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| **Time** | **Item of business** |
| 1230 | Welcome |
| 1235 | Confirmation of minutes of meeting of 24 June 2014 |
| 1300 | New applications (see over for details) |
|  | i 14/CEN/107  ii 14/CEN/108  iii 14/CEN/109  iv 14/CEN/110  v 14/CEN/111  vi 14/CEN/112  vii 14/CEN/113 CLOSED ITEM  viii 14/CEN/114 |
| 1630 | Substantial amendments (see over for details) |
|  | i WGT/04/06/040/AM01 |
| 1730 | General business:   * Noting section of agenda |
| 1745 | 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 | Absent |
| Dr Kay de Vries | Non-lay (observational studies) | 19/05/2014 | 19/05/2017 | Present |

## Welcome

The Chair opened the meeting at 1230 and welcomed Committee members, noting that apologies had been received from 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 24 June 2014 were confirmed subject to the following amendments to the minutes for 14/CEN/90 and 14/CEN/91:

Potential Conflicts of Interest: Dean Quinn declared a conflict of interest as he is a Committee member and Principal Investigator for the study. Dean Quinn was present in his capacity as a researcher to answer the Committee’s questions, but did not participate in the Committee’s decision making in relation to this application.

Helen Walker gave her apologies for Helen for August and September meetings. Raewyn Idoine will Chair the August meeting, Dean Quinn will Chair the September meeting.

## New applications

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| **1** | **Ethics ref:** | **14/CEN/107** |
|  | Title: | FiCare |
|  | Principal Investigator: | Assoc Prof Roland Broadbent |
|  | Sponsor: | Miracle Baby Foundation |
|  | Clock Start Date: | 10 July 2014 |

Dr Broadbent 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.

Decision

This application was *approved* by consensus. The following non standard conditions were requested by the Committee, but these changes do not need to be re-submitted to the ethics committee for further review.

Please add Central ethics committee details to PIS/ CF. Please add the first two inclusion criteria from f.2.1 to the PIS.

Please state that you *may* be covered by ACC.

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| **2** | **Ethics ref:** | **14/CEN/108** |
|  | Title: | Pacific Islands Families: Understanding growth |
|  | Principal Investigator: | Professor Elaine Rush |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 10 July 2014 |

Professor Rush 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 researcher clarified that the tissue will be stored to enable further analysis using new panel assays. These samples will be retained for 2-3 years and will only be used in relation to the current research project on these children.
* The Committee commended the researchers for specifically recognising that some children will have mixed Maori/ PI parentage.

Decision

This application was *approved* by consensus. The following non-standard conditions were requested by the Committee:

* + Please clearly label the PIS/Assent form for children and PIS/CF for caregivers.
  + Please remove reference on page 1 of the PIS to being “specially chosen”.
  + Please add the heder “Optional” to the PIS for the substudy.
  + Please include a confidentiality statement in the child assent form.
  + Please include reference to the Central HDEC in approval statement.

These non standard conditions do *not* need to be submitted to the HDEC for further review.

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| **3** | **Ethics ref:** | **14/CEN/109** |
|  | Title: | A study to evaluate if the study drug refametinib in combination with sorafenib is safe and effective in patients with liver cancer carrying a specific gene mutation (RAS mutation). |
|  | Principal Investigator: | Prof Ed Gane |
|  | Sponsor: | Bayer New Zealand Limited |
|  | Clock Start Date: | 10 July 2014 |

Professor 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 that this study is in two stages: Stage 1 is essentially a pilot study that precedes stage 2. The PIS refers to stage 1 in terms of numbers for screening and enrolment. The researcher clarified that stage 2 may not proceed as it depends on how many patients are identified as having the RAS mutation in Stage 1.
* The Committee commented on the fact that the study has 6 information sheets and 7 consent forms and noted that this is complex.
* The Committee noted that questions P4.1 and 4.2 were not answered well.
* Page 21 says identifiable data will be transferred prior to de-identification. The Committee sought clarification that encoding would occur onsite not overseas. Radiology data will be de-identified at ADHB prior to being sent offsite.
* P 5 of the main PIS refers to 2012 safety data for Refamenitib. The Committee queried whether more recent safety data was available. Professor Gane has agreed to update the safety data statement in the PIS.
* P4.1 doesn’t address the relevance of the research to Maori or cultural issues that may arise for Maori participants (eg future use of human tissue, images, transfer of data overseas). This needs to be addressed in future applications.
* In future please also explain how research might benefit Pacific peoples. Maori and PI are over-represented in Hep C carriers.

Decision

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

* Please state clearly in the PIS how long it might be between RAS mutation testing and enrolment in the study.
* The application suggests that participants need to sign a form to object to further data collection. This should not be a requirement. Participants should be able to do this orally and the researcher can document the request in writing.
* Please include in the main PIS a statement indicating the current study is stage one of the study, effectively a pilot study that may lead on the a larger study(stage 2). Note : if stage 2 goes ahead a revised main PIS/CF would need to be submitted to ethics.
* Page 5 PIS (main) – The safety data for refametinib relates to 2012. The Committee would like reference to more up to date data
* The contraception information is unclear on page 9 of the main PIS. Please clarify contraception requirements during and post treatment.
* Please state in the PIS and CF that the GP will be contacted.
* P 12, 16, 17 of main PIS give measurements referred to in both mls and with reference to teaspoons and tablespoons. The blood sample quantities are equated to variable measures, eg 5 mls is a teaspoon, not half a teaspoon as stated in the PIS. Please review and correct to ensure an accurate reflection of the volumes involved.
* F2.1 Please review the exclusion crtieria and include in the PIS any that would not be obvious from a participant’s medical record.
* Please refer to Central HDEC as the approving committee.

*Pharmacogenetic PIS/CF*

* Please include the heading *optional* in title of the pharmacogenetic PIS/CF.
* Pharmacogenetics – please discuss potential cultural issues relating to sending tissue overseas,
* The pharmacogenetic consent form says that the study doctor has “*apprehensively*” explained study, please delete this word.

*PIS/CF non study related data*

* In the PIS/CF for non study related use of data, please include *optional* in title and amend the title to: .”non study related date and tissue”
* The PIS on non study related use of data refers to future use of tissue samples, but this is part of an optional sub study which participants may or may not consent to
* Please clarify how participants can withdraw from this optional sub study.

*PIS/CF pregnancy and birth*

* In the PIS for pregnancy and birth “expecting fathers” – please change word “subject” to “participant” on page 6 and 7.

This information will be reviewed, and a final decision made on the application, by Dean Quinn and Helen Walker.

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| **4** | **Ethics ref:** | **14/CEN/110** |
|  | Title: | Phase 3 Study of Sofosbuvir + GS-5816 Or Ribavirin in Subjects with Chronic HCV Infection |
|  | Principal Investigator: | Prof Ed Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 10 July 2014 |

Professor 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 commended the application which was well prepared

Decision

This application was *approved* by consensus, but the Committee requested the following non standard condition be addressed before commencing the study. This change will not require further ethical review, but please provide the trial registration number to the HDEC secretariat for noting on the application file.

* Please clarify contraception requirements. The application is currently contradictory as it says hormonal contraception is unreliable and yet also suggests that this is an approved form of contraception. The Researcher will clarify requirements, but believes that OC alone is insufficient.
* Please state clearly on page 5 of 7 of the PIS the extent to which confidentiality can be guaranteed.
* Please review the exclusion/inclusion criterial to see if any further conditions need to be added to the PIS/CF.
* Please provide details of clinical trial registration number
* Please refer to the Central Health and Disability Ethics Committee as the approving committee.
* f.1.2 Please note for the future that the form asks for information about the impact/relevance of the study to Asian/Pasifika people.

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| **5** | **Ethics ref:** | **14/CEN/111** |
|  | Title: | Hydros and Hydros-TA Joint Therapy for Pain associated with knee OAAssociated with Knee OA |
|  | Principal Investigator: | Dr Alan Doube |
|  | Sponsor: | Carbylan Therapeutics |
|  | Clock Start Date: | 10 July 2014 |

Dr White 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 commended the researchers for presenting a well put together study.
* The Committee commented that weight can exacerbate knee pain and queried whether BMI would be measured and taken into account in considering pain relief. Patients with a BMI more than 40 will be excluded so BMI will be measured.
* For future reference, in the application form (p 24, f.1.2) – the question f.1.1 and f1.2 asks about how the study will contribute to reducing inequalities between Maori/Pacific . If you have statistics about disease burden within these populations it is very useful to set that out in the application and explain how the study will contribute to addressing this.
* p.4.1 was answered well.

Decision

This application was *approved* by consensus subject to non standard conditions to be submitted to and reviewed by the HDEC Secretariat.

* Please provide a table in the PIS to explain the events that will occur during the study (study visit activities).
* Please clarify in the separate consent form for the Exco device how people can withdraw their consent.
* The researcher agreed to review the exclusion/inclusion criterial to see if any further conditions need to be added to the PIS/CF.
* Please include a confidentiality clause in the PIS/CF.
* Please refer to Central HDEC as the approving committee.

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| **6** | **Ethics ref:** | **14/CEN/112** |
|  | Title: | A Study assessing the efficacy and safety of PF-06410293 in patients with Rheumatoid Arthritis. |
|  | Principal Investigator: | Dr Alan Doube |
|  | Sponsor: | Pfizer Australia and New Zealand |
|  | Clock Start Date: | 10 July 2014 |

Dr White 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.

* p.4.1 – For future reference, please provide information about prevalance of the condition in Maori and how the research may contribute to improved health outcomes. The researcher explained that there is limited information about prevalence of RA in Maori.
* Questions f.1.2 – In future please look at what the question is asking.
* Inclusion/exclusion criteria is mentioned in the protocol. The researchers clarified that participants will be screened for these criteria and offered alternative treatment options rather than participation in a TNF trial. The patient group is well known to the research team who will have access to all laboratory results and clinical records.

Decision

This application was *approved* by consensus with the following non standard condition.

* Please provide Maori support contact details provided for each site.
* This information does *not* need to be submitted to the HDEC for further review.

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| **7** | **Ethics ref:** | **14/CEN/113** CLOSED MEETING |

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| **8** | **Ethics ref:** | **14/CEN/114** |
|  | Title: | Legionnaires' Disease in New Zealand - LegiNZ Study |
|  | Principal Investigator: | Prof David Murdoch |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 July 2014 |

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 noticed that this study forms part of routine public health surveillance of legionnella.

Decision

This application was *approved* by consensus.

## Substantial amendments

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| **1** | **Ethics ref:** | **WGT/04/06/040/AM01** |
|  | Title: | Genetics of Alcohol Metabolism |
|  | Principal Investigator: | Dr Geoff Chambers |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 July 2014 |

Geoff Chambers was present in person or discussion of this amendment.

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 Chambers outlined to the Committee the history of his research portfolio dating back to the late 1980s early 1990s. The original research project aims were to measure genetic variation in NZ to identify individuals at risk of developing alcohol abuse behaviour, or be useful in tissue typing or to generate a forensic database for NZ.
* The original study collected samples from the NZ Blood Service. The study expanded to include genes related to alcoholism in 1990. New samples were collected from patients with alcoholism.
* The tissue from these studies has been sent to Loughborough, Stanford and Utrecht (with ethical approval), primarily to access better testing facilities. The Loughborough samples were destroyed. The Utrecht samples were returned, but to Auckland where they were used in research by Dr Paul Dunn.
* In 2005/06 the Central Committee declined an application to send samples overseas for use in a Temple Hill university study looking at genetics and migration. The Committee recommended that the researcher engage in consultation with Maori and Pacific communities about the proposal but this was not done. Samples from the Rakaipaaka study (MEC/05/12/174) were sent to the US instead. There is no evidence in HDEC files of ethics approval being sought or obtained in relation to this.
* Dr Chambers advised that a student, Edinur Atan had been working on tissue samples since 2009. Edi Atan was using molecular methods to look at platelet antigens, immune system markers (KIRs) and blood groups under Dr Dunn’s supervision. Two years ago Edinur Atan took 200 aliquot samples to Peter Parham’s lab at Stanford. Dr Chambers said that he had written to Central Committee, but received no response, so sent the samples to Stanford. The HDEC files hold no correspondence from Dr Chamber, or ethics approval from the Committee in relation to this. Edinur Atan’s study is complete and has been submitted to a journal for publication. The samples are being held at Stanford in case they need to be reanalysed. There is no evidence of ethical approval for this.
* Dr Chambers stated that Andres Moreno at Stanford wishes to look at genetic variation in Pacific populations and to screen for anomalous DNA variation. Dr Moreno wants to collect samples of reference populations around the Pacific to research the genetics of Easter Islanders. The current amendment relates to this request, but little information was provided in the amendment application.
* The NZ samples currently at Stanford are solely from Maori and Pacific people. The Committee queried whether consultation has been done with Maori and Pacific communities? Dr Chambers advised that no consultation has been carried out regarding this project.
* The Committee discussed the parameters of informed consent. Dr Chambers advised that participants were not specifically told that there tissue could be used for other research in the future or that it might be sent overseas. For that reason he had approached the Committee for advice.
* Following discussion with Dr Chambers, it appears that what is sought might perhaps best be described as a new study seeking to use tissue collected from the 1990 tissue collection. Whilst some collateral benefit might be derived from the further analysis, it remains unclear how specifically this fits within the existing research programme.
* Committee declined the amendment as it provided insufficient information to enable them to make a decision. Given the length of time since the original approval in 1990 and the complexity of the history of the research the Committee invited Dr Chambers to submit a full application outlining what the Stanford project will involve and how and why this complies with the original terms of consent.
* The application should be returned to Central Committee for consideration.
* Maori consultation will be required.
* The Committee also asked Dr Chambers to provide a spreadsheet detailing the samples held, samples destroyed and samples transferred overseas, with information about who is currently holding the samples.
* The Committee would also like an explanation of current research activity by Dr Chambers relating to WGT/90/00/011 and CEN04/06/040.
* Until the Committee has reviewed and approved the full application, the samples are not to be used.

Decision

This amendment was *declined* by consensus as the Committee did not consider sufficient information was provided to enable the Committee to assess the merits of the amendment. The Committee notes that the proposal raises issues relating to the following ethical standards:

NEAC Ethical Guidelines for Observational Studies: paras 11.4: Use collection or storage of human tissue without informed consent and use of stored samples for study purposes other than those for which they were originally collected constitutes a more than minimal risk activity.

Right 7(10) HDC Code of Rights: No body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved, or used otherwise than

(a) with the informed consent of the consumer; or

(b) For the purposes of research that has received the approval of an ethics committee.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 26 August 2014 |
| **Meeting venue:** | Terrace Conference Centre |

The following members tendered apologies for this meeting.

Helen Walker gave her apologies for August and September meetings. Raewyn Idoine will Chair the August meeting, Dean Quinn will Chair the September meeting.

1. **Problem with Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 1745.