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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 August 2015 |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 28 July 2015 |
| 12.30pm | New applications (see over for details) |
|  | i 15/CEN/106  ii 15/CEN/108  iii 15/CEN/111  iv 15/CEN/112  v 15/CEN/114  vi 15/CEN/115  vii 15/CEN/116  viii 15/CEN/117  ix 15/CEN/118 |
| 4.15pm | 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 |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 01/07/2015 | 01/07/2018 | Apologies |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | 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 | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | 01/07/2015 | 01/07/2018 | Apologies |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 01/07/2015 | 01/07/2018 | Present |

## Welcome

The Chair opened the meeting at 12.10pm and welcomed Committee members, noting that apologies had been received from Dr Angela Ballantyne and Dr Melissa Cragg.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 23 June 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/CEN/106** |
|  | Title: | The role of cancer stem cells and receptor signaling in liver and periampullary tumours |
|  | Principal Investigator: | Dr Swee T Tan |
|  | Sponsor: | Gillies McIndoe Research Institute |
|  | Clock Start Date: | 13 August 2015 |

Dr Tinte Itinteang and Ms Sophie de Jong 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.

Dr Dean Quinn declared a potential conflict of interest, and the Committee decided that it was not a significant conflict of interest and that he could remain in the meeting room and take a full part in the discussion and decision relating to this application.

Summary of ethical issues

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

* The committee noted that the researchers are requesting the use of tissue from an established tissue bank (liver and periampullary tumours) to study cancer stem cells and the role of ErbB dimers on cancer progression.
* The committee asked whether the researchers will look at normal tissue also. Dr Itinteang explained that they will look at normal tissue if it is found on the periphery of the tumour sample only. They will not be asking for an additional sample of normal tissue.
* The researchers confirmed that their process for accessing the tissue is to first seek ethical approval from an HDEC and once ethical approval is given they will request consent from the tissue bank governance board for access to the tissue. The committee noted that the line of questioning on the HDEC application form is not always relevant to tissue that is already stored and strongly suggest that a new application form should be created for such applications which could then be reviewed possibly via the HDEC expedited pathway.
* For future reference, the committee requested that the researchers seek scientific peer review of their study protocol from someone who is independent and has more recent experience in the cancer research field. The committee noted that the peer reviewer for this study is not at the forefront of cancer research and the comments provided in the peer review were too general. The committee would like to see comment that is more specific about the scientific validity and feasibility of a study. The researchers agreed that this was a fair comment and request.
* The committee noted that the obtaining of tissue from individuals is not part of this application but noted the answers at p.3.1 and 3.2 on page 22 of the application form about the ability of potentially vulnerable people to consent to their tissue being stored. The committee noted the researcher’s answer that if an adult is unable to consent then another person will give consent on their behalf. The committee queried whether proxy consent was in the initial approval (12/NTB/42). The committee noted that if a living adult is unable to consent to research then no one can consent on their behalf. The researchers agreed to double check the initial tissue bank application.
* The committee asked what process is in place should the research team discover any unexpected findings about a condition. The researchers explained they keep a record of identifiable information that only the research nurse can keep track of. If they were to come across gene susceptibility to cancer they would notify the participant’s clinician and ask them to open up the dialogue with the patient.
* The committee queried how helpful it would be to provide such information to individuals on the basis that it may be too early to provide a genetic analysis. The researchers thought it is useful at a group level but minimal on an individual level. They agreed that they would not want to provide people with information that in the long term is not valid or correct.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **15/CEN/108** |
|  | Title: | Investigating whether a targeted nutrient supplement reduces inflammation in people with Inflammatory Bowel Disease |
|  | Principal Investigator: | Ms Bobbi B. Laing |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 August 2015 |

Ms Laing 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 the study title being ‘Investigating whether a targeted nutrient supplement reduces inflammation in people with inflammatory bowel disease’ although people involved have ulcerative colitis. The researchers explained that they may include people with ulcerative colitis at another stage in the same study. The committee advised that if were to be a separate study with a different protocol then a new application would need to be submitted.
* The committee noted that there are a number of questionnaires for use in this study and specifically queried a question on the NuNZ Dietary questionnaire that related to functional bowel disease. This question has come from a latest update and this is a term that needs to be removed as inflammatory bowel disease is not a functional bowel disease.
* The committee noted that the peer review document provided was a review of the statistical methodology and was not easily understood by the committee. The committee explained that the evidence of independent scientific review of a study protocol that it is looking for will comment on the relative merit of the research, the quality of the study design and methods and the feasibility of the research. The committee explained that the review should come from someone who is independent of the study itself and who has the expertise to comment. The HDEC website has a peer review template that the researchers may find useful to provide to an independent peer reviewer for comment: http://ethics.health.govt.nz/
* The committee queried what will happen to tissue samples as it was not clear about this from the information given in the application. Ms Laing explained that some samples will be analysed in the immediate study and that some will be stored for further analysis that will be dependent of the receipt of funding. The committee explained the requirement that consent to participate in the main study needs to be separate from optional consent to collect samples for future use in subsequent applications.
* The committee queried whether the samples would be stored in an approved registered tissue bank as the researchers had stated that they intend to store tissue from this study for future research in the laboratory freezer. The committee explained to the researchers the requirement for tissue stored beyond the duration of the current study to be in an approved tissue bank. If the researchers wish to store tissue they would need to either put in an application to the HDECs to establish a tissue bank or they would need to arrange to store the tissue in an already approved tissue bank. The HDEC secretariat would be able to advise on the process should the researchers decide to apply to establish a tissue bank.
* For the testing of the basic genetic component the committee queried how sure the researchers were that they could do the further tests within the next 2-3 years. Ms Laing advised that would depend on whether they can get funding. The committee advised that if they could do the tests within the next 2-3 years then they could make it part of the same application, which would remove the need to get consent from participants for storage of tissue for future unspecified research (although separate information sheets and consent forms will still be required for the optional genetic studies). This would remove the need to apply to establish a tissue bank. If researchers don’t receive the funding within that time then they could destroy the tissue.

The committee requested the following changes to the participant information sheet and consent forms:

* Page 1 under the heading ‘About the Study’: the committee noted that healthy participants wouldn’t have inflammatory signs and asked that the researchers replace the words “inflammatory signs” with inflammatory markers.
* Page 2 and 3, under the heading ‘Entry into this study’: please reword some of the criteria so that is written in a less general way. For example, “Have never smoked or have smoked relatively few cigarettes in the past” could be changed to specify how many cigarettes smoked per day.
* Page 5 under the heading ‘What will happen with your blood?’: the committee noted that a large part of this section is taken up with explaining dna and genetics when genetic testing may not be part of this study and any RNA testing may occur as part of future research. To avoid confusion to participants, the committee asked that this section be removed from the main participant information sheet.
* If the researchers decide to do genetic testing in the future then they will need to include a separate optional information sheet and consent form and could include the information from page 5 in that document.
* Page 7: the committee noted that the contact details for the Health and Disability Advocate are no longer current. Please update the contact details. You may wish to refer to the HDEC participant information sheet and consent form template on the HDEC website for these details: http://ethics.health.govt.nz/
* Please make clear to participants that the researchers will contact their GPs to get medical information. Ms Laing noted that the original consent form makes reference to this. The committee confirmed that if the researchers are accessing information from same people from the previously approved study that they also need to get consent to sign up for this study and that there can be no assumption of consent for this study made by the researchers in this regard.
* Originally this application was submitted as an amendment to a previously approved study but what is proposed in this study is significantly different and the research team will need to seek ethical approval for this study and will need to consent participants to this study without reliance on what was approved in the previous study.

Decision

This application was *declined* by vote with 3 for and 2 against, as the Committee did not consider that the study would meet the following ethical standards.

6.6 Informed consent is best understood in terms of decision-making that is based on good communication between people, rather than simply as a transfer of information from one person to another.

6.7 Informed consent has two basic components. (a) The decision is informed by adequate understanding of any information that this relevant to that decision.

Given the extent of the changes requested by the committee, it agreed to decline the application to allow the research team to submit a new application. The committee explained that if it provisionally approved this study that the research team would run the risk of then having a ‘decline’ decision given the extent of the changes requested by the committee. The committee agreed to decline this application and suggested that the researchers resubmit an application taking into account the points of discussion and requested changes. The committee suggested that the researchers submit to the next central committee meeting as they are familiar with the study.

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| **3** | **Ethics ref:** | **15/CEN/111** |
|  | Title: | Living away from home: The views of disabled young adults |
|  | Principal Investigator: | Dr Brigit Mirfin-Veitch |
|  | Sponsor: | Ministry of Social Development |
|  | Clock Start Date: | 13 August 2015 |

Dr Jenny Conder 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’s understanding is that in this study the researchers intend to talk to people who are 18-20 years old and who have previously been in disabled care with a view to improve current care services. Dr Conder added that the participants will be young disabled people who are 17-22 years old and who have previously been subject to sections 141 and 142 of the Child, Young Persons and their Families Act and their families have asked for them to be cared for outside of the family home in a residential service.
* Best practice will be an intended end result.
* The committee complimented the researchers on well-designed participant information sheets and consent forms in particular the way in which the researchers had used pictures.
* The committee noted that this is a worthwhile and long overdue study. It did not have any major ethical concerns and sought the following minor clarifications only.
* Page 20 of application form, questions p.4.1 and p.4.2. The committee commented that it was helpful to see information and statistics that give a good picture of the way in which the study might benefit Maori and of any cultural issues that might arise for Maori. For future reference only, the committee noted that a cultural issue for Maori would be that of whakama - there can be in some whanau embarrassment or shame for having a disabled family member. Dr Conder acknowledged the value of having Ms Kelly Tikao available to advise and assist them. The committee noted that it was pleased to see such support in place.
* Page 20 of the application form, question p.4.3.1. The committee asked how the working group mentioned fits in with this study. Dr Conder explained that a piece of work came out of the MSD which found that in doing the bigger work on the CYFs Act the crucial role of talking to the young people was missed out. This study looks to learn from the young people themselves.
* Page 21 of the application form, question f.1.1. For future reference the committee noted that this question is not so much about Maori but about pacific peoples and other New Zealand populations.

The committee requested the following changes to the participant information sheet and consent form:

* Page 8: please replace the words “18 and 22 years” with 17 and 22 years.
* Consent form, item number 11 on page 4: the committee noted the statement “I know what will happen if I talk about abuse in my interview” and noted that this was not explained in the information sheet. Dr Conder explained that she will talk about that as part of the consent process. If something comes up during the interview, the researcher will check whether the participant has had counselling. If the participant is known to be at risk then as a team the researchers will explain they can’t keep the information private and that they will need to talk with someone appropriate including the police if needed. The committee noted that it is important that the participants know what the consequences will be and that should be covered in the participant information sheet.
* Consent form, item 19 on page 7: please separate out the two points in this item use of the words and no use of the participant’s name.
* The committee noted the answer given at question p.1.1 on page 17 of the application form that participants will be invited to use photographs or other personal items to show the researchers important people, places or events. The committee presumed that this will be explained in person as part of the consent process but also requested that this be stated in the information sheet.

Decision

This application was *approved* by consensus.

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| **4** | **Ethics ref:** | **15/CEN/112** |
|  | Title: | Antibiotics during cardiac surgery |
|  | Principal Investigator: | Professor Brian J Anderson |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 August 2015 |

Dr Jaquie Hannam 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 the researchers will look at pharmacokinetics of antibiotics during surgery and this is a low risk observational study
* For future reference, the committee noted that question p.4.2 on page 20 of the application form should be answered in relation to what potential cultural issues may arise for Maori in this study. The committee noted that the taking and storage of blood is one such issue.

The committee requested the following changes to the participant information and consent forms:

* Please review the wording in the parent/caregiver information sheet and consent form and rewrite it from the perspective that they are consenting for their child to take part in this study. Please explain up front why their child is being invited to take part in the study.
* Page 1 under the heading ‘What would your participation involve?’: please clarify what happens to blood here – i.e. that it will be analysed and disposed of.
* Please provide an information sheet and consent form for participants 16 years and older and information sheets and assent forms for 12-15 year olds and for 7-11 year olds. The committee noted that the participant information and assent forms for participants need to be age appropriate and include pictures so they understand what is involved. The committee noted that the assent form does not have to be separate from the information sheet for the participants.
* Please include more information about the participants’ health information and data. For example, how long it will be stored for and who will have access to the data.
* The committee requested that the following clause be included in regard to compensation in the event of an injury: *If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.*
* The committee noted it can only approve or decline the application once a response is received from the research team and noted the importance of getting the requested changes right.

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*).

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

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| **5** | **Ethics ref:** | **15/CEN/114** |
|  | Title: | Gastrointestinal motility study |
|  | Principal Investigator: | Dr Susanna Every-Palmer |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 August 2015 |

Dr Every-Palmer and Prof Ellis were present in person and Dr Inns 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 will look at patients on Clozapine because it can cause bowel motility problems and this particular population is at risk. Participants will swallow a ‘smart pill’, which is a wireless motility capsule and be monitored for a week.
* Dr Every Palmer noted that she had been interested in this issue since 2005 when she had a patient on Clozapine who died of bowel-related problems. Little is currently known about the gastrointestinal side-effects of Clozapine. The cohort in this study will be living on Ratonga Rua o Porirua campus and will be offered participation in the study which requires them to take a smart pill which relays information on temperature, pressure and intraluminal pH as it moves through the GI tract. Participants will wear a data recorder on a lanyard for four days and up to a week if the pill is taking longer to progress through the GI tract.
* About 50 percent of mental health patients in Ratonga Rua campus Rehabilitation and Forensic Services are prescribed clozapine. Dr Every-Palmer advised that it is currently the best antipsychotic treatment for an illness that has not responded to other available treatment.
* Prof Ellis explained that Clozapine can kill people by inhibiting bowel movement. Severe constipation can cause rupture of the bowel and peritonitis. There is little information about which parts of the GI tract are affected by Clozapine. This research will address that and may lead to interventions that will reduce the number of deaths from Clozapine from bowel hypo-motility. Dr Every-Palmer explained that there is a significant burden in terms of morbidity as well as mortality when people are taken off Clozapine. It is an effective treatment and stopping it will mean that people will go back to experiencing psychosis. Overall Clozapine improves life expectancy and people have a higher functioning life.
* Dr Every-Palmer emphasised that not only will the findings of this study be beneficial to academic literature but individual patients will also get a copy of the results and so have a better understanding of the risks for themselves and how to respond. Hypo-motility symptoms get taken to emergency department and assessed rapidly.
* For future reference the committee noted that any known statistics are useful for the committee to know at question p.4.1 on page 21 of the application form. (This question asks whether and how a study will benefit Maori). The committee noted that the researchers had stated at question p.4.2 that no areas of concern were identified during consultation. The committee noted that the cultural issue of ‘whakama’ may arise as there will be times that people won’t want to talk - especially about bodily functions and mental illness.
* For future reference the committee noted that questions f.1.1. and 1.2 on pages 22-23 of the application form relate to pacific peoples and other New Zealand populations other than Maori.
* Dr Every-Palmer confirmed for the committee that the lanyard participants will wear is safe. It has a safety clip and all participants are familiar with lanyards as they wear them during the day regardless of participation in this study. This minimises the risk for this population in this study.
* The committee agreed that patients in the study population would not be incapable of consenting to taking part in the study but asked how the research team would assess competency. Dr Every-Palmer explained that they will check with the patient’s psychiatrist to make sure they believe that they are competent and they will make sure that there are no concerns about a person’s ability to consent to treatment. They will also assess whether the person can retain and understand the information during the consent process. Some participants will be under compulsory treatment orders but there is no reason why they can’t consent because they are under the Act.
* Page 2 under the heading ‘What procedures does the study involve?’: the committee noted that it is stated participants would need to stop taking laxatives as they can affect the study results. The committee noted that it did not state that this would mean that participants would need to be withdrawn from the study altogether. Dr Every-Palmer explained that they did not wish for participants to feel that they could not ask for laxatives if needed. It was argued by the committee that these people are competent adults and can have the information to make decision to participate. The committee suggested a way to express this point so as to not discourage participation and suggested something along the lines of ‘should you have laxatives then all of your data may not be used’.
* The committee commended the research team on an excellent idea and noted the importance of allowing this study to go ahead in this population.

The committee requested the following changes to the participant information sheet and consent forms:

* Page 4: please include contact details for the Health and Disability Commissioner and also for Maori support person for Maori participants in this study.
* The committee queried what was meant by compensation provisions? The researchers explained that this was not compensation but an acknowledgement of participants’ time. The committee agreed that giving participants a Warehouse voucher is fine and asked that the researchers please make clear in the PIS that participants are getting a voucher, not payment.
* Please clarify the issue of taking laxatives and patient data not being able to be used as suggested above.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **15/CEN/115** |
|  | Title: | Self-directed rehabilitation RCT after stroke |
|  | Principal Investigator: | Dr Harry McNaughton |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 13 August 2015 |

Dr Harry McNaughton 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.

* Dr McNaughton introduced the study. It is a randomised controlled trial of a novel communication intervention for people after they have experienced a stroke. The intervention has been tested before in Maori and Pacific People populations and has been shown to be effective. Therefore, Maori and Pacific Peoples are excluded from the current study. This study is for non-Maori who survive a stroke and who aren’t discharged from hospital. Dr McNaughton explained that 15-20 percent of stroke sufferers die in hospital and 15 percent are discharged.
* The Take Charge intervention acknowledges that it is common after stroke to be overwhelmed by such a life changing event. The intervention encourages people to become who they are and take charge of their journey after experiencing a stroke. A focus is placed on who the person is rather than on physical goal setting, such as walking 10 metres in a certain timeframe. Dr McNaughton advised that this type of goal setting has been found not to be effective in transforming people’s lives after stroke. The intervention is cheap, and has been found to be very practical and generalizable.
* The research team will recruit only participants who can give informed consent. The committee noted that there may be people who following a stroke, can understand verbal information but who might struggle to read and asked whether there is an alternative way of getting information to them. Dr McNaughton noted that aphasia following stroke is always a challenge and that he has set the bar that a person will need to understand the information that is in the document and with family/caregiver help can express that they understand. No one will consent on behalf of participants in this study.
* Dr McNaughton explained that in the hospital setting clinicians will be asked to consider whether a person has the ability to understand the information and if not or if the clinician determines that it would be very close they won’t refer a patient. Once a patient is referred then the research team will organise a visit and further assess whether a participant will be able to enter the study. The committee noted that it is important that people who are reading impaired but can understand verbal information are included as the benefit could be great.

The committee requested the following changes to the participant information sheet and consent forms:

* Page 3, ‘Could this research be stopped unexpectedly?’: please remove this paragraph as it is not relevant for this type of study and could be confusing for participants.
* Page 3: the committee noted the information given that a participant’s GP will be told about their participation in the study as they may need to contact GPs if new medical problems develop after discharge from hospital or if the research team is unable to contact the participant for final assessments. The committee requested that more specific information is given here about what might happen. For example, high blood pressure and heart rate are critical in this respect.
* Page 4 under the heading ‘Will the information collected be confidential?’: please replace the words “NZ Multi Regional ethics committee” with the Central Health and Disability Ethics Committee.
* Pages 6 and 7: please review the statements and only include yes/no statements for those that are truly optional.
* Page 6: please remove the interpreter box as there will be no Maori or Pacific Peoples in this study.
* Page 6: please remove the statement “I know who to contact if I have any side effects from the study”.
* Page 7, last bullet point: please remove the words “I understand”.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **15/CEN/116** |
|  | Title: | Efficacy and safety of finerenone in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease. FIDELIO - DKD |
|  | Principal Investigator: | Professor Russell Scott |
|  | Sponsor: | Bayer Australia Limited |
|  | Clock Start Date: | 13 August 2015 |

Dr Jane Keir, Ms Zania Morrison and Ms Privana Kura 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.

Dr Quinn declared a potential conflict of interest, and the Committee decided that Dr Quinn would take no part in the discussion or decision relating to this application.

Summary of ethical issues

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

* The committee agreed to consider this protocol alongside the protocol in 15/CEN/117 as the two studies are related.
* The researchers explained that this protocol 16244 is a randomised, double-blind, placebo-controlled, multicentre trial of a drug called Finerenone and the research will look whether adding this drug to current therapy will have long term benefits for kidney disease in people with type 2 diabetes. Protocol 17530 will look at cardiovascular outcomes.
* The committee clarified that this research will look to test a new drug that lowers blood pressure and is thought to help to take pressure off the kidneys and help reduce other risk factors associated with high blood pressure. The committee notes that the study design is straightforward but the follow up is more involved with 4 visits in first month and visits for up to three years with questionnaires to complete.
* The committee queried why, given the similarity of the two studies why the research team would not combine the endpoints in one larger study? The researchers advised that the company that they are contracted to has designed the studies to measure different outcomes and that protocol 17530 allows for participants with better kidney function than protocol 16244.
* For future reference, please include any known statistics at question p.1.4 on page 26 of the application form as they help the committee see how Maori are represented.
* For future reference, question f.1.2 on page 27 of the application form refers to other New Zealand populations such as pacific peoples.
* The committee asked which Maori research committee had been approached for this study. The researchers advised that they consulted with Mr Peter Mason who has been reviewing protocols in the Canterbury region for some time.
* The committee was pleased to see an abbreviated participant information sheet that will be given to participants before they receive the full version.
* The committee noted the Declaration of Objection to the Collection of Study Data and Withdrawal of Consent form and advised that legally participants don’t have to withdraw in writing. The researchers explained that this is a sponsor requirement. In practice if they are not able to get withdrawal in writing they are satisfied with a verbal statement and note this down in participant records.

The committee requested the following changes to the participant information sheet and consent forms:

* Page 3 of 18 under the heading ‘What is the study drug being tested?’: please state that ethical approval is from the Central Health and Disability Ethics Committee.
* Page 7 of 18 under the heading ‘What are the possible benefits of taking part?’: the committee noted that the sentence “In addition, if Finerenone is proven to be more effective than placebo, you may be among the first to benefit” is misleading as some will receive placebo and will not benefit.
* Please state that participants may receive reimbursement for travel expenses and give a range for the amount that they may receive.
* The committee noted that the consent form made reference to proxy consent and reminded the researchers that participants must be able to consent for themselves. The researchers explained that they will only recruit competent people to the study and competent adults. The committee asked that the researchers remove any reference to proxy consent.
* Page 17 of 18: please remove the words “in writing” to inform study doctor of a decision to withdraw from the study as withdrawal does not legally have to be in writing.
* Please include important contact numbers and details at the end of the document rather than in the body of the document so that they are accessible. Please do the same in the short forms too.
* Please mirror the statement about information being collected on pregnancy and birth (page 7 of the pregnancy information sheet), in the main information sheet and consent form.

Decision

This application was *approved* by consensus.

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| **8** | **Ethics ref:** | **15/CEN/117** |
|  | Title: | Efficacy and safety of finerenone in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease. FIGARO-DKD |
|  | Principal Investigator: | Professor Russell Scott |
|  | Sponsor: | Bayer Australia Limited |
|  | Clock Start Date: | 13 August 2015 |

Dr Jane Keir, Ms Zania Morrison and Ms Privana Kura 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.

Dr Quinn declared a potential conflict of interest, and the Committee decided that Dr Quinn would take no part in the discussion or decision relating to this application.

Summary of ethical issues

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

* This study protocol was considered alongside protocol 16244. Please see discussion for study 15/CEN/116.

Decision

This application was *approved* by consensus.

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| **9** | **Ethics ref:** | **15/CEN/118** |
|  | Title: | IV ARX788 in advanced breast cancer |
|  | Principal Investigator: | Dr Anne O'Donnell |
|  | Sponsor: | Quintiles Pty Ltd |
|  | Clock Start Date: | 13 August 2015 |

Dr O’Donnell 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 commented that this is a well put together application.
* For future reference, the committee noted that at question p.4.1 in the application it would like to see any known statistics about how Maori are represented. In this case information about prevalence of metastatic or breast cancer rates so that the committee can see how relevant a study might be for Maori.

The committee requested the following changes to the participant information sheet and consent forms:

* Page 4 and 5 of 1b: please delete the information under the heading ‘Genetic testing’, specifically the last 3 paragraphs, as it is misleading.
* Additional tissue from a fresh biopsy may be requested as part of the study, therefore the researchers require a specific consent for this procedure as it is not a standard procedure and not consented for as part of the optional pharmaco-genetic consent. Please include a consent option within the optional pharmaco-genetic study to allow use of archival tissue only, without consent for an additional fresh tissue sample.
* While clearly advantageous it is not required as the study can achieve helpful outcomes without the additional tissue biopsy because of the nature of the drug studied.
* The committee noted that this is an exciting study that comes with responsibilities. The participant information sheet is extensive and detailed and would benefit from a simple flow diagram that gives an overview of the study as a brief reference. The researcher can talk people through the detail and people can also read more detail as they go through the PIS.
* Please make the margins bigger as it is better to have more pages that are easier to read.
* Please indicate number of pages in the document including the consent form.
* Page 2: the committee queried the level of reimbursement that may be provided for participants. Dr O’Donnell advised that this will depend on where patients are coming from. This is a class of drug not available in NZ but the recognised lead compound has significant activity and licences in Australia. Travel may be the equivalent of an airfare or may be petrol vouchers so will be patient dependent. The study is designed so that no one at a disadvantage to enter the study.
* Page 5: the committee queried whether participants have to pay for medication to manage their side effects. Doctor O’Donnell advised that current practice is that they may need to pay prescription charges. The issue of symptom control and or whether the symptoms are part of clinical trial can be hard to differentiate. Patients on trials do pay prescription charges. The committee recommended that if possible the research team include prescription costs in the study because participants may not have had some side effects if they were not on the trial.

Decision

This application was *approved* by consensus.

## 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:** | 22 September 2015, 08:00 AM |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington , 6011 |

* No members tendered apologies for this meeting.

The meeting closed at 4.30pm.