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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 22 March 2016 |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 23 February 2016 |
| 12.30pm | New applications (see over for details) |
| 12.30-12.55  12.55-1.20  1.20-1.45  1.45-2.10  2.10-2.35  2.35-2.50  2.50-3.15  3.15-3.40  3.40-4.05  4.05-4.30  4.30-4.55 | i 16/CEN/18  ii 16/CEN/24  iii 16/CEN/25  iv 16/CEN/27  v 16/CEN/28  vi 16/CEN/34  vii 16/CEN/35  viii 16/CEN/36  ix 16/CEN/37  x 16/CEN/38  xi 16/CEN/42 |
| 4.55pm | General business:  Noting section of agenda |
| 5.10pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |  |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |  |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 30/07/2015 | 30/07/2018 | Present |  |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |  |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |  |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |  |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |  |
| Dr Melissa Cragg | Non-lay (observational studies) | 30/07/2015 | 30/07/2018 | Present |  |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |  |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 23 February 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/CEN/18** |
|  | Title: | Effect of elective blood transfusion on regional oxygenation and cardiorespiratory stability of neonates |
|  | Principal Investigator: | Dr Maria Saito Benz |
|  | Sponsor: | Capital and Coast DHB |
|  | Clock Start Date: | 10 March 2016 |

Dr Maria Saito Benz 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 the study

* This is an observational study in new born neonatal babies who are anaemic and it aims to develop a better understanding of the mechanism by which elective blood transfusion benefits neonates with anaemia. More specifically, it will examine whether elective blood transfusion increases availability of oxygen to the brain, liver and muscle. Informed consent will be obtained from the study participants’ parents.

Ethical issues (resolved)

* The committee noted that question p.1.2 on page 19 of the application form that asks whether all participants in the study will be able to give informed consent was answered ‘yes’ when in fact they will not as they are neonates whose parents will consent on their behalf. The committee noted that the wording of the question is not entirely clear but noted for future reference that this question can be answered ‘no’ when parents are consenting on behalf of their children.
* Question p.3.2.1 on page 21 of the application form which asks how the study’s informed consent process takes the needs of the potentially vulnerable people into account was answered with information including that informed consent will be “sought from parents, or caregivers with a parental right of potential participants”. The committee noted that under s36 of the Care of Children Act that consent must be from a legal guardian, or if there is no guardian in New Zealand or no guardian of that kind can be found with reasonable diligence or is capable of giving consent, by a person in New Zealand who has been acting in the place of a parent.
* The committee noted that the scientific peer reviewer of this study had suggested clarification with the researchers about the timing of the transfusions and whether a capillary gas assessment of haemoglobin and PCO2 will be done pre transfusion. Dr Saito Benz explained that they chose the overnight timing after discussion with the unit’s nursing staff as prior to morning handover is the quietest time in the neonatal unit. In terms of the assessment of the capillary gas blood sample, Dr Saito Benz explained that the babies will be having regular blood samples taken as part of standard of care treatment and the monitoring of haemoglobin count and PCO2 count will be provided from the bloods taken from tests that the babies receive as part of standard of care treatment.
* The committee commented on the risk section of the application form, specifically question r.7.1 which asks applicants to briefly indicate whether the study may pose any significant risks to researchers and/or third parties, and how any such risks will be managed. To minimise additional workload the researcher had indicated that she will be on-site. Dr Saito Benz advised the committee that her PhD study is full-time and that she will be on-site all night.
* The committee commended Dr Saito Benz on the answers she had given at questions p.4.1 and p.4.2 that ask about how the study is of relevance to and may benefit Mãori participants.

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

* The committee complemented the researcher on a clearly written participant information sheet and requested only minor changes.
* Page 2, first paragraph, third sentence: please add the word “the” before the words “body’s requirement”.
* Page 2, This study is for observation only: the committee suggested that it would be clearer to state that: *We will recommend a blood transfer if needed.*
* Page 4: the committee requested that reference to the position of the baby during data collection be made consistent to read “baby to be lying in the cot facing up”.
* Consent Form: the committee noted that yes/no boxes be included only if the statement is truly optional (i.e – that a person could still participate if they answer ‘no’). The committee noted that the last statement on page 2 of the form that reads: “I wish to receive a summary of study findings” is optional. Please remove the yes/no boxes for the other statements.

Decision

This application was *approved* by consensus.

Non-standard conditions.

* Please amend the information sheets and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies, para 6.22)*

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| **2** | **Ethics ref:** | **16/CEN/24** |
|  | Title: | ALL SCTped 2012 FORUM |
|  | Principal Investigator: | Dr Lochie Teague |
|  | Sponsor: | ANZCHOG |
|  | Clock Start Date: | 15 February 2016 |

Dr Lochie Teague and Ms Paula Murray 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.

* In studies such as the one before the committee today often submit many participant information sheets and consent forms and the committee noted that it is often difficult to navigate the forms and therefore to fully understand what is involved for the different arms and cohorts in these studies. The committee acknowledged that the difficulty arises in part due to the way documents are uploaded and displayed in the online portal. The committee stressed that it would help make navigating the number of forms easier if the researchers submit a cover letter that lists and groups the forms together and states what arm/cohort they belong to.
* The committee noted the answer stated at questions f.1.2 on page 29 of the application form that the research team has no evidence that the incidence of ALL differs between Mãori and non- Mãori. The committee noted that it had seen a journal article that stated that NZ Mãori had the highest incidence of ALL out of all childhood groups. The committee agreed to forward the link to this article to the research team. *(Journal of Cancer 1996 May; 73(9):1141-7. Childhood leukaemias in New Zealand: time trends and ethnic differences. Dockerty JD, Cox B, Cockburn MG.)* The committee noted that this reference is 20 years old and for future reference the committee would like the researchers to provide current incidence rates for Mãori and non-Mãori.

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

* Main Information sheet for the MMD group: the committee noted that there is a lack of information about the study treatment being to be offered compared to usual/standard care. The committee requested that the researchers refer to their answer stated at question r.1.1 on page 17 of the application form that describes the procedures to be done in the study, and any risks that potential participants may reasonably wish to be informed of. The committee requested that some of the information stated at r.1.1 be included in the information sheet to help participants make a decision about whether they will take part in the study or stay with standard treatment.
* Assent forms MMD and MSD MD groups for children aged 7-10 years, page 1, first question ‘What is wrong with me?’: the committee noted that the use of the word “wrong” may cause the children to feel blame or guilt about being unwell and asked that the researchers replace this word or rephrase the question. The research team suggested replacing with “why am I unwell?” which the committee accepted.
* Main information sheet adult MSD MD group: please include a statement that clearly sets out what standard treatment is and what the alternatives to being in this study are.
* Information sheet for continued participation upon reaching the adult age of consent: The committee asked the researchers whether they provide a copy of the main information sheet when re consenting participants. The researchers advised that they can provide on request and the committee noted that it is important for the researchers to provide the main sheet regardless and as a right as the participants may not be in a position to remember.
* Main information sheet for MSD and MD groups: page 2, under the title ‘Confidentiality’: The committee noted the statement that participants’ research study records will be archived for up to 25 years and that this was at variance with information in the application form that stated they will be stored indefinitely and also the adult re consent form which stated 10 years from the age of 16. Please check for consistency and make changes to the information sheets as needed.
* The committee queried whether the rare treatment risks are particularly helpful for people to read. The researchers noted that they are clinically significant in rare category. The committee accepted that only those important and or common be listed and that this would include risks listed in the ‘Rare’ category.

Decision

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

* Please amend the information sheets and consent forms, 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 Dr Quinn and Mrs Gill.

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| **3** | **Ethics ref:** | **16/CEN/25** |
|  | Title: | ASSET; Acute Lymphoblastic Leukaemia Subtype and Side-Effects from Treatment. |
|  | Principal Investigator: | Dr Siobhan Cross |
|  | Sponsor: | Kids Cancer Centre |
|  | Clock Start Date: | 10 March 2016 |

Ms Sara Parkin 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 sought clarification on whether this research will involve the set up or a registry or whether the researchers wish to use information from this study to add to an existing registry.
* This research study will involve the establishment of a Registry within Australia through the Paediatric Trials Network Australia (PTNA) where severe toxicity data of children with ALL will be collected and stored. Currently, there is no national Australian incidence data on toxicities. In Australia, there are independent state registries in place for certain states but not a national Australian registry.
* In contrast, in New Zealand, a national registry is already in place for collecting data on children with cancer called the New Zealand Children’s Cancer Registry (NZCCR) but there is no specific registry looking at severe toxicities in childhood ALL. This study registry, which will be known as the ‘ASSET Registry’ will collect data on the four most common toxicities (namely venous thrombo-embolism, neurotoxicity, pancreatitis, and bone toxicity) of children with ALL and MPAL (Mixed Phenotype Acute Leukaemia) and will be of clinical relevance to research teams in New Zealand by providing a database with greater numbers to view these toxicities This, in turn, will be useful in our future treatment of ALL by enabling the research teams to determine the impact of these toxicities on the quality of life of children treated for ALL and their families.
* The secondary aim of this study will be to look at whether the presence of genetic markers can show the risk of a child developing severe toxicities. The researchers will use this information to guide future supportive and preventive strategies.
* In this cohort study they will look at unique biomarkers at diagnosis or remission to show whether they determine toxicity.
* The majority of the tissue samples for the optional biomarker studies will be those that are left-over after routine collection for diagnostics. In other instances, an extra sample may be taken at the same time as routine sample taking.
* The committee noted that the researchers intend to recruit 50 participants to the study and asked what the researchers plan to do when participants opt not to participate in the optional biomarker studies. Ms Parkin advised that participation is optional and that there is no obligation for participants to consent to the optional parts of the study. The committee asked whether non-participation in this cohort might mean that the researchers don’t reach the anticipated numbers and whether this would mean that they are not in a position to make the predictions that they hope to make. Ms Parkin stated that the study will still provide the registry component and will still provide an overview of the incidence of the four toxicities being investigated. Ms Parkin reiterated that participation is optional and that from the parents’ perspective there is little risk involved in taking part. In other similar optional studies they have done, they found that people appreciate being asked to take part in a biomarker study and feel like they are contributing positively to future research. They have had a high success rate for recruitment in the past.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee which require addressing by the Researcher are as follows.

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

* Under the heading ‘Why is this Study being done?’. Please remove the sentence: “The costs associated with the care of toxicities will also be calculated for certain sites but we will not perform this component of the study in New Zealand”, as is it not applicable in the New Zealand arm of the study. Please remove all other references to the economics study.
* The committee noted that in places it is stated that left over samples will be used and asked that it be made clear that an extra sample will be taken as in some cases an extra draw will be required..
* Page 4, ‘What are the risks in participating in the study?’: please remove the information in the second and third paragraphs that relates to the optional studies and include it in the optional study information sheets only.
* Page 5, ‘Will my samples be used in the future?’ Please remove this section and include it in the optional information sheet only.
* Main consent form, page 2: please removed the second optional bullet point that gives a yes/no option for consent to have left over samples collected, stored and used for future research. This statement should be in the optional FUR information sheet and consent form only.
* Information sheet for continued participation upon reaching the age of consent (16+ years), paragraph two: please remove reference to this study being a clinical trial and replace it with the words “cohort study”.
* The committee was concerned that the information in the information sheet and consent forms for the 7-10 year age group is too difficult for this age group to comprehend and noted that it appears to be the same information as that in the 11-15 year old age group PIS/CF. The committee asked for a new information sheet for this age group with simplified language and pictures if possible. Ms Parkin noted that historically they have produced an information sheet for children to have an overview but that it is becoming less of a pre requisite now – this idea could be applied for the information sheet and assent forms for the 7-10 year old age group in this study.
* Short consent form that is signed by the participants and interpreter: Ms Parkin explained that the written short form has been created in accordance with CTEP regulations based on US Federal Guidelines in 2014 for non-English speaking participants and is mandated for all COG studies. It has been included in non-COG studies for consistency. The approved document is translated into relevant languages and used as part of the consent process for participants for whom English is not a first language. The generic form is used to explain participation in a clinical trial and the type of information that the patient will be given regarding the study. It is study specific in that it includes the study title and contact details for the study but the remaining text is standard for all studies. As such, it cannot be changed as it has been signed off by COG quality assurance and ANZCHOG. The committee noted that the way the form is written is confusing as it suggests that the interpreter and another family member are giving consent for the participant to take part in the study and consent by either is not lawful in New Zealand. The consent must come from the participant or in the case of children, their parents. While this form is signed by the Parent/Participant, treating physician and translator therefore meets lawful requirements in New Zealand. Ms Parkin further explained that it is important to note that they use this short consent form in conjunction with the detailed study specific information sheets and consent forms. It does not replace them. The form has been submitted previously for each study, in addition to the study-specific PICFs. The committee acknowledged that the researchers may have submitted the forms previously but maybe not for a Central HDEC application.
* Withdrawal of consent form: Ms Parkin advised that this is not a standard form but is used in Australia and she included it with the documents in the interest of consistency. The committee advised that in New Zealand withdrawal from a study does not need to be in writing and can be done verbally. Therefore this form does not need to be included in the study.
* Statement of consent for future unspecified research, page 5: the committee noted that the four different options are hard to follow as they are currently stated and the difference between future genetic research and future unspecified research is unclear. The committee recommend that the research team use one statement and ask participants to consent to one or both future genetic research and future unspecified research.

Decision

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

* Please amend the information sheets and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies, para 6.22)*

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

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| **4** | **Ethics ref:** | **16/CEN/27** |
|  | Title: | MAGELLAN2 |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Abbvie |
|  | Clock Start Date: | 10 March 2016 |

Prof Gane and Ms Amy Cole 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.

* For future reference the committee noted that question p.4.1 in the application form that asks how a study may benefit Mãori is best answered when it includes information about incidence and prevalence (statistics) of the disorder under study (or treatment indication if a drug trial) in Mãori. Some disorders are particularly important for Maori health, while others are relatively rare in Maori and may have less of an impact. If the impact of treatment or prevalence of disease is low or the same as other populations please state this clearly to the Committee. Generally, any available statistics relating to Mãori should be provided where possible. If the study is an early phase trial, a caveat that no benefit is expected as a direct result of the study.
* If relevant, please include information on how researchers will ensure that Mãori benefit at least equally (and actually how they can disproportionately benefit if they are disproportionately represented) –for example, what extra measures if any are in place to ensure Mãori participation (iwi consultation, Mãori researchers, active follow up etc) as well as interpretation of results and presentation of findings back to those consulted. This could be explained in the question about consultation.
* The Committee noted that the answer stated at question p.4.2 in the application form made reference to Article One of the Treaty of Waitangi and that in future the researchers make reference to Article Three and this is about equality. The committee noted a further issue of note is Whakama as some people will have Hep C from an unsafe lifestyle.

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

* Main participant information sheet,
* Page 8, 4th paragraph: please amend to make clear that the PK sampling study is optional.
* Page 10, 3rd sentence: please reword this sentence to read that only study participants can take the study drug.
* Page 14: the committee noted the statement that to do the ECG, participants will have 12 small stickers placed on them when normally just 10 are put on.
* Page 19, second bullet point: the committee sought clarification about the samples taken to Singapore and stored for 20 years. What is meant by “plasma and serum” blood samples as this is not referred to anywhere else. Prof Gane advised that it should only refer to serum left over from routine testing and not make reference to the other two sub- studies. The research team will clarify this with the sponsor.
* Page 19, second bullet point: please remove reference to samples being stored for 20 years as you can’t store samples for 20 years for additional testing.
* Testing (of blood, serum or plasma) in the main consent form should be ‘specified’. It should relate to the main study, and be conducted during the main study. All future unspecified research needs to go in the optional forms.
* Main Consent form, page 21. The last bullet point states that: *I am authorising access, use and transfer of my personal information and samples as described in the participant information sheet.* The committee noted that this statement is generic and asked the researchers to make the statement more specific. The committee suggested that the researchers could say that in this consent form the participant is authorising the use of samples for this main study only for x number of years.
* Some of the key information about use of samples for future unspecified use has not been covered in the additional pharmaco genetic information sheet. For example, if blood samples go overseas then the HDECs won’t be able to approve use in further studies. Minimum information standards for future use are specified in “Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes.” Please amend the information sheets to include this information. You may wish to refer to the FUR pro forma on the HDEC website for guidance: <http://ethics.health.govt.nz/>
* Optional pharmacokinetic sub-study. The committee asked whether the PK tests are related to the current study only or for future unspecified research. Prof Gane advised that the tests will only be related to measuring drug levels or metabolites in plasma and not genomic material. The other pharmacogenomics sub-study will use genomic material whole bloods not just plasma. The committee advised that the use of samples for future unspecified research is not limited to genetic tests but includes any use of blood samples and data. The committee advised that if the researchers intend to store the PK samples for 20 years and test them in future then the pharmacokinetic information must cover FUR as well.

Decision

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

* Please amend the information sheets and consent forms, 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 Dr Dean Quinn and Dr Angela Ballantyne.

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| **5** | **Ethics ref:** | **16/CEN/28** |
|  | Title: | Phase 3 Study of Pembrolizumab in Combination with Epacadostat/Placebo in Unresectable/Metastatic Melanoma |
|  | Principal Investigator: | Dr Richard North |
|  | Sponsor: | Merck Sharpe and Dome |
|  | Clock Start Date: | 10 March 2016 |

Dr Richard North 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.

* Question p.4.1 on page 26 of the application form: the committee asked whether the researchers had any statistics relating to incidence of this disease in Mãori. The researcher advised that he did not have any statistics on hand except to say that it happens extremely infrequently. The committee noted for future reference that this is the kind of answer it would like to see in this question.
* Question p.4.2 on page 26 of the application form: the committee noted another issue was that of the use of tissue and that the opportunity to include whanau in any discussion around the use of tissue.
* For future reference the committee would like to see statistics on the incidence of the disease in other populations in New Zealand at question f.1.2.
* Question p.4.3 in the application form was answered ‘no’ that formal consultation with Maori is not required and the reason stated at question p.4.3.1 is that the target disease is not particularly prevalent in Mãori. Question p.4.4 was answered ‘yes’ that the study will involve kaupapa Mãori research methodologies. The researcher advised that they will have an interpreter involved for Te Reo speakers and offer the opportunity for whanau to be involved in a participant’s care. The committee noted that if Mãori will potentially participate in this study then consultation with a Mãori research group needs to be done prior to the study commencing. The committee noted that it had cited information from the Melanoma Foundation that although Mãori and Pacific peoples have a much lower chance of getting melanoma, they often have thicker (more serious) melanomas. In 2013 age-standardised Mãori rate for melanoma registrations was 7 per 100,000 compared with over 40 per 100,000 for non-Mãori. (Enviromental Health Indicators).

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

* The committee noted that the information sheets were generally clear to follow and comprehensive.
* Page 1: in the paragraph where you describe the study drug and what the study involves could be made clearer and simpler. The language is a bit convoluted. E.g Please explain what a placebo is.
* Page 2: Please include the words “in total” in the sentence: “In New Zealand about 20 people will take part at 2 sites”.
* Page 2: the committee noted the statement that the participant will be contacted by telephone every 9 weeks thereafter for “survival follow up” was a bit blunt, and asked that the research team it there is another way of phrasing this.
* Page 3, second to last bullet point: the committee asked whether the tests and signing of extra consent form apply in a New Zealand context. Dr North advised that some regions do but that this statement could be removed from the form. The committee confirmed that it this doesn’t apply in New Zealand then it would like to see the statement removed.
* Page 5, ‘Second course Treatment’: states that participants may be eligible for a second course but it doesn’t say what criteria are. Please advise what the criteria are otherwise it is a somewhat cryptic statement especially when there might be patient demand and issues that relate to long term access are important to note.
* Page 6, What will happen to my blood tissue and urine samples?: the committee noted that the application states differing lengths of time for samples to be retained and this form states 15 years. The researchers confirmed that samples will be retained for 15 years unless participants consent to Future Unspecified Research testing and those samples will be kept for 20 years.
* Page 18, 4 bullet points about the use of health data: please clarify further what data you are using and what the new tests include as ‘health data’ is a generic term. In the main consent form participants can only authorise specified tests and specified research. Anything that is open ended needs to go in the form for future unspecified use. In other words participants must consent to two different things.
* Page 18: the committee noted the statement that “Your permission to use and share health data about you will end 50 years from the date you sign this document.” This information would be best placed in the FUR information sheet and please clarify the 50 year timeframe.
* Page 18: the committee noted the statement that participants may “take away your permission to use and share health data about you at any time by writing to the study doctor”, and asked that the form state that participants can “inform” rather than “write” to their study doctor as they are not required to give notice in writing.
* Page 22: please removed the provision for a legally authorised representative to consent as in New Zealand the legal requirement for participants in research is that they must consent for themselves.
* Please make clear in the main information sheet and consent form that biopsies will be sent overseas and that Mãori might have concerns about their tissue being sent overseas.
* Future Unspecified Research forms: Minimum information standards for future use are specified in “Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes.” Please review the HDEC secretariat pro forma which is on the website for suggested wording about Mãori views about their data going overseas. <http://ethics.health.govt.nz/>

Decision

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

* Please amend the information sheets and consent forms, 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 Peter Gallagher and Dr Angela Ballantyne.

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| **6** | **Ethics ref:** | **16/CEN/34** |
|  | Title: | Older people in retirement villages: unidentified need & intervention research |
|  | Principal Investigator: | Professor Martin Connolly |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 10 March 2016 |

Professor Connolly 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 thanked the researcher for resubmitting this application and for addressing the committee’s main concern about recruiting non-consenting participants and resubmitting to indicate that they will recruit only people who are able to consent for themselves.
* The committee noted the answer stated at question a.1.6 on page 4 of the application form that it is possible that some residents who initially have capacity to provide consent will develop cognitive impairment during the study that impairs their capacity and they will inform the participant’s EPoA and next of kin about wanting to continue to collect data.
* The committee noted that anybody who is competent can make an advance directive to make a choice about a future health care procedure (Right 7(5) of the Code). The Code extends to research (Right 9). So participants who are fully informed could consent while competent to continue in the study once incompetent and that this would be legally binding. The committee asked the researcher to include provision for this in the participant information sheet and consent form.

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

* Please include a study title in the participation information sheet and consent forms.
* Page 1, ‘What will it involve?’: please give an example of what kind of questions will be asked in the questionnaires. The researcher explained that in the pilot study participants were given the options of: filling in the questionnaire by themselves or with an investigator and almost all chose to have an investigator do it with them. It is likely that this will be more of a chat than a questionnaire. The committee noted that the researcher could explain this in the participant information sheet and give an example question.
* Page 4: please remove reference to Ethics Chair Helen Walker and replace with reference to the Health and Disability Ethics committees.
* Information sheet for General Practitioners, ‘What happens if your patient takes part?’: please remove the sentence “If the resident lacks capacity, their guardian/NOK/EPOA will be asked to sign a consent form”.

Decision

This application was *approved* by consensus.

Non-standard conditions.

* Please amend the information sheets and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies, para 6.22)*

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| **7** | **Ethics ref:** | **16/CEN/35** |
|  | Title: | (duplicate) ALS-8176-510 |
|  | Principal Investigator: | Dr. James Taylor |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 10 March 2016 |

Dr James Taylor and Mrs Marina Dzhelali 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 thanked the researchers for resubmitting this application and for coming in person to talk to the committee. The committee noted that in the initial review it was concerned about how sick this group of participants will be and whether or not they can consent for themselves. The researchers advised that they are not intending to recruit patients admitted to ICU but rather from general medical units in hospital. The patients will be able to talk, respond and understand written information. If their illness happens to progress while they are in hospital and they go to ICU the researchers will keep them in the study but will not recruit at ICU stage.
* The committee queried the initial high dose rate in this population given that RSV is predominantly a childhood condition. The researchers explained that there is new data emerging to suggest effectiveness in adults. The researchers noted that this is an older population (over 50s) and they may not respond in the same way. If data suggests no drop in viral load then they might revisit trial design and extend the dosing timeframe in that case and would submit an amendment to the committee for review. The committee asked that the researchers take out reference to a longer dosage time in the participant information sheet.
* The committee noted that the diagnostic and main participant information sheets look the same and queried whether the diagnostic information sheet is just for the diagnostic test or whether the researchers want to do anything further with the samples. The researchers confirmed that the test will be diagnostic in nature only to test for RSV and will not give a broader diagnostic range.
* The committee asked whether the nasal samples will be used for future unspecified research. The researchers advised that the nasal sample will be used for diagnostic purposes only and if patients do not have RSV then they will not be eligible for this study.

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

* Please refer to the drug as “study drug” rather than repeating the drug’s name.
* Page 2: Please state main inclusion/exclusion criteria given in the application form at question f.2.1 on page 28 such as: over 50 years of age, RSV positive.
* The researchers clarified for the committee that participants will have three options for out-patient assessment: ideally patients will be able to come in and have an assessment, if they can’t come in then nurses will go to their home but if neither of those can happen then the nurse will phone the participants. Page 2, ‘Study Procedures’: please state that patients will have three options and then you won’t need to repeat. Day three only. Day three to six.
* Page 7, ‘What are the Possible Benefits of this Study?’ The committee noted that a lot of detail is provided in this section and queried whether that level of detail is needed. The committee noted that in the application form the researchers state that there are some benefits and this is much clearer and more concise. Because participants are randomised it is not known whether the study drug will work or not, there has been some benefit and the researchers are hopeful that this will work for you.
* Page 7, ‘What are the Risks and Disadvantages of this Study?’: Side-effects in humans please reduce the amount of information here. You might remove the information about breakage of chromosomes for example. There is some human data 1 month to 1 year and no significance and some evidence of low platelets but not significant. Please remove the information about animal studies if you have data in healthy volunteers and in children. The researchers explained the sponsor’s point of view of disclosure about potential side effects. The committee however recommended that the level of detail is removed.
* Page 11, ‘Who pays for the study?’: please remove reference to reimbursement for meals as in-stay hospital patients receive meals as a matter of course.
* The researchers confirmed that they are not going to retain the diagnostic nasal sample taken for future unspecified research.
* Pregnant Partner: consent for pregnancy testing & appropriate follow-up: the committee noted that mothers cannot consent for the use of health information related to the baby until the child is born as the baby is legally considered a person once born.
* Page 12, paragraph 6: the committee noted the statement that participants may *“ask for correction or to block personal data”* if it is inadequate or incomplete or is not being processed in compliance with the applicable regulatory requirements. The committee asked how this could be done given that the data will be de-identified.
* Optional study Participant Information Sheet: page 2, ‘What will my participation in this study involve?’ The first sentence has been repeated. Please remove the double-up sentence.
* Page 3: some of the content and heading have merged so please separate this out.

Decision

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

* Please amend the information sheets and consent forms, 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 Dr Patries Herst and Dr Cordelia Thomas.

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| **8** | **Ethics ref:** | **16/CEN/36** |
|  | Title: | TRK-450-0203: A study of Faldaprevir, TD 6450, and Ribavirin in patients with chronic HCV Genotype 1b |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Clinical Network Services (CNS) Ltd |
|  | Clock Start Date: | 10 March 2016 |

Prof Gane and Mrs Carolyn Harris 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 answer given at question r.2.2 on page 17 of the application form stated that the ethics committee will have access to the study records. It was explained that regulatory agencies don’t normally have access to this information but could through audit purposes. The ethics committee would need to see such information if there was a challenge.
* The committee noted the answer given at question r.2.3 on page 17 of the application form about participants being identified by a number during the study and queried how de-identification of the identification of patient data after the study as stated at questions r.2.4 and r.2.4.1 was going to occur. Prof Gane explained that research files will not have patient names but will have screening numbers and may include date of birth and initials. Data from the actual study is only identified by numbers which are produced randomly, and initials and date of birth.
* The committee noted that the answers stated at questions p.4.1 and f.1.2 were at variance. Question p.4.1 stated that Mãori are “particularly affected by this condition” and question f.1.2 stated that Mãori have the same incidence as non- Mãori. The researchers noted that incidence is the same and the committee suggested, for future reference as the form cannot be amended, that the word “particularly” should have been removed.
* The committee reminded the researchers that questions f.1.2 on page 25 is looking for statistics on population groups other than Maori and pakeha in NZ.
* The committee noted that p.4.2 describes better the aspects of the treaty that we need to consider but noted that the terms ‘Tapu’ and ‘Taonga’ are two quite separate terms with different meaning. The researchers asked for an explanation about the use of ‘Taonga’ in clinical research. The Committee advised that the term Taonga in Mãori is used to describe things of a high value or treasure by Mãori and that can be tangible or intangible. Mãori consider knowledge and information around whakapapa and health information to be Taonga. The term Tapu is something quite separate and is used to express the sacredness of something. Tapu and noa are used in regard to safety and keeping people safe.

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

* Optional pregnant partner data release form: the committee noted that consent to data on the outcome of a pregnancy is being sought but that any health information about the baby cannot be consented for until after the baby is born as legally the child is not a person until he or she is born.
* The committee asked that the researchers remove any reference to consent being signed by a partner’s legal representative as in New Zealand only the participant themselves can sign consent to participate in a study.
* Prof Gane explained that the request for data on the outcome of a pregnancy is related to teratogenicity of the drug. First bit about term is information about the mother and information about baby can only be done when baby is born. The committee requested that the researchers seek an additional signature for this data once a baby is born and that they add a sentence saying that they need to seek consent again once baby is born.

Decision

This application was *approved* by consensus.

Non-standard conditions.

* Please amend the information sheets and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies, para 6.22)*

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| **9** | **Ethics ref:** | **16/CEN/37** |
|  | Title: | Tangible interaction with everyday objects for home-based upper-limb stroke rehabilitation Tangible interaction with everyday objects for home-based upper-limb stroke rehabilitation Tangible i |
|  | Principal Investigator: | Miss Mailin Lemke |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 10 March 2016 |

Miss Mailin Lemke and Dr Brian Robinson 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 scientific peer review documentation submitted with this application and discussed whether it considered the review to be sufficient. The committee noted that the document does not allow the committee access to what the peer reviewers assessed. The researcher confirmed for the committee what was assessed as part of the peer review. The committee agreed that they would accept the documentation submitted in this case given the relative low risk involved in this study.
* The committee asked the researchers how they are planning to recruit participants to this study. The researchers advised that they will recruit via physiotherapists who are treating patients. The researchers will give their details to the physiotherapists and if patients are interested in being in the study the physiotherapists will forward the researchers contact details to the potential participants. The researchers confirmed that the physiotherapists will not release patient information to the researchers.
* The researchers confirmed for the committee that when they go to the participants’ homes, one person will interview and two others will photograph the participants using the device. The researcher advised that in a related application, 15/CEN/5, the committee noted that it was not appropriate for the researchers to go alone to people’s homes. The committee asked the researchers whether any members of the team that will go to people’s homes have any clinical expertise or background. The researchers confirmed that they will be design students who do not have such expertise. They do however, have a plan in place to provide education to the students from competent people about how to be culturally sensitive when in peoples’ homes.
* The committee asked what the researchers intend to do in the event that participants ask them for advice about rehabilitation or stroke. The researchers stated that they would ask the participant to contact their GP as they acknowledge that they can’t give medical advice. The committee was reassured that they have a plan to deal with this responsibly and asked that they include in the participant information sheet, agreed names of people to contact and the process to follow.
* The committee noted that the researchers had discussed how stroke survivors are likely to suffer from physical and cognitive limitations and impairments caused by their stroke (application question b.1.2, page 10). The committee asked how the researchers will be sure that the people they will work with are competent to give consent. The researchers explained that it will be made clear that physiotherapists will only refer people who are competent. The study protocol sets out that people who are not competent to make a decision about their participation in the study will not be eligible to take part.
* The researchers clarified the study methodology for the committee. They will first interview participants in their homes and then take photos of the participants in their homes and document daily living activities. They will then give the participants the prototype to use and they will supervise this use. The committee noted that one of the participant information sheets stated that the participants could use the prototypes for as long as they like and stop at any point and the committee asked whether this meant that the researchers will leave the prototypes with the participants to use unsupervised. The researchers clarified that the participants can use the prototype for up to 30 minutes but can’t keep them at home. The committee was reassured that participants would use the prototypes for up to 30 minutes under supervision. If the researchers had intended to leave them in the house then there would be more risks involved.
* The committee noted the answer given at question p.4.1 on page 20 of the application form. The question asks researchers to describe whether and how the study may benefit Mãori. The committee advised that the answer should include incidence and prevalence (statistics) of the disorder under study (or treatment indication if a drug trial) in Mãori. Some disorders are particularly important for Maori health, while others are relatively rare in Mãori and may have less of an impact. If the impact of treatment or prevalence of disease is low or the same as other populations please state this clearly to the Committee. Generally, any available statistics relating to Maori should be provided where possible.
* If relevant, please include information on how you would ensure that Mãori benefit at least equally (and actually how they can disproportionately benefit if they are disproportionately represented) –for example, what extra measures if any are in place to ensure Mãori participation (iwi consultation, Mãori researchers, active follow up etc.) as well as interpretation of results and presentation of findings back to those consulted.
* The committee noted that it had seen recent statistics that show Mãori are three times as likely to suffer from stroke and often return home to whanau rather than an institution for care. It would have been interesting to state information around differing cultural attitudes.
* The committee noted the answer stated at question r.2.5 on page 16 of the application form that the researchers will store health information from this study for 5 years. The committee reminded the researchers that health information retained in this study must be stored for 10 years as per The Health Regulations 1996.
* The committee noted the answer of ‘no’ stated at question r.5.2 on the application form that asks about potential conflicts of interest. The committee noted that designing a device and assessing one’s own intervention could affect how the researcher gathers and interprets the data and this could create a potential conflict of interest.

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

* The researchers confirmed for the committee that the same participants will be asked to do all three parts of the study and the committee recommended that it would be easier for participants if the researchers set out all three parts of the study in one participant information sheet instead of having three separate sheets. The committee noted that one sheet rather than three might help the participants make a decision about whether to take part as they can read about the study in one document. The consent form could provide the option for participants consent to do one, two or all three parts of the study.
* The committee asked that the researchers review the document and replace some of the more technical language with plain English. For example, use diary and disposable camera rather than ‘cultural probes’.
* Please include specific contact details for a Mãori support person. The researchers advised that they had been in touch with whanau support services and have the details of a support person who they can include in the participant information sheet.
* The committee noted that information stated about what will happen to data, information and images for participants should they decide to withdraw differs between the participant information sheet and consent form. The participant information sheet states that any data, information and images will be destroyed and the consent form states that the information collected about participants up to the time they decide to withdraw may continue to be processed. Please decide which of the two options will apply and make this consistent across both the information sheet and consent form.
* The committee noted that the researchers had stated that they would seek consent from participants to inform health practitioners with responsibility for their health care that they are taking part in the study but that they have not asked for participants’ permission to do so on the consent form. Please include this as an option on the consent form if you intend to seek such consent from the participants. The committee believed that it would not be necessary to inform the health practitioners in this study.

Decision

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

* Please amend the information sheets and consent forms, 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 Dr Melissa Cragg and Dr Angela Ballantyne.

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| **10** | **Ethics ref:** | **16/CEN/38** |
|  | Title: | STI Partner notification study: Stage 2 |
|  | Principal Investigator: | Dr Sally Rose |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 March 2016 |

A/Prof Sue Pullon 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 Angela Ballantyne declared a potential conflict of interest, and the committee agreed that she would not take part in the discussion or decision making for this application.

Summary of ethical issues

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

* The committee sought clarification about who this research is targeted at. A/Prof Pullon stated that the participants are health professionals working in primary care practices the intervention is targeted at them in first instance. The health professionals are provided with a method of advice for those diagnosed with an STI. The two main reasons for doing this study are to aim to stop reinfection and secondly to reduce the health burden of STIs in the community at large.
* Training intervention for practices – algorithm diagram test two models. One involves services of expert health advisor and the other to train practice nurses to deliver notification to patients. Patients who visit health care practices are getting best practice care anyway and in this study the researchers are looking to remedy a deficiency in standard care.
* A/Prof Pullon confirmed for the committee that the health practice professional will always get consent of the patient before they approach the patient’s partner/s. The first step is for the health practice professional to contact the patient and there will be no anonymous contacting of the partner/s. The health practice professional will work with patients to advise them of a number of ways of helping them to contact their partner/s.
* The research team already has HDEC approval for the audit of clinically held data that has been completed.
* The committee queried the fact that text messages will be sent to patients to remind them and A/Prof Pullon advised that no clinical information will be sent in the text messages – the text message will simply be a request for the patient to contact the clinic. A/Prof Pullon noted that it is usual practice to ask how people how they wish to be contacted.
* The committee queried what the health practice professional will do if a patient says no to to contacting their partner/s. A/Prof Pullon noted that all they can ask is that they consider contacting but the patient is at liberty to say no. The health practice professional will try to point out advantages of doing so for themselves and for others.

Decision

This application was *approved* by consensus.

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| **11** | **Ethics ref:** | **16/CEN/42** |
|  | Title: | A Trial of Transcranial Magnetic Stimulation in Treatment-Resistant Depression |
|  | Principal Investigator: | Dr. Nicholas Hoeh |
|  | Sponsor: | Auckland District Health Board |
|  | Clock Start Date: | 10 March 2016 |

Dr Hoeh 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 if found it interesting to read about a study that is trialling potential treatment that is not a drug for major depressive order. The committee noted that the treatment is FDA approved, is low risk but with potential high benefit.
* The researcher noted that there is excitement among the lay public about such treatment in the neuro modulation domain with this potential but the machines are expensive and in running the machine takes technical knowledge and skill to minimise any risk.
* This is a feasibility study introducing the potential treatment in NZ. NZ is overdue for a new treatment for depression and it is hoped that this treatment might lead to a new option for these patients.
* The committee noted that the researchers have stated that there is a small chance that participants may experience a seizure while receiving this treatment. The researcher explained that in this study they will screen out those with higher risk of seizure. The researcher noted that the risk overall in the general public is low (1 in 1000) but that they need to be prepared in case it does happen and to inform people of the risk.
* If a participant were to experience a seizure it would be likely that this is while they are on the machine and supervised by a clinician. The participants will not be on medications that would increase the risk of seizure happening. The researchers will make this call after talking with the participants about what medications they are taking.
* The committee complimented the researcher on the way question p.4.1 in the application form was answered.

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

* Page 4: The committee complimented the researcher of the use of a study timeline and asked that the font size be increased to increase readibility.
* The committee recommended including information about what participants might do if they start to feel unwell again following the treatment. It is helpful to remind participants that they can seek assistance in the event that their depression returns.
* Page 6, first bullet point: please replace the word “throughout” with “during”.
* Please include the names of any high risk medications that might mean that a person is not eligible to take part in this study.

Decision

This application was *approved* by consensus.

Non-standard conditions.

* Please amend the information sheets and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies, para 6.22)*

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. Application 16/CEN/25: in discussion around a short consent form that is signed by the participants and interpreter the Committee noted that if it is a generic form in child cancer research then it doesn’t need to see it as it is only approving documents related to the study and agreed that this could be added as an issue to discuss at the next HDEC Chairs’ day.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 26 April 2016, 12:00 PM |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington, 6011 |

The meeting closed at 5pm.