primary site in Geelong and had also been received at a number of other sites in Australia.
* The Committee noted that the researcher had answered yes to there being the possibility of unexpected or clinically significant findings. Dr Birch explained that he was not expecting individuals to receive unexpected findings but that people that are randomised to one day of intravenous treatment may end up being readmitted to hospital. The Committee noted that this would not be unexpected and that this question refers to new health issues for individuals.
* The Committee commended the researcher on the consultation with Māori but advised for future applications that the taking of blood samples may be a cultural issue for some Māori (P.4.2).
* The Committee advised for future applications that P.4.1 is looking for statistics, if available, of the prevalence of cellulitis in Māori.
* The Committee noted for future applications that F.1.2 is looking for the statistics of the prevalence of cellulitis in Māori, Pacific people and other communities
* The Committee commended the researcher for a clear and informative PIS.
* Dr Birch noted that he had received an email from the HDEC Secretariat requesting evidence of scientific review. He advised that this would be sent when it is received.
* The Committee requested the following changes to the PIS and consent form:
  + Please swap section 16 and 17 of the PIS so that the consent section is at the end of the document and on a separate page.
  + Please add the following statement to the consent form “I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.”
  + Please include that this study has received ethical approval from the Central Health and Disability Ethics Committee.

Decision

This application was *approved* by consensus subject to the following non-standard conditions

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

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| **6** | **Ethics ref:** | **14/CEN/169** |
|  | Title: | Plasma CNP peptides in Parkinson's Disease |
|  | Principal Investigator: | Dr Zoe Woodward |
|  | Sponsor: |  |
|  | Clock Start Date: | 08 October 2014 |

Dr Zoe Woodward 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 if the participants would be split into two separate groups. Dr Woodward explained that there would be two distinct groups - group M consisting of people who had never had treatment and group D consisting of people who have had treatment. However, once these groups are recruited, they will receive the same study procedures. The Committee advised that information on the recruitment process needs to be added to the PIS as this is not currently clear.
* The Committee advised for future applications that F.1.2 is not looking at collecting ethnicity data but rather, statistics on the prevalence of Parkinson’s Disease in Māori, Pacific people and other New Zealand populations.
* The Committee commended the researcher for the acknowledgement of cultural issues for Māori.
* The Committee asked for clarification on whether blood would be sent overseas (B.4.5.3). Dr Woodward explained that the Brain Research Institute in Christchurch has a blood bank where samples may be kept. She advised that some of the tests can only be done overseas so may be sent to overseas labs for testing. This needs to be included in the PIS.
* The Committee advised that there needs to be a separate PIS and consent form for the optional future unspecified research. Please refer to the *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes* at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> for advice on what information is required.
* The Committee noted that cognitive deficits may be discovered during the testing (R.4.1.1) and asked if participants would be told. Dr Woodward advised that they would ask participant’s permission to give the results to their GP or neurologist. This needs to be included in the PIS.
* The Committee asked for clarification on how participants could give consent free from undue influence, given that the request to participate may come from their treating doctor (P.3.1). Dr Woodward explained that Professor Tim Anderson will inform participants of the research and give them the PIS. A research nurse will make a follow up phone call and will take the informed consent.
* The Committee requested the following changes to the PIS and consent form:
  + Please amend “you would be eligible for compensation from ACC” to “you may be eligible” (page 3 of the PIS).
  + Please include in the PIS that there will be questionnaires in the testing.
  + Please include disorders requiring daily medication and any blood or kidney disorder as exclusion criteria in the PIS.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide a separate optional participant information sheet and consent form for future unspecified research *(Ethical Guidelines for Intervention Studies, para 6.22).*

The further information received will be reviewed, and a final decision made on the application, by Mrs Sandy Gill and Dr Kay de Vries.

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| **7** | **Ethics ref:** | **14/CEN/171** |
|  | Title: | Safety of tofacitinib compared to etanercept in Rheumatoid Arthritis (A3921133) |
|  | Principal Investigator: | Dr Sunil Kumar |
|  | Sponsor: | Pfizer Australia and New Zealand |
|  | Clock Start Date: | 09 October 2014 |

Dr Sunil Kumar 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.

* Dr Kumar explained that this is a post authorisation open label study and that tofacitinib has already been approved for use in the US but not in the UK. The study will be comparing two strengths of tofacitinib with etanercept which is already approved in New Zealand under a different name. The study will involve at least 1500 participants, in 40 countries over three years. All three groups will continue to receive methotrexate for the duration of the study.
* The Committee commended the researcher for a detailed PIS.
* The Committee advised for future applications that P.4.1 is looking for statistics relating to Māori and the condition being studied. If no statistics are available, then a statement to that effect should be included. P.4.2 is asking the researchers to identify any potential cultural issues for Māori, for example, sending of tissue overseas. The Committee noted that these were included in the PIS but not the application. They commended the researchers for their acknowledgement of cultural issues in the PIS.
* The Committee advised for future applications that F.1.2 is looking for statistics of the condition being studied in Māori, Pacific people and other New Zealand populations
* The Committee requested the following changes to the PIS and consent form:
  + Please include alcohol or substance abuse, malignancies and cardiovascular abnormalities as exclusion criteria in the PIS.
  + Please remove the first paragraph under consent “by signing this informed consent form…” (page 16 of the PIS) as there is a separate consent form.
  + Please make it clear that tofatinicib is not available in New Zealand (last para of (1), page 2 of the PIS).
  + Please add “except beyond the limits set out in the PIS” to the bullet point “I agree not to restrict the use of any data or results, which arise from this study” (page 18 of the PIS).
  + Please remove “I do not give up any of my legal rights by signing this consent form” as participants are giving up their rights to privacy by taking part in this study (page 18 of the PIS). If the sponsor does not agree to this, please add the words “other than as set out in the PIS.”

Decision

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

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

The further information received will be reviewed, and a final decision made on the application, by Mrs Gael Donoghue and Mr Paul Barnett.

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| **8** | **Ethics ref:** | **14/CEN/172** |
|  | Title: | Preterm birth and developmental outcomes |
|  | Principal Investigator: | Dr Shieak YC Tzeng |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 October 2014 |

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 acknowledged a well put together application.
* The Committee asked for clarification on who would provide support to families if any abnormalities were detected during the testing, particularly given that NICU may not have contact with the families at the time of the 18 month testing. They noted that this is a high risk vulnerable group, with potentially young mothers who might lose contact with follow up services. Please include contact details for this support service in the PIS, along with the statement “I understand that should there be any abnormalities found during testing, support will be provided by [support service]”.
* The Committee asked for clarification on whether Mark Brunton was the Māori cultural support contact (page 5 of the PIS). If he is, please provide an 0800 number as participants will need to call Christchurch to contact him. If he is not, please provide a contact person and 0800 telephone number they can be contacted on.
* The Committee requested the following changes to the PIS and consent form:
  + Please clarify in the PIS if babies will be sedated for the MRI scans.
  + Please amend “you will allow your medical information and results” to “you will allow your child’s medical information and results” (page 4 of the PIS).
  + Please include in the PIS that there can be a karakia for disposal of blood.
  + Please reword the statement “I understand that my child’s participation is voluntary” as it currently reads as if the child is able to volunteer (page 1 of the consent form).

Decision

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

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

The further information received will be reviewed, and a final decision made on the application, by Dr Kay de Vries and Mrs Helen Walker.

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| **9** | **Ethics ref:** | **14/CEN/173** |
|  | Title: | Study investigating ABT-493 and ABT-530 in Subjects with Normal and Impaired Hepatic Function |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | AbbVie Limited |
|  | Clock Start Date: | 09 October 2014 |

Professor Edward Gane 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 noted for future applications that F.1.2 is asking for statistics on the prevalence of Hepatitis C for Māori, Pacific people and other New Zealand populations.
* The Committee noted that under the Code of Health and Disability Services Consumers' Rights, withdrawal from a study does not need to be made in writing.
* Professor Gane confirmed that the insurance would be renewed as it expires in January 2015.
* The Committee asked for clarification on the DSMB. Professor Gane explained that as this is a pharmacokinetic study, the DSMB consists of internal pharmacologists rather than external clinical experts.
* The Committee noted that R.3.8.1 stated that this was a worldwide study but A.6.3 stated that participants would only be recruited from two countries. Professor Gane explained that New Zealand was the only country participating outside the US but there were multiple sites involved within the US.
* The Committee requested the following changes to the PIS and consent form:
  + Please include information under “Do I have to take part in this research project?” as this is currently blank (page 9 of the PIS).
  + Please include that this study has been approved by the Central Health and Disability Ethics Committee (page 17 of the PIS).
  + Please refer to the *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes* at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> to ensure that all the information required is provided in the optional genetic sub-study sample collection.
  + Please remove the optional section, including the three bullet points (page 19 of the PIS).
  + Please remove the statement “By signing this consent form, I am not giving up any of my legal rights” as participants are giving up some rights by taking part in this study (page 4 of the optional consent form).

Decision

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

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

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

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| **10** | **Ethics ref:** | **14/CEN/174** |
|  | Title: | A clinical trial to evaluate safety and efficacy of combination of ertugliflozin with sitagliptin in the treatment of participants with type II diabetes with inadequate glycaemic control on diet and |
|  | Principal Investigator: | Dr Michael Williams |
|  | Sponsor: | Covance New Zealand Limited |
|  | Clock Start Date: | 09 October 2014 |

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 well-constructed application.
* The Committee noted that this application acknowledged the risks for participants in taking a drug that has not been approved for sale in New Zealand.
* The Committee asked for clarification on the study aids or tokens of appreciation of nominal value (page 11 of the PIS).
* The Committee noted for future applications that P.4.1 is asking for the statistics on the prevalence of the condition being studied for Māori.
* The Committee noted that if this treatment works, it should help reduce inequalities for Māori and Pacific people (F.1.1)
* The Committee commended the researcher on including the exclusion criteria in the PIS.
* The Committee requested the following changes to the PIS and consent form:
  + Please include a lay title on the PIS.
  + Please clarify what the rescue medication is (page 1 of PIS).
  + Please include the title “Optional Consent Form for Future Biomedical Research” under the Māori health support contact (page 5 of the optional PIS).

Decision

This application was *approved* by consensus subject to the following non-standard conditions

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

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| --- | --- | --- |
| **11** | **Ethics ref:** | **14/CEN/175** |
|  | Title: | A study of ABT493 and ABT530 with or without RBV in patients with chronic Genotype 2 or 3 HCV |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | AbbVie Ltd |
|  | Clock Start Date: | 09 October 2014 |

Professor Edward Gane 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 whether the sub-study was optional. Professor Gane confirmed that it was.
* The Committee commended the researcher for the paragraph on cultural issues.
* The Committee commended the use of the diagram on page 21 of the PIS which makes it easier for people to understand the study.
* The Committee advised that the blood samples (plasma and serum) referred to on page 17 of the PIS should be included in the optional pharmacogenetic sub-study PIS.
* The Committee noted that there will be no time limit to make a decision (P.3.1) and advised for future applications that a time limit should be specified.
* The Committee requested the following changes to the PIS and consent form:
  + Please remove the optional section, including the three bullet points (page 22 of the PIS).
  + Please remove the statement “By signing this consent form, I am not giving up any of my legal rights” as participants are giving up some rights by taking part in this study (page 8 of the optional PIS and consent form).
  + Please refer to the *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes* at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> to ensure that all the information required is provided in the optional genetic sub-study sample collection.
  + Please remove the words “in writing” from the paragraph on withdrawing from the project as consent does not need to be withdrawn in writing in New Zealand (page 4 of the optional pharmacogenetic sub-study PIS).

Decision

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

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

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

## 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:** | 25 November 2014, 12:00 PM |
| **Meeting venue:** | Deloitte House, MEDSAFE - L6, 10 Brandon Street, Wellington, 6011 |

No members tendered apologies for this meeting.

The meeting closed at 4.31pm.