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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 30 January 2014 |
| **Meeting venue:** | Deloitte House, MEDSAFE, Level 6, 10 Brandon Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05 | Confirmation of minutes of meeting of 26 November 2013 |
| 12.30 | New applications (see over for details) |
|  | i 13/CEN/208  ii 13/CEN/200  iii 13/CEN/204  iv 13/CEN/209  v 13/CEN/215  vi 13/CEN/216  vii 13/CEN/217  viii 13/CEN/218  ix 13/CEN/220  x 14/CEN/1  xi 14/CEN/8  xii 14/CEN/10 |
|  |  |
| 4.35pm | General business:   * Noting section of agenda |
| 4.45pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2014 | Present |
| Mrs Gael Donoghue | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2014 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 11.30am and welcomed Committee members.

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 26 November 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **13/CEN/208** |
|  | Title: | 178-CL-102. Longterm multinational study comparing the safety and efficacy of two medicines, solifenacin succinate and mirabegron, taken together or separately, in subjects with symptoms of overactive |
|  | Principal Investigator: | Mr Stephen Mark |
|  | Sponsor: | Astellas Pharma Europe B.V. |
|  | Clock Start Date: | 05 September 2013 |

Mr Mark 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 requested the following changes to the participant information sheet:
  + Please consider making the study short title briefer.
  + Please revise the language and rewrite for a New Zealand population. For example, delete reference to Federal Law.
  + Page 10, item 13: please advise participants that samples will be destroyed after 12 months.
  + Page 11, item 16: The discussion confirmed that all hospitals will retain information, participants will receive a number that is given to Astellas and therefore participant information will be anonymous or de-identified. Please replace ‘personalised’ with anonymous or de-identified to avoid confusion for participants.
  + Please include exclusion criteria briefly and in lay language. The Committee acknowledged Mr Mark’s explanation that Overactive Bladder can be caused by neurological and non-neurological or out-of-the-blue causes and asked that both be summarised in the interest of participants having full information before consenting to join the study.
* The Committee asked for clarification on the answer given at r.2.4 on the application form. Mr Mark explained that the data generated in this study will not be identified back to an individual once it has been sent overseas.
* The Committee noted the answers given at r.1.8 and r.5.2 on the application form regarding remuneration of researchers were contradictory, and asked whether there might be a conflict of interest. Mr Mark explained that none of the medical staff involved in the study have shares or investments in the sponsoring company. The CI and other staff who give their time on the study will not receive personal payment but the sponsor will reimburse the research trust for their time. Mr Mark confirmed that there will be no bonuses for high recruitment rates. Therefore there would be no conflict of interest.
* Mr Mark clarified how participants will be recruited to the study and explained that it is an offsite process whereby patients will be assessed for eligibility to participate and randomised into the study. The researchers themselves will not recruit participants.
* The Committee noted the answer given at p.4.1 on the application form that this study will not benefit Mãori any more or less than other population groups and asked whether Overactive Bladder is pertinent in that population? Mr Mark advised that there is no evidence that OAB is greater in the Mãori or Pakeha population. Previous studies do not show evidence that drugs of these categories have effect. The Committee advised that this was the type of information that was asked for in this question.
* The Committee advised that question p.4.2 is asking researchers to demonstrate an awareness of the cultural issues that may arise for Maori who take part. Mr Mark noted that these issues are addressed in the study protocol, any Maori participants will be informed of the requirements, including the taking of tissue samples, and that their participation is voluntary. The Committee asked that in future, the researchers describe these issues at p.4.2, and also include issues around dealing with collecting tissue samples and whakama (shame or embarrassment).
* The Committee advised that question f.1.2 on the application form includes not just Maori but Pacific peoples and other cultural groups. Mr Mark said that they will take this into account in future and will show they are the aware of the differences. This is appropriate for the process of consent.
* Mr Mark clarified a discrepancy in answers given at a.1.5 and f.2.3 on the application form about the inclusion of a placebo arm in the study. The run in period of two weeks constitutes the placebo part of the study. OAB does have a degree of placebo effect of a 20 and 30 percent improvement. The run in part of the study further allows taking baseline measures for all subjects.
* The Committee queried why participants will not have access to the best proven intervention after the study ends (as answered in question f.3.1 on the application form). Mr Mark advised that all participants will have access to all treatment after the study ends and a discrepancy was noted between the paper and online application form.

Decision

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

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

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

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| **2** | **Ethics ref:** | **13/CEN/200** |
|  | Title: | A study investigating GS-5806 in Hospitalized Adults with Respiratory Syncytial Virus (RSV)Infection |
|  | Principal Investigator: | Professor John Kolbe |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 16 January 2014 |

Prof Kolbe 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 whether the study’s Clinical Trial Registration number has been received (question b.4.7.1 on the application form). Prof Kolbe said he will check and provide the HDEC secretariat with the number.
* The Committee sought clarification on the answer given at question r.5.4 on the application form and asked whether it was correct that none of the physicians will be treating participants. Prof Kolbe confirmed that it was correct as many but not all physicians will treat. The Committee noted that it appreciated how this works in the hospital as patients may be admitted under Prof Kolbe but asked how he intended to handle a situation when he would likely see a participant admitted under his care before they receive the study medication. Prof Kolbe advised that there are two teams working on the ward and he would ask another consultant to take over care.
* The Committee noted the answer given at question p.4.1 on the application form and sought further explanation on how this study might benefit Maori? Prof Kolbe stated that in the groups being studied the prevalence of COPD would be higher in Maori and that they might benefit more from results of this study. The Committee noted for future reference, that such information is included at p.4.1.
* The Committee noted that the study exclusion criteria listed at f.2.1 on page 27 of the application form had been clearly stated in the participant information sheet and asked that Prof Kolbe also list inclusion criteria in the interest of fully informed consent. Prof Kolbe agreed to do this and noted for the Committee that participants are unlikely to have symptoms solely related to RSV. Participants will be stratified into four groups and there will be none in the first group. It is exceedingly unlikely patients will be admitted to hospital without underlying co morbidities. Most will have an exacerbation of COPD and to a lesser extent an exacerbation of asthma. This study will provide information for causal factors of the virus and further information for a larger study. Professor Kolbe will include wording on the group most likely to be admitted to hospital rather than for RSV virus symptoms only.
* The Committee requested the following changes to the participant information sheet:
  + Please change Multi-region Ethics Committee to Central Ethics Committee on page 11
  + Please update New Zealand Injury Prevention Rehabilitation and Compensation Act 2001 to read the Accident Compensation Act 2001 in the second to last paragraph on page 11
  + Please clearly state the inclusion criteria listed at question f.2.1 on page 27 of the application in lay language
* The Committee asked that Prof Kolbe provide a separate information sheet and consent form for the future unspecified research on the blood and nasal swab samples.

Decision

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

* Please amend the information sheet, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please submit a separate consent form for the optional future unspecified research on the tissue samples.
* Please submit the study’s Clinical Trials Registration number when known, to the Ethics Committees’ Secretariat.

This information will be reviewed, and a final decision made on the application, by the secretariat.

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| **3** | **Ethics ref:** | **13/CEN/204** |
|  | Title: | Personal-best exhaled nitric oxide in chronic obstructive pulmonary disease |
|  | Principal Investigator: | Dr Jack Dummer |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 January 2014 |

Dr Jack Dummer 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 stepwise reducing steroid dose may adversely affect participants with significant inflammation; i.e. symptoms may get a lot worse. Dr Dummer said the researchers will closely monitor participants for symptom changes and participants would also be under instruction to contact the researchers if they experience any worrying symptoms. Dr Dummer explained that in previous studies the 20 percent of participants who had experienced increased symptoms experienced them as a gradual process over 1-2 weeks rather than as acute exacerbations within a 24 hour period. There is a protocol in place to help researchers decide whether participants can continue in the study or have an assessment and routine treatment of the exacerbated symptoms.
* Clarification was sought on the intended study population. Dr Dummer advised that the population would be all comers with reasonably severe rather than mild COPD. One important restriction will be current smokers. The Committee asked that the restriction be stated in the participant information sheet so that participants are fully informed before consenting.
* The Committee also asked that the inclusion and exclusion criteria for joining the study that are listed at question f.2.1 on page 23 of the application form be included in the participant information sheet.
* The Committee highlighted that they no longer have the mandate to peer review studies but must ensure that evidence of scientific review is submitted and that it has been done by an appropriate expert. The Committee asked whether the colleague who had peer reviewed this study was independent. Dr Dummer confirmed that a colleague who had previously supervised his work had reviewed the study and that he is currently entirely independent of work with this colleague.
* The Committee noted that the researchers intend to use their database and clinic referrals to identify patients, which Dr Dummer confirmed. Dr Dummer advised that he would not approach potential participants directly. A letter will be sent initially asking people who are interested to let the researchers know. The researchers would then phone people to further discuss the study.
* The Committee clarified that the researchers do intend to store sputum samples for possible investigation of inflammatory markers in the future and advised that sputum is classified as human tissue as it is recognised as containing cells. The Committee advised that the researchers would need to ask permission from participants to do this as this is about people having some control over how their tissue samples are used. Consent can be gained by participants signing an optional consent form. Please submit a separate consent form for the future unspecified research on these samples and include ‘optional’ in the title.
* The Committee noted that the inclusion and exclusion criteria listed in the participant information sheet are brief in comparison with those listed in the protocol and differ slightly. Dr Dummer confirmed that those listed in the protocol are correct and that they would be included in the participant information sheet.
* Dr Dummer confirmed that people on any dose of steroids can consent to this study and that steroid naïve people would not be included in this study.
* The Committee complimented the researchers on their responses to cultural issues for Maori in p.4.1. For future reference, please note that the question at f.1.2 includes Pacific Island peoples and other non-Maori populations.
* The Committee noted that the researchers had answered that they are also the usual health and disability providers for participants at question r.5.4 on the application form and that the researchers had also answered there are no conflicts of interest despite this. The Committee asked Dr Dummer to explain how he would manage this relationship so no that there is not perception of coercion. Dr Dummer explained that participants would not be under his care for health concerns at the time of the study. He noted the broader issue of resourcing, that there are three positions in the region, two of which are filled by his co-investigator and himself. To exclude their clinical input they would have to co-opt the third and remaining clinician for clinical decision making.
* Dr Dummer confirmed that most of the participants receive care from their GP and are not currently seeing a specialist. If they are seeing a specialist on a regular basis then they would not be included in this study. The Committee was satisfied that this conflict of interest could be managed as long as potential participants are under care of their GP and the investigators do not have anything to do with day to day pharmaceutical maintenance of participants.
* The Committee requested the following changes to the participant information sheet:
  + Page 3, last sentence. Please state that the sputum samples will be destroyed if consent is not given for their future use in research.
  + Page 3 under ‘What if something goes wrong? Please replace ‘you would be eligible for compensation […]’ with ‘you may be eligible for compensation […]’.

Decision

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

* Please amend the information sheet, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please submit a separate consent form for the optional future unspecified research on the tissue samples.

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

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| **4** | **Ethics ref:** | **13/CEN/209** |
|  | Title: | IMPACT study. |
|  | Principal Investigator: | Dr Gerard Devlin |
|  | Sponsor: | Waikato District Health Board |
|  | Clock Start Date: | 16 January 2014 |

Dr Devlin 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.

The Chair declared a potential conflict of interest, but the Committee did not require her to leave the room during the discussion of this application.

Summary of ethical issues

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

* The study protocol was reviewed by the study sponsor Astra Zeneca. Dr Devlin advised that consultants who work for the sponsor would have done the peer review. The Committee noted that the review was robust and discussed whether it could be considered independent. The Committee was satisfied that the sponsor review could be considered similar to a Health Research Council review whereby the researchers are applying for their funding. The Committee also noted that the sponsor wouldn’t want research to go ahead if the protocol was not sound as this would fall back on their product and was satisfied that the review was robust.
* The Committee noted that some questions in the application form were not adequately answered. The Committee asked for clarification on the answer given at question b.2.7 about how the researchers will ensure that participants receive information that becomes available during the study and is relevant to their continued participation. Dr Devlin advised that the CI will write to participants and inform them of any results with the offer to contact the CI to discuss if they wish.
* The Committee sought clarification on how much time participants would be given to make an informed decision about joining the study (p.3.1, page 21). Dr Devlin advised that participants who are admitted to hospital and scheduled for surgery would have 5-7 days. The Committee was satisfied that is sufficient time for participants to consider the information and decide whether to consent.
* The Committee advised that question p.4.2 could have been better answered to reflect the cultural issues for Maori who will participate in this study and reminded the researchers that the taking of blood is a cultural issue.
* Dr Devlin confirmed for the Committee that the research team have consulted with a Maori research body at Waikato Hospital.
* The Committee asked the researchers to note for future reference that the intent of question f.1.2 on page 23 of the application form is to address health outcomes for Pacific Island peoples and other cultural groups as well as Maori.
* The Committee requested the following changes to the participant information sheet:
  + Please include the inclusion and exclusion criteria listed at f.2.1 on page 23 of the application form in layperson’s terms.

Decision

This application was *approved* by consensus.

Non-Standard approval conditions

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

This information will be reviewed, and a final decision made on the application, by the secretariat.

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| **5** | **Ethics ref:** | **13/CEN/215** |
|  | Title: | ARIEL 3: Rucaparib or Placebo as Maintenance Therapy in Platinum-Sensitive Ovarian, Peritoneal or Fallopian Tube Cancer. |
|  | Principal Investigator: | Dr Peter C. C. Fong |
|  | Sponsor: | Clovis Oncology, Inc. |
|  | Clock Start Date: | 16 January 2014 |

Ms Beth Caudwell and Mr Stephen Duffey 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.

* Ms Caudwell gave apologies on behalf of Dr Fong, the study CI, and advised that she and Mr Duffey could address any questions from a study co-ordinator perspective.
* The Committee complimented the researchers on a well-put together application and noted this is a worthwhile study for the study population who may have no further treatment options. The Committee noted that standard treatment is not being withheld.
* The Committee asked the researchers to quantify how much time patients will be given to consent to the study. The researchers confirmed that participants will be treated within 8 weeks of completing previous chemotherapy if they are identified as being eligible to join the study during that time. The Committee was satisfied that that was enough time for participants to consider the information before consenting.
* The Committee noted that the wording in the last paragraph on page 2 of the participant information sheet is ambiguous as it states collection of tumour and blood tissue for further genetic testing is required for participation when the consent form states that this is ‘optional’. Ms Caudwell confirmed that consent to collection is required for randomisation into the study and that the consent form is for consent to future research. The Committee asked that the researchers reword the information so that it is clear in order to avoid any confusion for participants.
* The Committee requested the following changes to the participant information sheet:
  + Please include in layperson’s terms, the key inclusion and exclusion criteria listed at question f.2.1 on page 29 of the application form.
  + Page 4, last paragraph: the Committee was concerned that the words “and may recommend further treatment if your cancer comes back or spreads” might be seen to be intimidating for participants. The Committee would be happier if these words were removed.
* The Committee is cognisant of the median survival rate for this population but was concerned that the words may seem coercive. Ms Caudwell advised that no standard treatment would be withheld should there be signs that the disease has progressed and will ask Dr Fong if there is any significant impact if these words are removed.
  + Page 14, item 7 ‘Compensation for injury’ Please update the New Zealand Injury Prevention, Rehabilitation, and Compensation Act 2001 to read Accident Compensation Act 2001.
  + Page 15, item 8 ‘Confidentiality’ please removed the word vendor and change the wording to reflect that some of the data collected will be sent to a third party radiology review with a similar function to a laboratory.
* The Committee advised for future reference that it would like to see statistics that may relate to the Maori population in question p.4.1 on the application form and asked whether the researchers had given any consideration or investigation to statistical information. Ms Caudwell did not have any at hand but advised that the researchers had submitted the application to a Maori research review body and had received a favourable response.

Decision

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

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

This information will be reviewed, and a final decision made on the application, by the Chair, Mrs Donoghue and Mr Barnett.

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| **6** | **Ethics ref:** | **13/CEN/216** |
|  | Title: | The Dynamic Patterns of Thinking in AttentionDeficit/Hyperactive Disorder (ADHD) |
|  | Principal Investigator: | Dr Fabian Labra-Sprohnle |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 January 2014 |

Dr Fabian Labra-Sprohnle was present in person and Dr Garth Smith 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 Labra-Sprohnle confirmed that this is a phase I study that will trial assessments of children with attention deficit hyperactive disorder to inform development of a diagnostic tool. If successful, the diagnostic tool would be the first of its kind.
* The Committee noted that this is the second application for this study after the first was declined. The Committee was satisfied that the researchers had sufficiently addressed many of the points highlighted in the previous decline letter but had a couple of concerns about the informed consent information for Dr Labra-Sprohnle to address before it will approve the study.
* The Committee requested the following changes to the participant information sheet for parents/guardians:
  + The Committee noted that there is no information for parents/guardians on how data from the game will be assessed. The Committee acknowledged that while the child participant information sheet set out the objective of the game well, that from a parent or caregiver perspective, it would be important to know how their child would be assessed. The Committee requested that this ‘how’ be included in the information sheet.
  + Please replace the word kid with child and please used child or children consistently throughout the document.
  + In item number 8 on page 3, please replace Northern B with Central.
  + Please briefly add the inclusion and exclusion criteria listed at question f.2.1 in the application form in layperson’s terms in the interest of fully informed consent for those considering participation.
* The Committee requested the following changes to the parent/guardian consent form:
  + Please replace the word ‘and’ with ‘an’ in the third bullet point
* The Committee noted that the child information sheet is more effective and the parent/guardian will be with the child and see this sheet. The Committee complimented Dr Labra-Sprohnle on information that was well tailored for the age group in this study.
* The Committee noted that the child assent form was not as young person friendly and will need to be reworded so that it is age appropriate. For example “I agree to take part” rather than “I am participating voluntarily”.
* The Committee requested the following changes to the parent/guardian information sheet for the control group:
  + Page 2, first sentence: please replace ‘normal’ with ‘other’ to avoid stigmatisation.
* The Committee noted that question p.4.1 on page 22 was taken literally and concentrated on the validity of the assessment being used. The Committee clarified the meaning of the question and advised that long-term rather than immediate benefits could be listed here including statistics on ADHD and Maori and how the intended diagnostic tool may be of benefit to Maori.
* The Committee also clarified the cultural issues that could be included at question p.4.2, including whakama or shame, embarrassment.
* Dr Smith further explained the recruitment process for the Committee. The process has been modified from the first application to avoid any element of coercion. A consultant paediatrician will receive and assess a referral from the paediatric department or child health service and will then post a set of questions to parents and the child’s school to ask for more information before the child is seen. The child will then attend an interview and this is where the recruitment process begins. The information sheet is given to the child and parent/giver at this point.
* Participation in this study will mean that there is a delay in treatment, but the researchers advised that the delay would be no more than one week. A paediatric consultant would decide and the Committee was happy with this.
* The full Committee would like to see the final report for this study as all members are interested in the outcome.

Decision

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

* Please provide an assent form that is age appropriate for participants (*Ethical Guidelines for Intervention Studies para 5.32*).
* Please amend the information sheet, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

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| **7** | **Ethics ref:** | **13/CEN/217** |
|  | Title: | An interventional study looking at caregiver education in managing BPSD |
|  | Principal Investigator: | Dr Bhamini Patel |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 January 2014 |

Dr Bhamini Patel 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 was satisfied that the researchers had addressed 85-90 percent of the points listed in the previous decision letter of 3 December 2013. The Committee noted however, that an assent form for participants with dementia who have the cross-over period was not provided. Dr Patel advised that there will be a universal consent information session where family and patients will consent and assent. The Committee would like to see an assent form.
* The main issue the Committee is concerned about is a lack of information about how the researchers intend to train staff and exactly what training staff will receive. The Committee noted that the researchers intend to run sessions for staff to show them how they are expected to act towards clients and how to interpret the data but there is no evidence submitted that outlines and shows the method. Dr Patel advised that this information is included in the study protocol. The Committee noted that the protocol mentions the fact that staff will be provided with training so that they can learn to use the BMI process and report back but no information was provided about the specifics of the training, what it would cover, how it would be done and what specific instructions would be given to the staff.
* The Committee noted that while the researchers might know what Dementia Care Mapping is and how it is done, they have not provided the Committee with any information about this area. If these questions cannot be answered, then the researchers have not covered everything needed to ensure the safety of their participants, and the staff who will be using BMI in their care of patients.
* The Committee noted that this is a worthwhile study but advised that before it can make a decision on the application that it needs an understanding of what the researchers are trying to achieve and how they intend to achieve it.
* The Committee requested the following inclusion in the participant information sheet
  + Please include contact details for the Health and Disability Commissioner.

Decision

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

* Please provide an outline of the planned staff training and what it will cover. (*Ethical Guidelines for Intervention Studies para 5.2*).
* Please provide an assent form that is appropriate for participants (*Ethical Guidelines for Intervention Studies paras 5.30 and 5.33*).
* Please amend the information sheet, taking into account the suggestion made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This information will be reviewed, and a final decision made on the application, by the Chair, Mrs Gill and Mrs Donoghue.

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| **8** | **Ethics ref:** | **13/CEN/218** |
|  | Title: | The PLUS 1 Trial |
|  | Principal Investigator: | Mr Stephen Mark |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 January 2014 |

Mr Mark 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 complimented the researchers on a well put together application and asked Mr Mark to congratulate the person who completed it.
* The Committee noted that compared to the study’s Patient Diary Card, the Restricted Medication Dosing Diary used language more relevant for an American population than a New Zealand population. The researchers stated that the medication listed in the Restricted Medication Dosing Diary is not available in NZ with the exception of one. The Committee asked the researchers to double check whether all medications listed in the Restricted Dosing Diary are available in New Zealand and Mr Mark agreed to double check this as the New Zealand list is included in the diary and questionnaires.
* The Committee queried whether participants could leave out any questions they felt uncomfortable answering on the EjD questionnaire. Mr Mark advised that the form is useful from a clinical perspective but that completing it is totally voluntary. The Committee noted that it would be helpful for participants to be advised on the participant information sheet and questionnaire that completing the questions is voluntary.
* The Committee requested the following changes to the participant information sheet
  + Please clearly state inclusion and exclusion criteria in layperson’s terms.
* Mr Mark noted that some of the exclusion criteria are listed in the participant information sheet and asked the Committee to clarify whether they were advocating for a more prescriptive approach. The Committee advised that it would normally expect to see an ‘exclusion criteria’ section and those criteria listed as a discrete matter rather than being scattered throughout the document. This approach allows participants to focus on and make a fully informed decision.
  + Page 2, 3rd parargraph, first sentence: please replace ‘The’ New Zealand Health and Disability Ethics Committee with ‘A’.
  + Page 2, 4th paragraph. Please complete the URL. The Committee noted that some careful checking of the document is required.
* The Committee reminded the researchers for future reference that question f.1.2 on the application form covers Maori, Pacific Island peoples and other non-European New Zealanders.

Decision

This application was *approved* by consensus.

Non-standard approval conditions

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

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

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| **9** | **Ethics ref:** | **13/CEN/220** |
|  | Title: | Evolut R Study |
|  | Principal Investigator: | Dr Sanjeevan Pasupati |
|  | Sponsor: | Medtronic, Inc. |
|  | Clock Start Date: | 16 January 2014 |

Dr Pasupati 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 acknowledged the worthwhile nature of this study for a population at risk of experiencing major complications during aortic stenosis.
* The Committee noted that Material being used in the Evolut R™ valve is a Nitinol alloy and asked whether there is any risk of rejection by the body. Dr Pasupati said no and advised that the Nitinol alloy had been used in thousands of procedures and no problems were reported.
* The Committee requested the following changes to the participant information sheet:
  + Page 11, please include the statement “I understand that my information will be kept confidential”.
  + Please include in layman’s terms the inclusion and exclusion criteria listed at question f.2.1 on page 24 of the application form.
  + Page 3, under the title ‘Patient Eligibility’. An electrocardiogram (ECG) has been repeated. Please remove the repeat.
* The Committee noted the answer given at question p.4.2 on page 23 of the application form that asks about the main cultural issues for Māori. The Committee advised that blood will be taken in this study and this may give rise to cultural sensitivities. For future reference, please acknowledge such issues in your application.
* The insurance certificate of currency submitted with the application refers to Australia only. Please provide evidence of insurance being extended to the New Zealand trial.
* Dr Pasupati clarified for the Committee that participants will come under his care when they join the study and that he may not be their usual cardiologist.

Decision

This application was *approved* by consensus.

Non Standard approval conditions

* Please submit a certificate of currency that shows insurance is extended to the New Zealand trial.
* Please amend the information sheet, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This information will be reviewed, and a final decision made on the application, by the secretariat.

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| **10** | **Ethics ref:** | **14/CEN/1** |
|  | Title: | Phase II PI3K inhibitor in relapsed, indolent or aggressive NHL”. |
|  | Principal Investigator: | Dr J.E. Edwards |
|  | Sponsor: | Bayer New Zealand |
|  | Clock Start Date: | 16 January 2014 |

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.

* The Committee requested the following changes to all participant information sheets:
  + Please include inclusion and exclusion criteria listed at f.2.2 on the application in lay language
  + Please include the study’s Maori contact person’s details
  + Please replace the word ‘subject’ with ‘participant’
  + The Committee noted that the researchers had answered question p.4.2 well but had not acknowledged the cultural issues and how they will be managed in the participant information sheets. Please ensure that the cultural issues stated at p.4.2, page 23 of the application form and how you intend to manage them with participants is stated on all participant information sheets.
* The Committee requested the following explanation for the informed consent form:
  + It is unclear what is meant by “Mandatory if applicable but if answer no can still participate” on page 15 of the informed consent form. Please provide an explanation of these consenting options for the Committee.
* The Committee requested the following change to the participant information sheet and consent form for the pharmacogenetic research study:
  + Please clearly state in the title that this is an OPTIONAL study
* The Committee requested the following change to the Part B participant information sheet :
  + Please replace reference to approval from The Ministry of Health and the Ethics Committee with the Central Health and Disability Ethics Committee.
* The Committee discussed the need for a second declaration of objection to collection of study data for participants who withdraw their consent and agreed that this it is an appropriate check to cover both participants’ and researchers’ rights.
* The Committee noted that the answer given at question r.5.1 on the application form contradicts that given at question p.3.3 page on page 22. Please clarify for the Committee whether or not participants will receive reimbursements
* The Committee noted that the answer given at question f.1.2 on page 23 of the application form does not adequately answer the question. Please clarify for the Committee and provide further information.
* Please confirm for the Committee that biomarkers will be for known tests performed within the duration of this study and not for further unspecified research.

Decision

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

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

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

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| **11** | **Ethics ref:** | **14/CEN/8** |
|  | Title: | Carrageenan Cold Prevention Spray Study |
|  | Principal Investigator: | Professor Julian Crane |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 January 2014 |

Prof Julian Crane was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee complemented Prof Crane for what it views as a worthwhile and beneficial study. The Committee noted that the safety of participants in this study appear to be well addressed.
* The Committee was satisfied that the peer review submitted has covered the necessary aspects of scientific review sufficiently.
* The Committee suggested advising hypertensive participants and those with an allergy to iodine of the need to discuss with their doctor, any risks of taking the nasal spray. Prof Crane advised that the product is not absorbed across mucus membrane. In previous trials no serious adverse events were reported and the product has been shown as safe to use including during pregnancy.
* Prof Crane advised the Committee that the product would be classed as a medicine if it was sold and SCOTT approval is being sought. The study would begin after both SCOTT and Ethics Committee approval is given.
* The Committee acknowledged that while sputum is a tissue, it would seek advice on whether the use of sputum in particular would raise cultural issues for Māori.
* For future reference, please include Pacific Island and other cultures in answers to question f.1.2 on the application form.
* The Committee noted that 75 percent cold symptoms must be dependent on time of the year and suggested that the researchers may wish to check their power calculations bearing in mind they plan to start in the summer. Prof Crane advised that the researchers are in touch with all of families already as they are enrolled in a larger study and participants would be excluded if they hadn’t had at least one cold over past 12 months. Prof Crane said that rhinovirus infections are not a winter phenomenon alone but noted that they may not have adequate power if they don’t see enough colds. This is a pilot study only and data will be used to develop a larger study.
* The Committee noted that there is no information about intended home visits in the information sheet and asked that information about the number of visits, duration, and remuneration costs be included. Prof Crane advised that the visits will be done in conjunction with other visits that are part of the larger study and that this information can be added to the participant information sheet.
* Please include footer and version numbers on the nasal spray instructions and nose swab instructions.
* The Committee requested the following changes to the participant information sheet:
  + Please include the inclusion and exclusion criteria listed at question f.2.1, page 22 of the application form.
  + Please include the study’s Māori contact person’s details.

Decision

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

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

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

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| **12** | **Ethics ref:** | **14/CEN/10** |
|  | Title: | Probiotic intervention to reduce streptococcal disease burden in NZ children |
|  | Principal Investigator: | Professor Julian Crane |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 January 2014 |

Prof Julian Crane was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee noted that a key issue is that the researchers intend to gain verbal consent from parents or caregivers of children who will participate in this study. Prof Crane explained that written consent may not be available because of the nature of the population and geographical area. The protocol states that consent is preferred in writing but Prof Crane also noted that the researchers need to take cultural norms into account when seeking consent.
* The Committee asked whether Prof Crane had considered some form of independent evidence to show that consent has been given. Prof Crane said that the researchers would consider either recording the phone call, or having two people present for a conversation via speaker phone where one would act as a witness.
* The Committee agreed to approve the gaining of verbal consent where necessary with reliance on the National Advisory Ethics Committee guidelines for intervention studies (para 6.15) that state verbal consent can be gained when written consent is culturally unacceptable or good reasons exist for not recording consent in writing on the proviso that the researchers document the procedures by which informed consent is given.
* As children will participate in this study, the Committee asked whether Prof Crane had considered distilling the information in the parent/caregiver information sheet into more age appropriate language for participants who are 7-12 years of age. Prof Crane noted that he was cognisant of not wanting to add more complexity in the process as the children who will participate in this study are already participating in the Ministry of Health’s Rheumatic Fever Prevention Programme and the only difference in this study is that they will be asked to take a lozenge daily.
* Prof Crane acknowledged that in the sub-study where researchers intend to take two blood samples and a saliva sample that an additional age appropriate information sheet and assent form could be provided.
* The Committee explained that they must ensure that the principle of participants having full information before consent is given, and that such fully informed consent also provides protection for clinicians is met. The blood tests are a separate part of the study and the Committee would like to see information and assent forms in a child-friendly format.
* Prof Crane explained that the sub-study may not go ahead as they are awaiting confirmation for funding. The Committee asked how the researchers intended to recruit the 200 participants for this study. Prof Crane explained that there is no detailed selection process yet but that they would need to develop a system for randomly assigning only those who have a sore throat and have given consent.
* The sub-study will not be given approval with this application and the Committee asked that Prof Crane submit the sub-study for approval once details are finalised.
* The consultation with Ngai Tahu is outdated and the Committee queried whether Prof Crane intended to look to consult with the local community. Prof Crane acknowledged the importance of consulting with the community and explained how the researchers intended to do this. The Committee suggested further consultation with Ngai Tahu who could advice of standard practice in a university context, which is what the researchers are bound by.
* Prof Crane acknowledged that the answer at question r.1.7 on the application form should have been ‘yes’. The Committee requested that Prof Crane submit evidence that indemnity cover is in place. He noted for the Committee that he assumed the question r.1.7 on the application form meant that health professionals involved in the study are not involved in giving other therapy treatments to participants.
* The Committee noted the HRC peer report general comments that it was not clear about what the probiotic company’s contribution to funding was. Prof Crane confirmed that the sponsor has no commercial interest other than providing the probiotic gratis. There will be no input into the study other than this and the company will have no ownership of the data.
* Prof Crane advised the Committee he has had discussions with Medsafe and that SCOTT approval is not needed.
* The Committee Requested the following changes to the participant information sheet. Please:
  + clearly state the inclusion and exclusion criteria listed on page
  + remove reference to the taste of the lozenge on page 2 of 6 as this may be seen as coercive.
  + include contact researcher contact details.

Decision

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

* Please submit evidence that the CI is professionally indemnified, for example through membership of the Medical Protection Society (MPS).
* Please provide a participant information sheet and consent form that is age appropriate for participants who are 7-12 years old (*Ethical Guidelines for Intervention Studies para 5.32*).
* Please amend the information sheet, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This information will be reviewed, and a final decision made on the application, by the Chair, Dr Quinn and Mr Barnett.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee may receive increased notification of renal denervation results following the results of a recent US study that shows efficacy is not demonstrated.
3. The Committee noted a newspaper article provided by Mrs Donoghue that reported on the release of new medicines as treatments for cancer that harness the body’s immune system to fight the disease.
4. The Committee discussed the issue of whether standardised assessment tools/questionnaires come under the heading of surveys or questionnaires in r.2.3.1 of the application form with reference to a particular study where the researchers do not want to disclose their questionnaires on the basis that doing so would jeopardise intellectual property rights. The Committee agreed by consensus that they do come under that heading and then discussed the issue of non-disclosure to the committee of the questionnaires. The Committee acknowledged that it would not be able to change the content of standardised questionnaires but it should sight the documents in order to decide whether or not they are relevant to and safe for use in the study population and to recommend the researchers make any necessary changes to participant information if needed.

Prior to meeting the Committee had consulted with an independent psychologist and psychiatrist and other Committee chairs and members who had advised that the Committee should be able to sight such documents in order to carry out their statutory obligations.

The Committee agreed by consensus that they still want to see the questionnaires and that they are prepared to do this in a closed meeting environment where the researcher/s attend so that the Committee can sight and return the documents to the researcher in person. The Committee would also like to see a more detailed response from the researcher about what the standardised questionnaires are appropriate and ethical.

1. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 25 February 2014 |
| **Meeting venue:** | Terrace Conference Centre, 114 The Terrace, Wellington |

No members tendered apologies for this meeting.

The meeting closed at 5.00pm.