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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 24 March 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 24 February 2015 |
| 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  2.35-3.00  3.00-3.25  3.25-3.50 | i 15/CEN/29  ii 15/CEN/27  iii 15/CEN/26  iv 15/CEN/25  v 15/CEN/28  vi 15/CEN/32  vii 15/CEN/33  viii 15/CEN/34 |
| 3.55pm | General business:   * Noting section of agenda |
| 4.15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Gael Donoghue | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Apologies |
| Dr Nicola Swain | Non-lay (observational studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Dr Dean Quinn.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Dr Nicola Swain confirmed her eligibility, and was co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 24 February 2015 were confirmed subject to the following amendments:

Page 12, final bullet point: please change *“The Committee is satisfied with legal consultation that researcher has been sought”* to *“The Committee is satisfied that legal consultation has been sought”.*

## New applications

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| **1** | **Ethics ref:** | **15/CEN/27** |
|  | Title: | Long term follow-up registry of subjects with chronic Hepatitis B |
|  | Principal Investigator: | Prof Ed Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 12 March 2015 |

Prof Gane, Dr Christian Schwabe and Ms Rebecca Hu 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 study

* This study will evaluate treatment previously received in a Gilead trial for Chronic Hepatitis B, as a long term follow-up registry of these patients. The researchers will look at a particular biomarker to see whether after treatment the patients recovered.

Summary of ethical issues (resolved)

* The committee noted the answer given at question b.1.4.1 on page 11 of the application form which suggested that this is an intervention study when it is in fact an observational one. The researchers acknowledged that the information was entered in error.
* In regard to a request for further comment about scientific peer review, prior to the meeting, Dr Schwabe noted that a similar letter was submitted for other related/similar studies and stated that he was surprised that the committee is seeking more comment. Dr Schwabe explained that the study went through cross functional review and that the researchers have assurance that this is a scientifically valid protocol. The committee stated that it did not doubt the validity of the review. The committee noted that one of the criteria of scientific peer review for ethics committees to consider is that it offers an independent opinion from an expert in the field. The committee suggested that it could come from a colleague who can comment on the protocol. Prof Gane offered to contact a colleague who could offer peer review. The committee noted that the HDEC website has a peer review template that the researchers may wish to use.
* The committee noted for future reference that it would like to see any known statistics in respect of Māori set out in summarised form at question p.4.1 that asks whether and how a study may benefit Māori. The committee noted the same request for question f.1.2 that relates to how a study might contribute to reducing inequalities in health outcomes between Pacific peoples and other New Zealanders.
* The committee complimented the researchers on their use of graphs and flow charts in the participant information sheet.

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

* The committee noted that the information sheet and consent form require a quality review for typographical errors.
* The committee requested that the researchers include two further exclusion criteria listed at question f.2.1 on page 23 of the application form: that they can’t be participating in or planning to participate in another clinical study and that they can’t have a history of a clinically-significant illness or any other major medical disorder that may interfere with the study requirements.
* Please include the following clause in the consent form: *“I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.”*
* The committee noted the answer given at questions b.4.5 on page 13 of the application form that tissue collected in this study will be made available for future research. The committee reminded the researchers of the requirement for consent to future unspecified research to be separate from consent to the main study and asked that the researchers submit a separate participant information sheet and consent form for this optional aspect of the study in accordance with the requirements set out in the *2007 Guidelines for the Use of Human Tissue for Future Unspecified Research*.
* The committee noted the answer given at question Mc on page 4 of the application form stated that the application involved the establishment or maintenance of a tissue bank and asked the researchers for clarification on whether they will set up a tissue bank or keep collected samples until the end of the study. The researchers confirmed that they will keep samples for up to 15 years after which time the samples will be destroyed. The samples will be stored at Gilead in California. Page 4 statement that is ‘yes’ is incorrect. Tissues will be stored in Gilead in California. The committee noted that the optional PIS/CF for future research needs to state that tissue will be stored overseas at Gilead for 15 years.

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 Observational Studies* *para 6.10*).
* Please provide a separate participant information sheet and consent form for future unspecified research (*2007 Guidelines for the Use of Human Tissue for Future Unspecified Research*).
* Please provide evidence of peer review of this study’s protocol from an external peer reviewer. You may wish to use the peer review template from the HDEC website: <http://ethics.health.govt.nz/>

This information will be reviewed, and a final decision made on the application, by the Chair, Ms Gael Donoghue and Mr Paul Barnett.

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| **2** | **Ethics ref:** | **15/CEN/29** |
|  | Title: | Study Evaluating GS-6615 Pharmacokinetics in Subjects with Normal and Impaired Hepatic Function |
|  | Principal Investigator: | Prof Ed Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 12 March 2015 |

Prof Gane and Ms Mary Ellis-Pegler 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 study

* The committee noted that this is a fairly straightforward non therapeutic study that will look at how the study drug behaves in two different sample groups. 84 participants will be recruited internationally and the researchers intend to recruit 10 people from New Zealand.

Summary of ethical issues (resolved)

* The committee had no major ethical concerns.
* The committee noted for future reference that it would like to see any known statistics in respect of Māori set out in summarised form at question p.4.1 that asks whether and how a study may benefit Māori.
* The committee commended the researchers on their use of diagrams and charts in the participant information sheet and consent form noting that they can be of particular help for people who may have a low level of literacy.

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

* Please include a lay title.
* Please state upfront that participation in this study is voluntary.
* Page 5 under the title ‘What are the possible risks of being in this study?’: please indicate how likely participants are to experience the side effects listed (from most likely to least likely).
* Please include the following inclusion criteria from question f.2.1 on page 25 of the application form: ages 18-65 years with Body Mass Index (BMI) range of 18-36.
* Page 10 under the title ‘Who can you contact for more information about this study?’: the committee requested separate contact details be included for a Māori support person. The researchers advised that Māori can receive advice via the HDC number listed. The committee agreed that if the researchers could guarantee that this is the case then the one number is acceptable.
* Page 12 under the title ‘Are there any cultural considerations?’: please add that tissue samples are being sent overseas and where they will go as this is an issue that some Māori may wish to consider before consenting to the study.
* Page 12 under the title ‘Do I have to decide straight away?’: please specify how long participants have to consider the information before making a decision.
* Consent forms – lacking in terms of template that is available. Consent form needs confidentiality clause as well as HDEC.

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, Dr Nicola Swain and Mrs Sandy Gill.

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| **3** | **Ethics ref:** | **15/CEN/26** |
|  | Title: | Pediatric Vasculitis Initiative or PedVas |
|  | Principal Investigator: | Dr. Arno Ebner |
|  | Sponsor: | University of British Columbia |
|  | Clock Start Date: | 12 March 2015 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

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

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

Summary of the study

* This is a reapplication of a previously declined application, 14/CEN/188. The study is observational, will be carried out over three years and will recruit two participants in New Zealand.
* The committee reviewed the researchers’ response to the previous decline letter and noted that they have made a concerted effort to address the committee’s concerns.

Summary of ethical issues (resolved).

* The committee had no major ethical concerns but agreed that some work was still needed on the participant information and consent and assent forms before it would give ethical approval.
* The committee noted the answer ‘no’ given at question p.1.8 on page 21 of the application form and noted that this may have been in error as participants will give informed consent or assent to take part in the study.
* The committee discussed the number of participants the researchers intend to recruit to this study (2) and the likelihood of participants being Māori and agreed that it would be unfair to suggest that the researchers go through a full Māori consultation process. The committee noted that the researchers had addressed cultural issues at questions p.4.1 and p.4.2 of the application form.

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

* Please check Arno Ebner’s email address and make it consistent across all documents.
* Please state how many study visits participants will be asked to make.
* The committee noted the answer ‘no’ given at question p.1.7 on page 21 of the application form that some non-consenting participants could become eligible to consent during the study. Some participants may reach the age of 16 during the study. Please prepare a further information sheet so that these participants can then consent for themselves once they reach the age of 16.
* Please include the statement that participants are free to talk about the study with other people, such as family, whānau, friends, or healthcare providers before they decide whether they will consent. Please also include the statement that recognises that different cultural views may inform choice about donation of tissue; for example, for some Māori, human tissue contains genetic material that is considered to be collectively owned by whanau, hapu and iwi. Cultural concerns may arise with tissue samples are sent overseas, including how tissue samples are stored and disposed of. The donors may want to discuss the issue of donation with those close to them, for example; family, whanau, hapu and iwi.
* The committee noted that tick boxes on the consent form should only be in place for statements that are truly optional. Please remove all tick boxes that are for statements that are not optional.

Patient information and assent form for children aged 5-7:

* Please include the words “Participant Information Sheet” in the information sheet header.
* Please review for consistent use of first person tense.
* Page 3 of 5: please replace “has given informed consent” with “has given informed assent”.
* Please review the document and replace the word “Mom” with “Mum”

Optional Patient information and assent form for children aged 5-7

* Please include the words “Participant Information Sheet” in the information header.
* Page 5 of 5: please replace “has given informed consent” with “has given informed assent”.

Patient information and assent form for children aged 8-15:

* Page 1: under the heading ‘What will happen if I agree to take part in this study?’, 4th bullet point. Please add missing words after “vasculitis”.
* Page 2: under the heading ‘Who do I contact for more information or if I have concerns?’ please include contact details for a Māori support person.
* Please review the document and replace the word “Mom” with “Mum”

Optional Patient information and assent form for children aged 8-15

* Please add the words “Participant Information Sheet” in the information sheet header.
* Page 5: under the heading ‘Who will know what I did in the study?’ Please replace the word “secret” with “private”.
* States that researchers are going to keep tissue as long as possible. R.3.11 storage by research team as part of new tissue bank. Even if kept for a long time they should be specific. Please give a number of years. Give option of child withdrawing their samples when they reach age of consent.

Patient information sheet for teenagers/young adults aged 16 to 20

* Page 2: under the heading ‘What if something goes wrong?’ Please replace “I would be eligible..” with “I may be eligible..”
* Page 2: under the heading ‘Who do I contact for more information or if I have concerns?’ please include contact details for a Māori support person.

Optional Patient information sheet for teenagers/young adults aged 16 to 20

* Please clarify why you have used “children” in the title instead of teenagers/young adults aged 16 to 20. If this was entered in error please correct the title and change the file name in the footer.

Optional Consent Form for the Use of Tissue for Future Unspecified Research (for Parents)

* Please include the following confidentiality clause: *I understand that my child’s participation in this study is confidential and that no material, which could identify my child personally, will be used in any reports on this study.*
* Please make this a separate form as it is currently part of the main participant information sheet and consent form document.
* Please clearly state that individuals who are aged 16 and above can legally consent for themselves.

Participant Information sheet for Parents/Caregivers

* Page 3: under the heading ‘What if something goes wrong?’ Please replace “I would be eligible..” with “I may be eligible..”

Decision

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

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

This information will be reviewed, and a final decision made on the application, by the Chair, Mrs Gael Donoghue and Dr Cordelia Thomas.

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| **4** | **Ethics ref:** | **15/CEN/25** |
|  | Title: | Efficacy and safety of riociguat in patients with symptomatic pulmonary hypertension associated with idiopathic interstitial pneumonias (IIP)/RISE-IIP |
|  | Principal Investigator: | Professor Lutz Beckert |
|  | Sponsor: | Bayer New Zealand Limited |
|  | Clock Start Date: | 12 March 2015 |

Prof Lutz Beckert 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(resolved)

* The committee noted that it agrees that this is a worthwhile study for a group of patients for whom current treatment offers little. The study will take part in three phases and the application states that all participants will be able to take the study drug after the main study is completed.
* The committee noted that the participant information sheet states that in the extension phase of the study all participants will receive the study drug until it receives official approval and is commercially available. The committee asked how likely it was that New Zealand would receive official approval. Prof Beckert explained that it would be difficult to judge but that the drug is currently available in Australia and it may not be far away from being approved in New Zealand. The committee emphasised that if the researchers make this promise in the participant information sheet then they need to meet that promise.
* The committee noted the requirement for the principal inclusion/exclusion criteria to be in the participant information sheet. The committee was satisfied however that there was nothing in the criteria listed at question f.2.1 on page 28 that would not already be in patient notes.

Summary of ethical issues (unresolved)

* It was not clear to the committee whether an optional genetic study is intended and whether the researchers are seeking consent from participants for future unspecified research on their tissue samples. Prof Beckert agreed to check and confirm these aspects for the committee. The committee advised that if the researchers do want to do future unspecified research that it would like to see a separate participant information sheet and consent form that has information in accordance with the *2007 Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes*.

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

* The committee noted that for a study that involves a significant number of visits and some invasive treatments it is not very lay person friendly. The committee noted the importance of writing for a lay audience and noted that technical language can be off putting. The committee asked the researchers to review the information with this in mind. Some suggestions put to the researchers during the discussion were: including a lay title for the study along the lines of ‘A treatment to reduce a specific type of heart-lung disease’, removing page 1, referring to ‘your condition’ or ‘your lung condition’ rather than (PH) or (IIP).
* Page 8 and 9: the information about data is repetitive in some places. Please revise the information and remove repetition. Please include information about who will see participants’ health information. You may wish to refer questions r.2.2 and r.2.3 on page 19 of the application form as this states who will see the information and explains how it will be kept confidential.
* Page 8 under the heading ‘What are the possible benefits of taking part?’. Please rewrite this section in lay language. The main benefit of this study is that the drug may help participants to manage their breathlessness, the drug has been approved in other countries for similar but different conditions for example.
* Page 9: second paragraph. Please include the word “form” after “informed consent”.
* Page 9 under the heading ‘Blood Samples’: please acknowledge that Māori have special considerations when it comes to the collection, storage and use of tissue samples. Different cultural views may inform choice about donation of tissue; for example, for some Māori, human tissue contains genetic material that is considered to be collectively owned by whanau, hapu and iwi and the donors may want to discuss the issue of donation with those close to them.
* Page 11: please include contact details for a Māori support person.
* Page 16: in headings numbered 3 and 5 please include that data and tissue will be stored “securely” so that patients are reassured that their information will be treated confidentially.
* Page 17: in the heading numbered 6, third bullet point: please replace the word “secrecy” with “privacy”.
* The committee noted the answer given at question p.3.3.1 on page 26 of the application form that participants may be provided with taxi vouchers, parking fees or petrol vouchers to cover expenses on a case by case basis and asked what this means? Prof Beckert explained that people who live outside of Christchurch and need to travel may be reimbursed. The committee noted that this may be relevant for some participants and asked that an explanation that such reimbursement of expenses may be available for people who live outside of Christchurch only.
* There is no statement that records that tissue is being sent overseas. Please clearly state that tissue samples will be analysed overseas and that they will be destroyed at the end of the study.
* Please state that participants will have the opportunity to discuss the information provided with family and whanau. Please include the following statement in the consent form: I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.

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*).
* If you intend to seek consent for future unspecified research on the tissue samples collected, please provide a separate participant information sheet and consent form for future unspecified research (*2007 Guidelines for the Use of Human Tissue for Future Unspecified Research*).

This information will be reviewed, and a final decision made on the application, by the Chair, Dr Patries Herst and Mr Paul Barnett

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| **5** | **Ethics ref:** | **15/CEN/28** |
|  | Title: | Cancer stem cells and receptor signalling in brain and spinal tumours. |
|  | Principal Investigator: | Mr Agadha Wickremesekera |
|  | Sponsor: | Gillies McIndoe Research Institute |
|  | Clock Start Date: | 12 March 2015 |

Mr Agadha Wickremesekera was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The researchers have prior ethical approval to collect tissue samples from patients with tumours for storage at the Gilles McIndoe Research Institute tissue bank. This application is for approval to use the samples to look at a family of proteins (Erbs) in relation to cancer stem cells in four types of tumour (glioblastoma, meningioma, vestibular schwannoma and brain and spinal metastases).
* The committee noted the researchers’ comments that some patients with brain and spinal tumours may be vulnerable due to confusion or other neurological deficits and that particular group of patients may not be competent to consent for themselves. Mr Wickremesekera confirmed that patients who had consented to the storage of their tissue are adults (16 years or older).
* The committee reminded the researchers that the only apparent basis for participation in research by persons lacking capacity is to satisfy Right 7(4) of the Code of Health and Disability Services Consumer Rights. The committee agreed to approve this application on the condition that the researchers give assurance that any tissue used in this study is tissue that has been consented for use by a competent individual only and not tissue that has been consented by next of kin. Mr Wickremesekera gave his assurance that this would be the case.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **15/CEN/32** |
|  | Title: | PLASTIC |
|  | Principal Investigator: | Dr Julie Reeve |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 March 2015 |

Dr Julie Reeve 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 reminded the researchers of Right 7(1) of the Code of Health and Disability Services Consumers’ Rights that: “Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent […]” With this in mind the committee noted that the researchers are intending to conduct the proposed research without seeking consent from participants. The reason for not seeking consent that is stated in the application was that patients will be in a pain medicated state and seeking consent could lead to unnecessary emotional stress and non-consent and the committee was not satisfied that this was a compelling enough reason for consent not to be sought.
* Dr Reeves explained that the additional monitoring they intend to do should be part of standard care and a thorough assessment on a daily basis. However, they can’t currently rely on that as it is not done fastidiously. The only addition to normal care is that the researchers will listen to a patient’s chest, ask them to cough and will monitor oxygen saturation. Dr Reeves explained that they could argue those are things should be done anyway but they can’t say with confidence that they are routinely being done.
* The committee noted that it understands that the study is low risk and observational but that doesn’t seem a reason for not seeking consent. The committee noted that the researchers will do access patient records and do physical tests for this research rather than standard care.
* Difficult emotionally because they may not be fully understanding that what they are doing shouldn’t be part of standard care. The committee noted the need for researchers to explain to participants that they won’t receive any care beyond that of standard care but that the researchers are collecting information and doing the standard tests for the purposes of research. The committee noted that people want to participate in research for various reasons including that they may feel good about contributing and the researchers would be denying them this knowledge by not telling them.
* Some options for seeking consent from participants were discussed including the researchers doing the post-operative monitoring, and seeking consent from participants the next day before they use the data. It could be possible to consent participants after the monitoring so long as records aren’t accessed prior.
* Ways of seeking consent before the operation were also discussed. Dr Reeves explained that patients come in via all sorts of mechanisms and the physiotherapists don’t see patients pre-operatively. Tracking and being able to see in a timely manner is virtually impossible and would make pre-op consent more stressful. The committee suggested that nurses could identify patients for the physiotherapists and could then contact them.
* The committee recommended that the researchers may wish to have a letter for distribution in pre-operative clinic that states that patients may be approached after surgery and what is involved in the proposed research.

Decision

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

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| **Reference** | **Reason for declining** |
| *6.10* | *The NEAC Ethical Guidelines for Observational Studies provide that “investigators should obtain the prior informed consent of study participants (with certain exceptions). The Code of Rights, Right 7(1) states that ‘Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this code provides otherwise”. The committee was not satisfied that the reasons the researchers gave for not seeking participant consent were compelling enough for consent to not be sought.* |

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| **7** | **Ethics ref:** | **15/CEN/33** |
|  | Title: | Periostin 9 |
|  | Principal Investigator: | Professor Richard Beasley |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 12 March 2015 |

Dr Ruth Semprini 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.

* This is a very straightforward application and the committee did not have any major ethical concerns.
* The committee complimented the researchers on providing a participant information sheet that clearly informs patients about what this research involves and also clearly acknowledges cultural issues that may arise in regard to the use of human tissue.
* The committee complimented the researchers on the answers given in the application form in regard to consultation with Māori.
* The committee wished to bring it to the researchers’ attention that the optional participant information sheet and consent form makes no mention of Periostin.

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

* Consent form page 6: please remove the word “that” from the statement “I understand that the compensation provisions in case of injury during the study”.

Decision

This application was *approved* by consensus.

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| **8** | **Ethics ref:** | **15/CEN/34** |
|  | Title: | V89\_18 |
|  | Principal Investigator: | Dr Simon Carson |
|  | Sponsor: | Novartis Vaccines & Diagnostics |
|  | Clock Start Date: | 12 March 2015 |

No member of the research team 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.

* This study will look at developing a new vaccine against a specific strain of bird flu. Two stage two trials are completed and vaccines dose will be trialled for this phase III study. Healthy adults will be randomised in a 3:1 ratio so each participant has a 75% chance of receiving one of the vaccines.
* The safety data for the phase II trials showed relatively minor side effects.
* The committee noted for future reference that it would like to see any known statistics in respect of Māori set out in summarised form at question p.4.1 that asks whether and how a study may benefit Māori. The committee noted the same request for question f.1.2 that relates to how a study might contribute to reducing inequalities in health outcomes between Pacific peoples and other New Zealanders.
* R.2.1 and another are at variance – It was not clear from the information stated in the application form whether participants’ health information will be identifiable or de-identified. Please clarify this for the committee.

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

* The committee noted that the participant information sheet and consent form read well and was clear. It did note some minor changes to the forms however.
* Please state upfront that participation is voluntary.
* Page 9 under the heading ‘What happens when the research project ends?’: please make clear when the study will be concluded. The committee also noted that it may be important for participants to know whether they have been vaccinated against this strain of bird flu at a later date and requested that the researchers also state here that participants be informed whether they have been vaccinated at the end of the trial as this information may be of significance.
* Page 10 under the heading ‘Complaints and compensation’: please state that participants will not be eligible for ACC compensation.
* Page 13: the committee noted that Yes/No tick boxes should be included for statements that are truly an option only. Please review the statements on this page and remove the tick boxes for statements that are not optional.
* Page 14: please remove the statement: “I allow the left overs of my specimens to be used for future research not related to this study”.
* Please refer to your main exclusion and inclusion criteria listed at question f.1.2 on pages 25 and 26 of the application form and include the exclusion criteria of BMI and a history of drug or alcohol abuse.
* The committee noted the information about consent for future unspecified research under the heading ‘What will happen to my test samples?’ on pages 7 and 8 and asked that this optional component of the research be submitted on a separate participant information sheet and that the information in this sheet is in accordance with the requirements set out in the *2007 Guidelines for the Use of Human Tissue for Unspecified Research Purposes.*
* Please remove the following statement from page 14 of the consent form: *“I agree to my blood samples being sent overseas and acknowledge that they may be retained for up to 15 years after which time I am aware that these samples will be disposed of using established guidelines for biohazard waste.”*
* Please acknowledge that any cultural issues that may arise with tissue donation and how they might be managed by participants. For example that they will be given time to consider the information and can consult with whanau hapu and iwi before making the decision to donate tissue.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide a separate participant information sheet and consent form for future unspecified research (*2007 Guidelines for the Use of Human Tissue for Future Unspecified Research*).

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

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 28 April 2015, 12:00 PM |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington , 6011 |

The following members tendered apologies for this meeting.

Mrs Sandy Gill.

1. **Problem with Last Minutes**

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

The meeting closed at 3.45pm