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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27 May 2014 |
| **Meeting venue:** | Deloitte House, MEDSAFE, Level 6, 10 Brandon Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
|  | Confirmation of minutes of meeting of 22 April 2014 |
|  | New applications (see over for details) |
|  | i 14/CEN/67  ii 14/CEN/72  iii 14/CEN/73  iv 14/CEN/74  v 14/CEN/76  vi 14/CEN/77  vii 14/CEN/81  viii 14/CEN/82  ix 14/CEN/83  x 14/CEN/84 |
| 4.10pm | General business:   * Noting section of agenda |
| 4.30pm | 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 |
| Dr Coredelia Thomas | Ethical and Moral Reasoning |  |  | Present |
| Dr Kay de Vries | Non-lay (observational studies) |  |  | Present |

## Welcome

The Chair opened the meeting at 12.18pm and welcomed Committee members.

The Chair welcomed two new members, Dr Cordelia Thomas and Dr Kay de Vries, to the Committee.

The members introduced themselves.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

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

## New applications

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| **1** | **Ethics ref:** | **14/CEN/67** |
|  | Title: | Fatigue in Inflammatory Bowel Disease |
|  | Principal Investigator: | Mr Rashid Almandhari |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 15 May 2014 |

Mr Rashid Almandhari (CI) and Dr Hamish Osborne (supervisor) 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 the application was well put together, particularly the protocol, as it discusses the reasons why this is a pilot study and explains the study design.
* (R.1.5) Please provide more information on the data safety monitoring committee in place. What happens if there is a serious adverse event (SAE)? The researchers explained if there are SAEs the existing public hospital processes would be implemented. The researchers explained they generally worked from private practice and were not familiar with public hospital procedures but were confident that there were adequate measures in place. The Committee requested some further information on the process in place for SAE at the localities that would conduct the study.
* (R.1.6) Are there any stopping criteria for the study? The researchers explained that if there were many instances of adverse events it would result in study termination – however the researchers do not expect this. The study drug has been shown to be safe in previous trials and general use to the extent that we do not anticipate this occurring. Many of the participants will have already had this study drug in prior treatment. The Committee appreciated the response but added most clinical trials have termination criteria.
* (R.4.1) There is a risk of unexpected results being identified because the participants will have blood tests. How are unexpected results dealt with? The researchers referred to current hospital processes in place. The Committee requested information about processes in place to refer and manage unexpected findings.
* (P.2.1) How are potential participants going to be approached with respect to privacy. The researchers confirmed the participants would be outpatients and would be approached in a consulting room with the consultant and the PHD student. The Committee was satisfied with the private consultation context of recruitment.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The Committee requests including the known risks associated with the injection treatment (Ferinject), even if it is very low.
* (F.2.1) Inclusion and exclusion criteria – please include this information in the PIS/CF. Make it clear to patients what would exclude them from participation.
* Please review for grammar. Some statements are not complete.
* Pg.3 – currently states you ‘would’ be eligible for ACC. Please amend to you ‘may’ as it is not a guarantee that ACC will pay.

Decision

This application was *approved* by consensus with non-standard amendments. Secretariat to confirm.

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| **2** | **Ethics ref:** | **14/CEN/72** |
|  | Title: | Lipoprotein biomarkers in Maori and Pacific communities |
|  | Principal Investigator: | Dr Allamanda Faatoese |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 May 2014 |

Allamanda Faatose was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee asked for more information on the tissue banking component of the study. Ms Faatose stated it was for storage of plasma and DNA samples taken from all participants in the study. The Committee explained that this constitutes bio-banking. Ms Faatose explained they would conduct future research but only in the context of pacific health research.
* The Committee requested a separate, optional, PIS and CF for storage beyond the study procedures being conducted.
* The Committee queried the statement about property rights on discoveries from the study (pg.2 PIS). Ms Faatose explained this relates to the discovery of new bio-markers. The Committee discussed the statement and whether it was necessary to keep the statement. The Committee requested that the sentence is reworded to explicitly explain that this statement means that any resulting discoveries are not able to be patented by the participants and that these discoveries are owned by the research team, and that this does not relate to owning human tissue. Please amend in PIS as it is currently has the potential to confuse participants.
* The Committee queried if there would be vulnerable people may be in this study. Ms Faatose explained there may be adult participants with learning difficulties. The Committee explained that adult participants are not able to participate unless they can give fully informed consent. Ms Faatose queried who determines the level of competence. The Committee advised that if there is doubt there should be an assessment and that the researcher is responsible for conducting the assessment or finding the appropriate person to do so. Ms Faatose confirmed she would not recruit anyone who is not able to provide informed consent.
* The Committee stated that an independent person should recruit, as there is a potential conflict of interest between participants and the recruiter if they are involved in the study. Ms Faatose explained that the pacific community is quite small – this may also raise a conflict of interest. Ms Faatose cannot guarantee that the participants will not know the person who will recruit participants. The Committee noted that the recruiting study staff will be trained, and urged Ms Faatose to ensure they understand how to mitigate conflicts of interests.
* The Committee asked for clarification of the statement ‘only Pacific participants being included’. How will you account for mixed marriage, or Samoan and Maori mixed participants? Ms Faatose explained that Pacific or Pacific mixed ethnicity, including Maori, will be included. Ms Faatose was understanding of the high chance of mixed ethnicity participants and explained that self-identification of Pacific ethnicity would be the main factor in eligibility. Ms Faatose added that identification as Pacifica would be very likely as her recruitment avenues are through strong pacific communities.
* The Committee commended the face to face consenting process, though added that the researchers need to be vigilant in letting participants say no if they want to. There can be a tendency to agree with researchers in clinical settings.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* (F.2.1) Inclusion and exclusion criteria – please include this information in the PIS/CF. Make it clear to patients what would exclude them from participation.
* The Committee requested a separate, optional, PIS and CF for storage beyond the study procedures being conducted.
* Please make it explicit that the tissue samples will be sent overseas. The Committee noted that this was specifically for the optional research – so please include this information, including where it is going to be stored.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*). <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>.

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

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| **3** | **Ethics ref:** | **14/CEN/73** |
|  | Title: | Abbvie Veliparib in NSCLC |
|  | Principal Investigator: | Dr David Gibbs |
|  | Sponsor: | abbVie |
|  | Clock Start Date: | 15 May 2014 |

Dr David Gibbs was not 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.

* (B.4.5) suggests that the researchers do not intend to store tissue however the PIS states the researchers are requesting permission to store tissue. Please explain.
* (P.4.1) the Committee noted that this response did not accurately answer the question. For future applications please include statistics and information about higher prevalence within Maori or Pacific populations and how this study would address inequalities.
* (P.3.3) please explain what ‘reasonable reimbursement’ is.
* Explain why the participants’ compensation policy in this study have a cap of NZ$1 million when two other studies are identified as having NZ$10 million per participant.
* How will you identify potentially vulnerable participants?
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* (F.2.1) Inclusion and exclusion criteria – please include this information in the PIS/CF. Make it clear to patients what would exclude them from participation.
* Refer to the Central Health and Disability Ethics Committee (for all PIS/CF).
* The Committee requested an optional participant information sheet and consent form for future unspecified research, as well as the optional participant information sheet and consent form for genetic research.
* Please clarify the various options to ‘what will happen to my samples’ in the main PIS and refer to the optional sub studies (pg.10 of main PIS).
* Pg.11 of 16 – states that after withdrawing from the study a participant’s health information will continue to be used. The Committee requests justification of why participants can’t remove their health information from the study, as the study is de-identified, which indicates that the data can be traced back to the individual. This is standard in clinical trials and is done to prevent bias from withdrawals i.e. intention to treat analysis
* The Committee suggests that the participants can withdraw from the study orally but acknowledges that having evidence in writing is useful.
* The sentence from the bottom of page 1 concerning inclusion of Maori and Pacifica is patronising and should be removed, or reword to ‘all ethnicities’.
* Include Maori contact for sub studies PIS/CF.

Decision

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

* Submit payment information. All payments, reimbursements and health services provided to study participants must be disclosed to an ethics committee (Ethical Guidelines for Intervention Studies para 6.36)
* Please provide a two separate Participant Information Sheets and Consent Forms for the use of tissue for future unspecified research AND for genetic testing (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*). <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>
* Please amend the information sheet and consent form, 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 Mr Paul Barnett and Dr Patries Herst.

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| **4** | **Ethics ref:** | **14/CEN/74** |
|  | Title: | The Cxbladder Repeatability Study |
|  | Principal Investigator: | Dr. James Johnston |
|  | Sponsor: | Pacific Edge Ltd |
|  | Clock Start Date: | 15 May 2014 |

Dr Paul O’Sullivan was present in person and Dr Manmeet Saluja was on 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 study.
* (P.4.3) ‘according to HRC guidelines this study does not require Maori consultation’. Please justify. The researchers explained that they were going off advice from the Health and Disability Commission from years ago, which stated that Maori consultation was not required for observational studies, and because the samples were urine. The Committee explained HRC guidelines noting they state “as a general rule, consultation should take place if Māori are to be involved as participants in a project or the project relates to a health issue of importance to Māori.” The Committee stated some form of Maori consultation would be appropriate for this study. The Committee does not need to see the consultation before approval but must be assured it will occur.
* (F.1.2) For future applications please include information on other NZ populations, as the question is not about Maori.
* The Committee queried the method involved to collect human tissue (urine). The researchers explained that the participants will be given a collection kit to take samples at home. The participants will then send them to the researchers.
* The Committee queried if the urine would be sent as a dangerous good. Researchers explained it is not required as the kit denatures the samples.
* Please change participant remuneration to pro-rata remuneration.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* (F.2.1) of the application – please include the core exclusion and inclusion criteria in the PIS in lay language.
* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*). <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>
* Amend to Central Health and Disability Ethics Committee.
* Please revise technical language and replace with lay language. e.g. Haematuria - use "blood in the urine" see Pg 1 of PIS.

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*). <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>
* Please amend the information sheet and consent form, 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 Mrs Gael Donoghue and Mrs Sandy Gill.

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| **5** | **Ethics ref:** | **14/CEN/76** |
|  | Title: | RSV in children hospitalised with lower respiratory tract infections |
|  | Principal Investigator: | Dr Tristram Ingham |
|  | Sponsor: | Janssen Research & Development |
|  | Clock Start Date: | 15 May 2014 |

Dr Tristram Ingham 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 study aims to enrol 200 children with Human respiratory syncytial virus.
* The purpose of the study is more about detecting the most appropriate window of opportunity for effective treatment.
* The Committee queried if the under 2’s would include new-borns. Dr Ingham confirmed it would, with the majority of participants being under 6 months of age.
* Dr Ingham explained that the blood test is optional.
* The Committee queried how long the participants have to consider participating. Dr Ingham explained it was usually on the same day. Dr Ingham explained that they gave the participants as much time as possible to consider by doing the rounds in the morning to let the family discuss the PIS.
* The Committee queried if one parent needed to consent or both. Dr Ingham explained that standard practice was just one consenting parent.
* The Committee queried if the parents disagreed would the child be excluded. Dr Ingham explained that if there was a disagreement between parents the research team would not pursue recruitment. Furthermore if a parent later decided that they did not want the child to participate they would withdraw the child.
* Dr Ingham stated that legal guardian was required – this means it is the parents or legal guardian.
* The Committee thanked the researcher with respect to the understanding of cultural issues and degree of Maori consultation.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please provide a separate PIS/CF that is headed as ‘optional’ for the future unspecified research.
* Please make it clear that participants have less than 24 hours to decide if they want to participate.
* Pg.5 – please include information on where the samples are going, particularly if overseas. Please distinguish between samples staying in-house and those that are sent overseas.
* Please include the diagram from page 15 of the protocol in the PIS.
* Ensure inclusion and exclusion criteria are in lay language.

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*). <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>
* Please amend the information sheet and consent form, 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 Dr Patries Herst and Mrs Helen Walker.

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| **6** | **Ethics ref:** | **14/CEN/77** |
|  | Title: | SAND |
|  | Principal Investigator: | Professor Bridget Robinson |
|  | Sponsor: | CDHB |
|  | Clock Start Date: | 15 May 2014 |

Anne 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.

* (B.4.5.1) Please clarify if consent for future unspecified research would be obtained separately. Ms Smith explained that it was. The Committee noted it was currently part of the main PIS and explained that tissue taken for future research requires a separate information sheet and consent form.
* The study will first consent participants to take extra core samples. The samples will be tested. If ER positive (and other inclusion criteria are met) the participants will asked if they would participate in the main study. If the participant is not ER positive the study team will seek consent for the additional samples be stored for future research.
* (R.1.13) – answered no to radiological exposure. Please confirm. Ms Smith stated this would be ultrasound – no radiation.
* (R.2.1) – answered no – how will you identify your participants without reviewing any health information. The Committee explained that the researchers are actually reviewing health information to identify potential participants. Ms Smith acknowledged this.
* The Committee queried the length of time participants had to decide to participate. Ms Smith explained that this was left up to the GP. The consent for the additional samples to be taken was at the same time as the standard practice biopsy. The Committee queried if this was enough time as currently participants would be approached right when they are having the biopsy. The current approach does not give the participant anytime time to decide or any opportunity to discuss participation with family or whanau. The Committee requested the researchers discuss if it is possible to get consent earlier, or further justify the consent process in place.
* Ms Smith suggested she could get in contact with Canterbury breast care to see if the potential participants could be approached before their biopsy.
* The Committee stated there will need to be three consent forms. One for the additional biopsies to be taken for diagnosis. A consent form for the main study. A third, separate and optional PIS/CF for the future research and bio banking. The Committee noted that if the storage for future research was for an existing tissue bank the samples may be stored by using their PIS/CF however this would need to be submitted to ethics.
* The Committee requested clarification on the aromatase inhibitor, as there are currently two listed (anastrozole and LetrozoL), though mainly talking about letrozol.
* The Committee queried if the samples taken for the study would be able to be used for diagnosis if the other samples were not sufficient for diagnosis. Ms Smith explained that they would not withhold any samples if they failed have a successful diagnosis from the standard practice samples.
* Are the two other biopsies (used for research) made available to the person who will be performing diagnostics? Ms Smith explained the pathologist would assess all of the core biopsies. The Committee noted this was unlikely if one of the research samples was to be snap frozen. Please confirm that this was the case.
* The Committee asked if there were any trial related follow up other than 10 days prior to biopsy and right after biopsy to see whether there were any SAE. Ms Smith explained that there would not be any trial related follow up. Committee asked for clarification, as the application currently indicates there will be 4 years of follow up.
* The Committee clarified that no participants would participate without informed consent, but if a participant was competent to give consent but had cerebral palsy or another difficulty in ‘signing’ the actual form another method of recording consent could be taken – but only if the participant was fully competent.
* (P.4.2) The Committee noted there are cultural issues related to human tissue that should have been covered in this question.
* The Committee stated the PIS should have some information about aspirin and its side effects.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please clarify if any of the research samples canl be used for diagnosis purposes
* Please provide a separate participant information sheet and consent form for future unspecified research.
* Please change storage of health information to at least 10 years (not 5 years).
* Please clarify the duration of follow up. States 4 years as well as indefinitely.
* Please include further information about the main study in the PIS for the extra core biopsy – for instance include exclusion criteria in lay language.
* Please include information on the chances of being eligible for the main study.
* The women to have the biopsy need to be made aware of the purpose of the request for an additional biopsy as it pertains to the main study. Please provide more information. Ms Smith suggested ‘if you are diagnosed with cancer / are ER positive’ and other eligibility criteria (explain the core ones such as post-menopausal).
* Include information on aspirin side effects in lay language.
* Change to central HDEC.

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*). <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Address questions raised by the Committee in a cover letter.

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

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| **7** | **Ethics ref:** | **14/CEN/81** |
|  | Title: | AMG 416 Open Label Extension Study - 20130213 |
|  | Principal Investigator: | Dr Chris Hood |
|  | Sponsor: | Amgen Australia Pty Ltd |
|  | Clock Start Date: | 15 May 2014 |

Dr Chris Hood 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 patients are currently on dialysis.
* Could the participants have been in a placebo arm in the prior studies? The researchers explained that the placebo arms would have been on a standard treatment – so yes but they were not ‘untreated’.
* (B.2.2.2) Committee confirmed SCOTT was pending.
* (B.4.3) Restrictions on dissemination. Please briefly state what these are in future rather than referring to the protocol.
* (F.1.2) The researcher confirmed this was an error and should be ticked yes.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The Committee noted there was a good cultural statement on pg.6 of main PIS – please include in the sub study PIS.
* Include ‘Optional’ on the sub-study PIS/CF.
* Please include Maori contact information on the sub-study PIS.
* Please make it clear how much time people have to consider study participation, rather than ‘as much time as you need’. The researchers explained this would potentially be several weeks. Please be explicit.
* Please add the main inclusion and exclusion criteria in lay language for participants.
* Please include as exclusion criteria that women participants must have gone through menopause.

Decision

This application was *approved* by consensus with non-standard conditions. To be checked by Secretariat.

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| **8** | **Ethics ref:** | **14/CEN/82** |
|  | Title: | The impacts of cancer, chronic disease and acute health events on future employment, earnings and benefit receipt |
|  | Principal Investigator: | Ms Sarah Crichton |
|  | Sponsor: | Ministry of Health |
|  | Clock Start Date: | 15 May 2014 |

Ms Sarah Crichton 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 discussed the Primary Health Organization process for explaining that patient data may be used for research. How aware are patients that their data will be used for research? The researchers explained that they were not sure. Their understanding was that each PHO developed their own form which had custom information on how the information will be used. There was an effort to make this information nationally consistent.
* The Committee queried how the pharmaceutical information was collected. The Ministry of Health has this data from claims from pharmaceutical information.
* The Committee queried if the pharmacists were aware of the information and use sent to the Ministry of Health. The researchers explained that they could not comment, but it was not likely that they would be aware of particular studies.
* The researchers explained that on-going research was publically available online, adding that the research is for the public good.
* There is a privacy pact being developed with this particular project.
* The Committee and researchers discussed the internal confidentiality procedures within Statistics New Zealand.
* The researchers explained the secure environment that data was accessed from.
* Any data leaving the secure environments had to be checked to make sure it was anonymous.
* Pg.15 of application – please explain what ‘other research purposes’ would be. The researchers stated that the data may be seen as valuable by other researchers. The Committee discussed the need to seek ethics approval for other researchers to access identifiable information. If the data is in aggregate or anonymous form the data can be used without ethical review.
* Pg.18 ‘no need for Maori consultation’. Committee requests whether there is any Maori consultation that has occurred so far. Researchers responded that there has not yet been any consultation. The researchers have access to the Maori business unit as a possible consultation group. The Committee explained that this research may impact Maori and should therefore have some degree of consultation. The researchers confirmed they would consult with Maori later this year, before the study starts. Please review the HRC guidelines for research involving Maori for guidance. <http://www.hrc.govt.nz/news-and-publications/publications/guidelines-researchers-health-research-involving-m%C4%81ori>

Decision

This application was *approved* by consensus.

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| **9** | **Ethics ref:** | **14/CEN/83** |
|  | Title: | The relationships between obesity, lifestyle behaviours, and cardiovascular health in children. |
|  | Principal Investigator: | Mr Nicholas Castro |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 15 May 2014 |

Dr Sally Lark and Mr Nicholas Castro 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.

* (B.2.2.2) Please explain the relationship between the peer reviewer and the student. The researchers explained that the person is another lecturer that is unrelated to the study team. The Committee was satisfied with the response.
* (R.2.3) please explain the term ‘pseudo-anonymous’ – please clarify how data will be handled. The researchers explained that no other participants will see any other data. The researchers explained that the data will be de-identified.
* (R.4.1) incidental findings. The Committee noted the study involves a variety of tests and measurements. This could identify abnormalities (diabetes etc.) What process is in place to follow up or refer to other healthcare providers? The researchers stated they would consult the family and then would see whether it was appropriate to contact the GP. Committee requested this information is included in the PIS so participants are aware of the referral processes in place.
* The Committee suggested being aware of pre-existing clinical conditions that may impact the reliability of the HbA1c test e.g. haemoglobinopathies e.g. thalasaemiatest.
* Does the study involve photographs or video? The researchers stated no. Please remove all mention of photographs and videos from the PIS/CF.
* Please explain how the risk of stigmatisation is managed, noting the words ‘fatness’ and ‘obesity’ may cause distress and stigmatisation, adding this will be given to children (8-10 year olds) and their parents in a school environment. Please remove fatness / obesity and use overweight or another more appropriate word that does not put a label on or risk stigmatising any child participating in the research.
* Furthermore, ‘unable to continue’ indicates that that the child can’t keep up. These are pejorative terms. Please amend.
* The Committee queried if the researchers give a presentation to the school. The researchers explained that the results would be fed back to the school – a broad summary.
* (P.4.2) please note a cultural issue is whakama (embarrassment / shame).
* (F.1.2) please consider other health groups other than Maori for this section.
* The Committee noted that the parents are also participants – all participants should consent and the forms should be tailored to what will be undertaken by the different groups (children and parents).
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please remove mention of photos or video as this is not involved.
* Include information on the referral places and explain the chase of incidental findings.
* Please remove from ‘potentially be chosen to participate in phase 2’ as this is randomised and not guaranteed.
* Please include a Maori support contact. Committee added Massy University has a support mechanism in place.
* Please submit a separate PIS/CF for the parents as they are participating as well. Reframe the PIS in the context of health and activity rather than obesity, as all children will be included.
* Remove obesity from the title.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please submit a PIS/CF for the parents of the children outlining what is involved for them if they were to participate in the study.

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

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| **10** | **Ethics ref:** | **14/CEN/84** |
|  | Title: | OVERFLOW MOVEMENTS IN PARKINSON'S DISEASE |
|  | Principal Investigator: | Dr Sepehr Sadeghi |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 May 2014 |

Dr Sepehr Sadeghi was not 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 notes the research project is commendable and advises the researcher takes the comments into consideration and resubmits.
* The Committee noted that the first part of the is purely observational: video recording of hand and jaw movements. The second part of the study is considered interventional as it requests patients stop taking their medication LDopa (standard treatment) for 12 hours before recording hand and jaw movements using video and sensors.
* There are 130 participants. 30 control, 15 untreated or early stage patients, 85 with Parkinson’s disease. The Committee noted there is no rationale given for numbers or the reason for controls.
* The protocol does not mention what happens with controls.
* The Committee noted that generally the application had lots of jargon, important information missing particularly in the PIS.
* (a.1.5) English summary: explain terminology, abbreviations in lay language.
* (a.1.6) Ethical issue is withholding medication for 12 hours before the recording in patients who show symptoms of hand-jaw movements. The Committee noted there is no rationale given for the length of time (12 hours).The Committee discussed that it takes several days for Dopa to deplete in body and they consider that unethical, so why 12 hours and not 6 or 18? Dosage of PD patients is complicated and leaving out a single dose can upset the chemical balance which could possibly take a long time ot regain.
* The Committee requested more information on ‘discomfort’ upon not taking medications; what does that mean? Need a description of what discomfort is expected and how easy this is alleviated by taking another dose.
* Lasting effects? Page 21 mentions excluding patients that will have side effects when medication is withheld> How do they know this in advance?
* (a.5.1) The researcher ticked no sponsor but the study is supported by the university and NZ brain research institute (r.5.1).
* (b.2.2.2) Evidence of peer review is a letter from the Chair of the higher degrees committee but it is rather general. Presumably the review is based on the protocol (as well as talking to the PhD student) which is far too brief to base a thorough review on.
* The protocol mentions 2 parts: video recording and measuring movements by using sensors. It does not mention withholding of medication. The Committee is not clear that the committee knows about the withholding of medication. Please explain.
* The protocol mentions 30 control patients but then goes on to say that only the PD patients will be tested so what is the point of having control patients?
* The Committee requests independent review particularly to validate withholding of medication.
* (R.1.1) The Committee noted the applicant stated there is ‘little foreseeable risk’. What about withholding medication?
* Where will these observations take place and how often? Patients will be unaware that they are interested in jaw movements. This constitutes withholding of information? If sensors are to be placed on the jaw this is obvious?
* (R.2.1.1) How will patient info be de-identified?
* (R.5.6) The Committee is concerned that there may be a conflict of interest. Is it possible that patients may feel pressure to join the study because the supervisor makes the referral and the PhD student will be doing the observations? Please say how this will be managed.
* (R.8.1) Risks and benefits. This study is an observational pilot just to see if these hand jaw movements are a possible sign of PD, not even sure at this stage. It seems that withholding medication is an unnecessary risk at this stage and makes this an intervention study
* (F.2.1) States they want to exclude people who will have side effects from withholding the medication, how do they know this in advance?
* (p.2.1)How much time do patients have to think about this?
* (p.2.6)Withholding information should be a YES.
* (p.2.9) Any results to participants should be in lay language.
* (p.3.1) Who will approach the patients? The supervisor or the PhD student
* (p.4.1) Must provide stats: are Maori over represented in PD?
* (p.4.2) Head is a tapu area for Maori, sensors will be placed on the jaw. Needs to be discussed before they sign informed consent. This is clearly stated in the Maori consultation letter uploaded.
* (f.2.1) Exclude patients who will experience a side effect for withholding LDopa
* The PIS needs to be completely re-written.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The PIS needs to be completely re-written.
* Incorporate the changes suggested in the comment section, including far more information about the study, what is involved, the potential risks, the exclusion criteria.

Decision

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

1. *5.15 of the Guidelines for Intervention Studies:* Withholding a proven intervention for a short time, whether or not it is replaced by a placebo, can sometimes be ethically justified to validate a measurement technique or to confirm the sensitivity of a therapeutic study design. An investigator who proposes any such approach should justify this to an ethics committee and explain how it can be undertaken without significant risk of harm to participants.
2. 6.22 *of the Guidelines for Intervention Studies:* Informed consent is essentially a matter of good communication between people. Information should be provided to potential participants in a form and in a way that assists their informed decision-making. For example, the information should as far as possible be provided in lay terms. In general, such information should:

Explain the study, including:

* + the purpose of the study, including its expected contribution to knowledge and its potential benefits to communities
  + how the study meets the best intervention and equipoise standards
  + the purpose and practical significance of the use of randomisation, blinding or placebos, as relevant
  + the nature and sources of funding of the study, the institutional affiliations of the investigator(s), and who can be contacted to answer questions and how to contact them
  + the study’s status, with a current approval from an ethics committee

describe what the study involves, including:

* + what will be done in the study, including how participation in it will differ from not being in the study
  + the time involved in participation (eg, the number and duration of any visits to the research centre, and the expected finishing date of the study)
  + the purpose and expected number of any extra tests to be performed during the study
    - outline potential benefits, risks and compensation, covering:
  + foreseeable risks, side-effects, discomforts and possible direct benefits of study participation, including any risks or benefits to the health of a participant’s family members
  + arrangements for personal compensation for injury, including whether the study is covered by the Accident Compensation Act 2001
  + payments or other forms of reimbursement, if any, provided in recognition of participation
  + the extent of the investigator’s responsibility to ensure that care is provided to participants during the study

explain the rights of participants, covering:

* + the voluntary nature of participation, including that they are free to decline to participate or to withdraw from the research at any practicable time, without experiencing any disadvantage
  + the fact that participants have the right to access information about themselves collected as part of the study
  + the fact that participants will be told of any new information about adverse or beneficial effects related to the study that becomes available during the study that may have an impact on their health
  + what provision will be made for the privacy and confidentiality of individuals

describe what will happen after the study, covering:

* + whether any study intervention will be available to participants after the study and, if so, under what conditions (including any cost to them)
  + how study data will be stored and for how long, whether the data will be retained for possible future use, who will be responsible for their secure storage and how they will be destroyed
  + whether any biological specimens collected during the research will be destroyed at its conclusion and, if not, details of their storage and possible future use
  + how the study findings will be communicated on completion of the study, including to participants, and in what expected timeframe.

1. Please provide evidence of favourable independent peer review of the study protocol ensuring to comment on the withholding of standard treatment (*Ethical Guidelines for Intervention Studies* Appendix 1).

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee discussed conflict of interests in recruitment, particularly in instances where study personal are recruiting.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 24 June 2014, 12:00 PM |
| **Meeting venue:** | Terrace Conference Centre, 114 The Terrace, Wellington, 6011 |

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.

The meeting closed at 4.25pm