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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 26 August 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 22 July 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/CEN/122  ii 14/CEN/127  iii 14/CEN/128  iv 14/CEN/129  v 14/CEN/130  vi 14/CEN/125 |
| 3.00pm | General business:   * Noting section of agenda |
| 3.05pm | 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 | Apologies |  |
| 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 | Present |  |
| 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 | Apologies |  |
| Dr Kay de Vries | Non-lay (observational studies) | 19/05/2014 | 19/05/2017 | Apologies |  |
| Ms Raewyn Idoine (co-opted from Southern HDEC) | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 12.10pm and welcomed Committee members, noting that apologies had been received from Mrs Helen Walker, Dr Cordelia Thomas and Dr Kay de Vries.

The Chair noted that fewer than five appointed members of the Committee were present, and that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Ms Raewyn Idoine confirmed her eligibility, and was co-opted as Chair of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

The Committee acknowledged Dr Chambers letter of 29 July 2014 in relation to study WGT/04/046/040/AM01 and agreed that the Secretariat would send him a letter acknowledging his response and advising him to submit a full application

## Confirmation of previous minutes

The minutes of the meeting of 22 July 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/CEN/122** |
|  | Title: | The effect on Fampyra on visual function following optic neuritis. |
|  | Principal Investigator: | Dr Jennifer Taylor |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 August 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 is a study on the effect of the drug Fampyra on visual function following optic neuritis.
* The Committee noted that the study appears to present moderate risk for those participants who are fully informed.
* The Committee noted that this application did raise possible cultural issues for Māori, including treating the head and taking blood and tissue samples. These should be included in future applications (P.4.2).
* The Committee requested the following changes to the PIS and consent form:
  + Please amend “you would be eligible for ACC” to “you may be eligible for ACC”
  + Please list exclusion criteria more fully in the PIS.
  + Please include Māori cultural support contact details.
  + Please include if there is any remuneration for participants.
  + Please include that participants’ GPs will be informed of them taking part in the study.
  + Please amend “we are happy to ask any questions about the study” to “we are happy to answer any questions about the study” (para 1 of the PIS).

Decision

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

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

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| **2** | **Ethics ref:** | **14/CEN/125** |
|  | Title: | AVELINA |
|  | Principal Investigator: | Dr John Baker |
|  | Sponsor: | Boehringer Ingelheim Pty Limited |
|  | Clock Start Date: | 14 August 2014 |

Dr John Baker and Mrs Catherine Howie were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee noted that this is a study of linagliptin to be added to basal insulin in people over the age of 70 who have type 2 diabetes and insufficient glycaemic control.
* The Committee queried whether linagliptin is registered in New Zealand and noted that SCOTT approval will be required if it is not. Mrs Howie agreed to confirm this with SCOTT and let the HDEC Secretariat know.
* The Committee noted that study involves 800 participants from 18 countries, with 42 participants coming from New Zealand. They asked if New Zealand is the first country to seek ethics approval. Mrs Howie advised that Australia has also applied for ethics approval.
* The Committee noted that the PIS is very extensive but suggested that the researchers consider whether the language and amount of detail is appropriate given that it will be read by people over the age of 70.
* The Committee thanked the researchers for the paragraph acknowledging Māori cultural beliefs (para 2, page 11 of the PIS) which they felt was one of most respectful statements that they had seen. The researchers agreed that the Committee could use this as an example for the PIS template.
* The Committee requested the following changes to the PIS and consent form:
  + Please amend “approved by an independent Ethics Committee” to “approved by “Central Health and Disability Ethics Committee” (page 16 of the PIS).
  + Please amend reference from Q Tip to cotton bud in the PIS.
  + Please remove reference to “if you are unable to read, you will need a caregiver or relative who can read and write to attend all visits with you” on page 5 of the PIS as if participants are unable to read, they will not understand the previous four pages of the PIS.
  + Please remove the reference to the study drug being investigational (page 14 of the PIS) as if it is registered for use in New Zealand it is not investigational.
  + Please include essential exclusion criteria in the PIS.
* Following the meeting, Mrs Howie confirmed with Medsafe that SCOTT approval is not required. She also advised that the CMDHB Māori Research Committee had advised that it would not be appropriate at this time to use the cultural statement on tissue sampling for the PIS template.

Decision

This application was *approved* by consensus, subject to confirmation that SCOTT approval is not required and the following non-standard condition.

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

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| **3** | **Ethics ref:** | **14/CEN/127** |
|  | Title: | Social context and smoking by people experiencing mental illness |
|  | Principal Investigator: | Ms Stella McGough |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 14 August 2014 |

Ms Stella McGough 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 acknowledged the effort the researcher had made to prevent participants feeling coerced by their health provider to participate in the study.
* The Committee suggested putting up a study invitation poster at The Clubhouse in Newtown, to advise potential participants of the study.
* The Committee recommended providing a Māori cultural support contacts, for example the Māori mental health officers at CCDHB, as people may not call the university contact due to whakama.
* The Committee noted that the interviews would be 45 minutes and asked what strategies would be in place for dealing with stressed patients. Ms McGough explained that she would give people breaks and offer them a cold drink and fresh air. She assumed that people will want to take a smoking break and will ask at the beginning of each interview how often people smoke so these breaks can be factored into the interview.
* The Committee noted for future applications that question F.1.2 is looking for information on Pacific people and other groups and not just Māori.
* The Committee noted that other funds may be sought for the study and queried whether these had been obtained (R.5.1). Ms McGough explained that the University of Otago will fund the basic study but she is likely to look for back up funding. These would be applied for in October/November and she will inform the Committee if the applications are successful.
* The Committee requested the following changes to the PIS and consent form:
  + Please amend any references in the PIS from “mental illness” to “mental health issues” as this is potentially stigmatising.
  + Please include contact details for Māori cultural support.
  + Please spread out PIS as it is currently quite cluttered.
  + Please amend “one thirty dollar supermarket or department store voucher to “a $30 supermarket or department store voucher” as people may think it means $130.
  + Please include a footer and page numbers on the PIS.
  + Please include in the PIS that participants can bring a support person if they wish to.
  + Please include this study has received ethical approval from the Central Health and Disability Ethics Committee.
  + Please include the key exclusion and inclusion criteria in lay language.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Observational Studies, para 6.10).*

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| **4** | **Ethics ref:** | **14/CEN/128** |
|  | Title: | A study assessing the similarity of Avastin and a new cancer drug, BS-503A (AVA-1) as compared to commercially available bevacizumab (Avastin®) from the US. |
|  | Principal Investigator: | Dr Rod Ellis-Pegler |
|  | Sponsor: | Daiichi Sankyo Pharma Development |
|  | Clock Start Date: | 14 August 2014 |

Dr Rod Ellis-Pegler and Dr Christian Schwabe were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee noted that this was a bioequivalence study of an anti-cancer drug Avastin vs a new study drug BS-503A.
* The Committee commended researchers on a clear and informative PIS
* The researchers confirmed that they do not want any participants who have just quit smoking to take part in the study.
* The Committee asked why the frequently asked questions were included as they appeared to be referring participants to other contacts rather than answering the questions. Dr Schwabe explained that these are a standard component of the PIS and they are often not required.
* The Committee asked how long potential participants would have to make a decision whether to take part in the study. Dr Schwabe explained that the standard process is for the study coordinator to send out the PIS to potential participants four or five days before they come in to consent, which gives them time to discuss the study with friends, family and whanau. The Committee were satisfied with this length of time.
* The Committee noted for future applications that questions P.4.1 and P.4.2 are not asking for information on the Treaty of Waitangi. The response to these questions needs to be quite specific in how it relates to this trial and the answer to F.1.2 would have been appropriate.
* The Committee noted for future applications that F.1.2 should include information not only on Māori but also Pacific people and other New Zealanders.
* The Committee asked whether the researchers were happy that ACC equivalent cover would be provided. Dr Schwabe confirmed that he will discuss with the sponsors and get it in writing that ACC equivalent cover will be provided.
* The Committee asked which independent Māori review organisation had been used (P.4.3.1). Dr Schwabe confirmed that this is Dr Helen Wihongi who does the reviews for Auckland and Waitemata DHB.
* The Committee thanked the researchers for the inclusion of cultural issues for Māori in the PIS.
* The Committee requested the following changes to the PIS and consent form:
  + Please remove the sentence “if you choose not to take part, it will not affect the quality of medical care you receive” (page 1 of the PIS) as these are healthy participants.
  + Please amend “if you do not understand any of the words or information” to “if some of the words or information are unclear” (page 1 of the PIS).
  + Please add the word whanau to “you may also want to discuss this study with your family, friends or doctor” (page 1 of the PIS).
  + Please amend “you will not be told which treatment you will be given” to “you and your doctor will not be told which treatment you will be given” (page 4 of the PIS).
  + Please amend “you must not abuse drugs” to “you must not abuse recreational drugs” (page 4 of the PIS).
  + Please add Māori contact details for each site.
  + Please move point 6 on page 5 of the PIS to after point 2 so participants are clear about the study procedures.
  + Please reformat the document so there is not the large white space on page 6 as it currently appears that this is the end of the PIS.
  + Please amend reference from “Central Regional Ethics Committee” to “Central Health and Disability Ethics Committee” (page 12 of the PIS)
  + Please remove reference to 19 tablespoons of blood (page 9 of the PIS).
  + Please include information on contraception (as listed in the protocol) in the inclusion criteria on the PIS.
  + Please include the statement “I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy” in the consent form.
  + Please include investigators’ contact details in the PIS.
  + Please include HDC contact details in the PIS.

Decision

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

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

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| **5** | **Ethics ref:** | **4/CEN/129** |
|  | Title: | HPV related Oropharyngeal Cancer Study |
|  | Principal Investigator: | Dr Swee T Tan |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 August 2014 |

Mr Hyok Jun Kwon 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.

Dr Dean Quinn declared a potential conflict of interest, and the Committee decided he would take part in the discussions but not voting.

Summary of ethical issues

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

* The Committee noted that this was a retrospective audit, taking oropharyngeal cancer tissue blocks to test for HPV.
* The Committee noted that informed consent was not being obtained as many of the patients may have passed away or moved.
* The Committee noted that the researchers would like to add the remaining tissue to the Gillies McIndoe Tissue Bank for future unspecified research.
* The Committee noted that the information obtained from this study would be useful but were concerned with the future unspecified research to which participants had not given consent.
* The Committee agreed that they were happy for the tissue blocks to be used in this study but declined the remaining tissue being stored in a private tissue bank for future unspecified research as consent had not been obtained. The Committee agreed that any unused blocks should be returned to the lab of origin.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **14/CEN/130** |
|  | Title: | Citizens' interactions with public services |
|  | Principal Investigator: | Ms Sarah Crichton |
|  | Sponsor: | Ministry of Health |
|  | Clock Start Date: | 14 August 2014 |

Ms Sarah Crichton, Mr Rob Templeton, Ms Andrea Blackburn and Ms Jackie Fawcett were 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 asked if this study would go through any other ethics committees. The researchers confirmed that it did not require ethical approval from any other agency but that the broader project had been discussed with the Office of the Privacy Commissioner.
* The Committee asked how much effort was made to inform people on what happened with the information being collected about them. The researchers explained that under some elements of the Privacy Act, Statistics New Zealand does not require informed consent and that a lot of information can be collected for wider statistical purpose. They advised that they were planning some focus groups to explain how the statistical information would be used.
* The Committee were concerned about the small possibility of data being produced where an individual could be identified. The researchers explained that there are a number of processes in place to minimise this, for example vetting researchers. Researchers also have to sign an undertaking after being vetted to say that they will not try to identify individuals and there are sanctions for breaching this.
* The Committee asked whether the researchers wanted approval for a particular project or for a number of projects. The researchers explained that there were a number of projects that could use the same dataset but for this application, they would be looking at updateable datasets rather than just one. The Committee advised that amendments would need to be submitted for any variations to the datasets.
* The Committee noted that progress reports should include interim results as it would be useful for the Committee to see how the data was being used.
* Ms Fawcett explained that the Ministry of Health are keen to use IDI as it offers a consistent process and protection for health information.
* The Committee asked if the project would primarily be looking at people on low incomes. The researchers advised that this would depend on what agencies data was included in the IDI.
* The Committee asked what approximate percentage of information would relate to Māori. The researchers advised that the health data would help provide this figure as they do not currently hold any ethnicity data.
* The Committee asked why the researchers did not feel it necessary to consult with Māori at the beginning the process. The researchers advised that they were planning to consult with the Māori research team at the Ministry of Health next week.
* In order to verify privacy and safety issues, the Committee asked to see a copy of the undertaking that researchers sign.
* The Committee agreed that it would beneficial for health data to be added to be added IDI project.
* The Committee noted that data needs to be retained for a minimum of 10 years.
* The Committee agreed to forward this application to the other HDECs for their information as the study covers the whole of New Zealand.

Decision

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

The information received by the researcher will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine, 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:

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| **Meeting date:** | 23 September 2014, 12:00 PM |
| **Meeting venue:** | Deloitte House, MEDSAFE, Level 6, 10 Brandon Street, Wellington, 6011 |

The following members tendered apologies for this meeting.

Mr Paul Barnett

Dr Patries Herst

The meeting closed at 3.05pm.