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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 23 July 2013 |
| **Meeting venue:** | Via Teleconference |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 25 June 2013 |
| 12:10pm | New applications |
|  | i 13/CEN/97  ii 13/CEN/100  iii 13/CEN/101  iv 13/CEN/102  v 13/CEN/103  vi 13/CEN/104  vii 13/CEN/105  viii 13/CEN/106 |
| 4pm | General business:   * Noting section of agenda |
| 4.05pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Apologies |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 01/07/2012 | 01/07/2015 | Present via T/C |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2014 | Present via T/C |
| Mrs Gael Donoghue | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2014 | Present via T/C |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Present via T/C |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present via T/C |
| Dr Dean Quinn (Acting Chair) | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present via T/C |
| Dr Lynne Russell | Non-lay (observational studies) | 01/07/2012 | 01/07/2014 | Present via T/C |

## Welcome

The Chair opened the meeting at 12 pm and welcomed Committee members, noting that apologies had been received from Helen Walker. Due to the Wellington earthquakes, the conference was held via teleconference.

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 25 June were confirmed subject to the following amendments:

Page 5 of 14, Adina (add surname of researcher), please insert researcher’s full name

Item 3, third bullet point add “language” after lay.***New applications***

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| **1** | **Ethics ref:** | **13/CEN/97** |
|  | Title: | The TrACY Study |
|  | Principal Investigator: | Associate Professor Sally N. Merry |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 11 July 2013 |

Associate Professor Merry, Dr Karolina Stasiak and Dr Mathijs Lucassen were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee noted that the trial will compare standard treatment with MATCH, a modular CBT programme, in children and young people (7-14) who experience anxiety, depression trauma related symptoms. The researcher explained that the MATCH programme has a strong evidence base but the researchers want to see if this model of evidence based care will work here and in particular whether MATCH works for Māori and Pasifika people. In particular they want to see how it will work with children with more than one symptom/behavioural problem.
* The Committee asked how MATCH (a US programme) will be adapted to a NZ setting? The Researcher said MATCH will be delivered via Kaupapa Māori services and Pasifika services. Māori and Pacific clinicians will work alongside US clinicians to align practices.
* The Committee questioned what MATCH involved from a participant/parent/caregiver perspective as this was not clear from the PIS/CF. The researcher explained that MATCH involves CBT strategies and techniques alongside parent management training.
* The Committee noted that the clinicians will be randomised to delivering treatment.
* The Committee noted that the study has been peer reviewed by the HRC.
* The researcher clarified that there are two PIS for differing age groups and one for clinicians delivering the therapy.
* PIS: parent/clinician section please include exclusion criteria in parent /caregiver PIS.
* The Committee advised the researcher to obtain consent from parents/caregivers in most cases, as well as assent from younger children. The researcher confirmed that they would seek a child’s consent depending on child’s developmental stage, rather than applying a crude age cut off. The researcher agreed that they will seek parental/caregiver consent. The researchers will ensure that they comply with legal requirements when seeking consent.
* The Committee commented that the PIS refers to parents, and many children are not be in the care of their parents (they may be whāngai or be in a foster arrangement). The Committee suggested accommodating this by referring to either: “parents/caregivers” or “people who look after you” (as relevant).
* The Committee congratulated researchers on the readability of the PIS/CF and for the Māori consultation that has been undertaken. The Committee wished the researchers well with their project.

Decision

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

Please make the following changes to the PIS/CF (*Ethical Guidelines for Intervention Studies* *para 6.22*):

* Please explain clearly in the PIS/CF what MATCH is, and what is involved from the participant’s perspective.
* Please amend the PIS to refer to “parents/caregivers” or “people who look after you” (as relevant) as not all children have parents as their primary caregivers.
* Please include information about exclusion criteria, in lay language, in the PIS.
* Please ensure that you obtain assent from younger children.
* Please ensure that you obtain consent from the parents/caregivers of children participating in the study.

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

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| **2** | **Ethics ref:** | **13/CEN/100** |
|  | Title: | An Investigation of Orteronel in patients with Prostate Cancer and Rising Prostate-Specific Antigen |
|  | Principal Investigator: | Dr Shaun Costello |
|  | Sponsor: | PPD Global Ltd (NZ Branch) |
|  | Clock Start Date: | 11 July 2013 |

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.

* At P.4.1 of the application the researcher states that there have been no studies looking at incidence of prostate cancer in Māori males. The Committee notes that the Ministry of Health publishes information about cancer incidence broken down by ethnicity.
* The Committee commended the researcher for producing a well prepared application.
* The PIS should state the time commitment for visits and screening visits.
* The researcher needs to justify why they will plan to exclude people who cannot speak English?
* Committee noted that there is a consent form for main study and additional research for blood samples. The Committee noted that tissue samples will be sent overseas.
* The separate PIS/CF for future use of tissue should be headed with “Optional”
* The Committee noted that the study has been peer reviewed and that it will also be reviewed by SCOTT
* PIS – please delete the word “alternatively” in the consent form as participants may want a copy of results and/or may also want to discuss the study results with the researcher.
* Please list the exclusion criteria in the PIS in lay language.
* The researcher needs to upload evidence of personal indemnity insurance
* Please provide copies of any questionnaires that will be administered

Decision

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

1. The PIS should state the time commitment involved in all visits as part of the study (including screening visits) (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. Please justify why you plan to exclude people who cannot speak English?
3. Please outline for the Committee how a person who is not fluent in English would be identified. Some cultures would not acknowledge that they are non fluent, and also appear to understand, and/or also be unable to recognise that they are in fact excluded from the study if they are unable to read and completely understand the information given to them.
4. The separate PIS/CF for future use of tissue should be headed with “Optional” (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
5. PIS – please delete the word “Alternatively” in the main PIS as participants may want a copy of results and/or may also want to discuss the study results with the researcher (*Ethical Guidelines for Intervention Studies* *para 6.22*).
6. Please list the exclusion criteria in the PIS in lay language (*Ethical Guidelines for Intervention Studies* *para 6.22*).
7. Please upload evidence of personal indemnity insurance.
8. Please provide copies of any questionnaires that will be administered.

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

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| **3** | **Ethics ref:** | **13/CEN/101** |
|  | Title: | Topical vs intravenous tranexamic acid in total knee arthroplasty |
|  | Principal Investigator: | Dr James Aoina |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 July 2013 |

Dr James Aoina was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee noted that the peer review provided was all internal to BOPDHB. The Committee would like to see evidence of independent peer review. The HDEC Secretariat will provide link to NEAC guideline on this
* The Committee noted that all participants will be adults.
* Health information needs to be retained for 10 years not 5.
* Questions p.4.1 and p 4.2 were not answered well. For future reference, please see below two examples of more compliant answers to these questions:

**p.4.1.** Please describe whether and how your study may benefit Māori.

The proposed research process is consistent with the provisions of the Treaty of Waitangi, in that Māori have equal access to participation in the study as non-Māori. Māori health services will have the opportunity to review and comment on this study. All potential participants will be given as much time as they require to enter the study, including to discuss the research with whānau. The Treaty of Waitangi acts as a mandate for equal rights and therefore by extension, access to healthcare for all New Zealanders and health research is an integral part of this.

This study is an early phase, nontherapeutic trial and as such will not directly benefit Māori. Should the study drug prove a viable new therapy, Māori patients with psoriasis may potentially benefit.

**p.4.2.** Please identify the main cultural issues that may arise for Māori who may participate in your study, and explain how these issues will be managed. *If Māori will be excluded from participating, please state this. You will be asked to explain your inclusion/exclusion criteria in the next section of the Form.*

The main cultural issues are the collection of tissue samples and health information, which are considered by many Māori to be tapu taonga belonging to tāngata whenua so shouldn’t be removed or handed on without their approval. Māori subjects will be informed specifically regarding the storage, testing and destruction of tissue samples and information. They are encouraged to consult with whānau before entering the study. In this way they are able to make informed decisions regarding participation and consult with the right groups about how the study may affect their cultural beliefs.

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| **p.4.1.** Please describe whether and how your study may benefit Māori.  Cardiovascular disease (heart, stroke and blood vessel disease) is still the leading cause of death in New Zealand, accounting for 40% of deaths annually, thus it has a large impact on the delivery of health services. Ischaemic heart disease was the second leading cause of death after cancer in 2007. Māori had a higher proportion of deaths in the 45–64 year old age group than nonMāori. The gap in life expectancy between Māori and non Māori in New Zealand increased over the period 1980–1999. Most notably, the slow decline in Māori cardiovascular disease (CVD) mortality rates over this period contrasted with the rapid decline in non Māori rates. As a consequence, CVD remains the major contributing cause to the widening life expectancy disparity between Māori and non Māori people in New Zealand. (The New Zealand Medical Journal, 02March2007, Vol 120 No 1250) As this study seeks to improve outcome for patients with Coronary Artery Disease, Māori will benefit.  **p.4.2.** Please identify the main cultural issues that may arise for Māori who may participate in your study, and explain how these issues will be managed. *If Māori will be excluded from participating, please state this. You will be asked to explain your inclusion/exclusion criteria in the next section of the Form.* [< 1200 characters]  The main cultural issues are the collection of tissue samples and health information, which are considered by many Māori to be tapu/taonga and belonging to tangata whenua so shouldn’t be removed or handed on without their approval. Māori subjects will be informed specifically regarding the storage, testing and destruction of tissue samples and information. They are encouraged to consult with whānau before entering the study. In this way they are able to make informed decisions regarding participation and consult with the right groups about how the study may affect their cultural beliefs. |

* The Committee would like to see evidence of Māori consultation.
* The PIS needs a footer.
* The Central Ethics Committee should be specified in the PIS rather than ‘the Health and Disability Ethics Committee’.
* The researcher needs to explain in the PIS whether, and if so, how, tissue will be disposed of at the end of the study.
* PIS, p 2 – Please state “you will be asked standard medical questions” rather than “you will undergo standard medical questions”.
* PIS p 3 – ACC cover – Please reword to state that participants “may” be eligible for ACC cover rather than that they “would” be eligible for cover.
* PIS, page 2 bottom of page: states “there will be no difference in your clinical care”. Please qualify this by adding “in respect of your knee joint replacement”.
* Please state exclusion criteria in lay language in the PIS.
* The PIS needs proof reading to correct minor errors.
* At the start of the consent form, there should be an option to access an interpreter provided.
* As samples will not be sent overseas in this study, please remove reference to this in the consent form.
* The researcher needs to add the title of study to the beginning of the consent form.
* The researcher stated that pregnant women will be excluded from the study. The paragraph in the consent form relating to pregnancy can be removed.
* The Committee noted that blood samples will be taken and stored according to ‘usual practice’ The Committee sought clarification about what standard practice is in this case.

Decision

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

1. Please provide evidence of independent peer review. (Ethical Guidelines for Intervention Studies, Appendix 1)

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# Appendix 1: Joint Health Research Council and NEAC guidance on features of robust peer review for assessing the scientific validity of research

## Background

This document seeks to outline the principles of peer review that might be undertaken to assure New Zealand’s Health and Disability Ethics Committees (HDECs) of the scientific validity of a research proposal. Scientific validity of a research project is one component of the research being ethically sound. Research with insufficient scientific validity will waste scarce resources, will misuse the trust and commitment of participants, and may needlessly expose them to risk for no appropriate return.

The term ‘scientific validity’ is used in the 2012 *Standard operating procedures* (SOPs) for HDECs, without definition. NEAC’s *Ethical Guidelines for Observational Studies* (2012) and these *Guidelines* refer to studies being ‘scientifically sound’, which encompasses the expectation that a proposal’s objectives can reasonably be expected to be achieved. *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants* (WHO 2011) refers to ‘valid scientific methods’ as part of Standard 7: Ethical basis for decision-making in research ethics committees. Important factors in this standard include how the study will be conducted, the qualifications of the researcher(s), the adequacy of provisions made for monitoring and auditing, and the adequacy of the study site (eg, availability of qualified staff and appropriate infrastructures).

The Government, in its response to the Health Committee’s 2011 Inquiry into improving New Zealand’s environment to support innovation through clinical trials(Health Committee, June 2011), decided that researchers and research sponsors will be ‘responsible for ensuring that their research has been peer-reviewed for scientific quality’ (response to recommendation 14). The SOPsstate that HDECs will check that appropriate peer review (of scientific validity) has been carried out, but will not conduct it themselves. HDECs may not require specific, defined changes to research protocols on the grounds of lack of scientific validity as a condition of HDEC approval.

This guidance does not explain *how* review of a research proposal can be obtained, but lays out the features of a fit-for-purpose peer review process. It is anticipated that these guidelines will be of use both to those seeking ethical approval for their health and disability research, and to those undertaking ethical review of research proposals, to verify that the scientific validity of proposed research has been assured through an appropriate peer review process.

## Peer review

The role of New Zealand’s HDECs is to check that proposed health and disability research meets established ethical standards that aim to protect participants(see the SOPs). The SOPs require that researchers and sponsors ensure that the scientific validity of proposed research has been peer-reviewed before an application is made to an HDEC. In this context, peer review is the process by which an applicant can assure an HDEC that a proposal has an appropriate degree of scientific merit, feasibility and likelihood of impact.

## Areas of focus during peer review

Peer review can be tailored to deliver opinions on a variety of matters relating to a health and disability research proposal. In order to determine scientific validity, the following factors should specifically be determined:

* **The relative merit of the research:** A key consideration is whether the proposed work is important, worthwhile and justifiable. The research should address a health issue that is important for health and/or society. The aims, research questions and hypotheses will build on and address gaps in existing knowledge.
* **The design and methods:** The quality of study design and methods should be reviewed to assess its robustness. This might include study methodology, a description of sample recruitment and characteristics (including number, gender and ethnicity where relevant) and proposed methods of data analysis. Indication of timelines for the research should be included.
* **The feasibility of the research:** This includes whether the overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project. It should determine whether the research has the likelihood, on balance, of improving scientific knowledge, concepts, technical capacity or methods in the research field, or of contributing to better treatments, services, health outcomes or preventive interventions. The research will be achievable within the specified timeframe and the research team has the appropriate experience and expertise to undertake the research.

## Core features of the peer review process

A peer review process should be commensurate with the type of proposal, the potential risk to participants and where the research will be undertaken. The type of peer review process that is used must be fit-for-purpose and justifiable. For example, the mechanism for delivering peer review of a graduate student project carried out largely within a tertiary institution will differ from that of a multi-centre clinical trial. Opinions from one or more peers may be sought; again, the extent of peer review should be fit-for-purpose. Despite potential differences, an appropriate process for ensuring scientific validity will have the following features:

* **Peer review delivers an informed opinion:** An effective peer review process provides perspectives from subject matter experts. It may be suitable for informed perspectives to be sought from individuals in the same organisation as the researcher, as long as the requirements of freedom from bias, equity and fairness can be met. An appropriate peer is one who can deliver an informed opinion on some or all of a proposal. Reviewers will be knowledgeable about the topic and/or context for the research, have the appropriate expertise relative to the breadth and scope of research under review and, as a result, will be well placed to make a statement as to whether the research in question has verifiable scientific merit. Peer review of scientific validity may include consideration of cultural relevance and appropriateness.
* **Peer review delivers an objective opinion:** Those acting in the capacity of reviewers are charged with delivering a balanced and considered analysis of the research. Generally, the success of the peer review process is determined by the extent to which these evaluations can be considered free of bias, equitable and fair. Objectivity can be compromised if peer reviewers have conflicts of interest, and so appropriate peer reviewers typically will not be materially connected to the researcher(s) in a way that might undermine objectivity, and be free from either positive or negative inducements.
* **A consensus opinion on scientific validity is formed:** An HDEC will need to receive assurance that the peer review process has delivered support for the scientific validity of the proposed research. When a peer review process has engaged a range of experts, there needs to be a process that leads to a consensus opinion about the quality of the research.
* **Intellectual capital in the research proposal is respected:** A peer reviewer is in a privileged position through having access to the unexploited ideas and intellectual capital of the researcher. A peer review process should require that reviewers do not disclose the substance of any research proposal, unless there is explicit permission to do so.

## Limitations of peer review

Peer reviewers typically are not privy to the operational details of a proposed research study. Research proposals usually will outline a methodology, but not explain its implementation in detail. For example, a proposal might state how many patients will be recruited, but will not necessarily explain how patients will be approached, how they might be compensated for participation, nor what information any participant information sheet might contain. Similarly, the detailed clinical trial protocols are not typically included in a peer review. (Detailed examination of a trial protocol is often undertaken by the independent data and safety monitoring committee associated with the trial.) Ethics committees should be aware that studies can be of satisfactory scientific quality as judged by peer review, but still pose ethical concerns because of how the research is to be operationalised. Necessarily, consideration of the safety of participants and researchers, and the balance of risk and benefit, by ethics committees is likely to involve scrutiny of study design and execution.

1. Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).
2. The response to questions p.4.1& 4.2 - Maori Consultation & Cultural Issues – were not well answered. Please see above examples where these questions have been well answered. The Committee would like to see evidence of Māori consultation. (*Ethical Guidelines for Intervention Studies, para 4-6-4.10)*
3. Please insert a footer in the PIS.
4. Please include specific reference to the Central Ethics Committee details in the PIS.
5. Please explain in the PIS whether and how tissue will be disposed of at the end of the study (*Ethical Guidelines for Intervention Studies* *para 6.22*).
6. PIS, p 2 – Please state “you will be asked standard medical questions” rather than “you will undergo standard medical questions”.
7. PIS p 3 – ACC cover – Please reword to state that participants “may” be eligible for ACC cover rather than that they “would” be eligible for cover (*Ethical Guidelines for Intervention Studies* *para 6.22*).
8. PIS, page 2 bottom of page: states “there will be no difference in your clinical care”. Please qualify this by adding “in respect of your knee joint replacement” or, alternatively, that sentence might be deleted.
9. Please state the main exclusion criteria in lay language in the PIS (*Ethical Guidelines for Intervention Studies* *para 6.22*).
10. Please proof read the PIS.
11. Please include an option to access an interpreter at the start of the consent form. Please see the example below.

**If you need an INTERPRETER, please tell us.**

*If you are unable to provide interpreters for the study, please clearly state this in the Participant Information Sheet*

1. Please remove reference in the consent form to samples being sent overseas.
2. Since pregnant women will be excluded from the study, please remove the paragraph in the CF relating to pregnancy.
3. Please add title of study to consent form.
4. Please explain what standard practice is for the storage and disposal of laboratory samples.

This following information will be reviewed, and a final decision made on the application, by Paul Barnett and Angela Ballantyne.

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| **4** | **Ethics ref:** | **13/CEN/102** |
|  | Title: | Amgen 416 H2H Study |
|  | Principal Investigator: | Dr Mark Marshall |
|  | Sponsor: | Amgen Australia Pty Ltd |
|  | Clock Start Date: | 11 July 2013 |

Dr Mark Marshall 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.

Summary of ethical issues

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

* PIS/CF – optional use forms could be altered (p 5).
* The Committee sought clarification about whether tissue was going to be used for pharmacokinetic research?
* The insurance certificate provided states that it applies to Australia, it needs to apply to NZ.
* The Committee asked how long participants have to give consent? The researcher advised that this is the length of time that the trial is open for (i.e. the period it is open for recruitment). This needs to be stated in the PIS.
* The PIS should state exclusion criteria.
* The Committee noted that the Māori consultation undertaken was appropriate, but would like to see evidence that this consultation is underway.
* The PIS/CF for future unspecified use of tissue should be separate from the main PIS/CF. This optional PIS/CF must give participants the option of withdrawing at any time without prejudice.
* The PIS should provide more information about what will happen to the samples e.g. how will they be stored, who will have access to them, and can a participant request that they be returned?
* Where the PIS refers to Table 2 in the PIS, there needs to be a reference to the page number to help participants quickly locate the table.
* The instruction boxes relating to other countries (pages 10 and 11 of the PIS) need to be removed
* The study title should be added to the PIS/CF.

Decision

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

1. Please clarify whether tissue will be used for pharmacokinetic research?
2. The insurance certificate must cover NZ.
3. Please state how long participants have to give consent in the PIS (*Ethical Guidelines for Intervention Studies* *para 6.22*).
4. Please state the exclusion criteria in the PIS (*Ethical Guidelines for Intervention Studies* *para 6.22*).
5. Please provide evidence of Māori consultation (*Ethical Guidelines for Intervention Studies* *para 4.7*).
6. The PIS/CF for future unspecified use of tissue should be separating from the main PIS/CF, with OPTIONAL in capitals (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
7. This optional PIS/CF must give participants the option of withdrawing at any time without prejudice (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
8. The PIS should provide more information about what will happen to the samples, e.g. how will they be stored, who will have access to them, and can a participant request that they be returned? If genetic research is intended, this information should be included(*Ethical Guidelines for Intervention Studies* *para 6.22*).
9. Where the PIS refers to Table 2 in the PIS, there needs to be a reference to the page number to help participants quickly locate the table.
10. Please remove the instruction boxes relating to other countries (pages 10 and 11 of the PIS).
11. The study title should be added to the PIS/CF.

This information will be reviewed, and a final decision made on the application, by Lynne Russell and Sandy Gill.

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| **5** | **Ethics ref:** | **13/CEN/103** |
|  | Title: | Laboratory production and functional studies on Mesenchymal Stromal Cells |
|  | Principal Investigator: | Dr James M (Jim) Faed |
|  | Sponsor: | Spinal Cord Society NZ Inc |
|  | Clock Start Date: | 11 July 2013 |

Dr Faed and Dr Turner 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 discussed the recruitment process.
* The future unspecified consent form is inadequate. There needs to be a separate PIS/CF in accordance with the guidelines (http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0).
* The Committee notes that samples will be sent overseas for use in animal models, but this further research would require separate approval.
* The consent form for future unspecified use, should state that the samples may be used in animal models.
* The Committee noted the adequacy of peer review.
* The Committee discussed the cultural issues associated with the umbilical cord blood. As the connection between the whenua (placenta) and mother, the pito (umbilical cord) is particularly significant for many Māori. Both the pito and whenua are buried in a place of meaning to the whānau to reinforce the link between the pēpi (baby) and Papatuanuku. Removal of blood from this tapu body part is, therefore, of some significance.
* The PIS should acknowledge this tikanga and associated need to talk to whānau about participation in the study and should include information about who to contact for further discussion.
* The Committee noted that the Ngai Tahu Research Consultation Committee was consulted.
* Please list all exclusion criteria in lay language the PIS.
* The PIS should refer to the Central Ethics Committee not Southern.
* The researcher will approach women having elective caesarean section for consent, as this will be a managed process and they would be consented 24 hours prior to surgery.
* The Committee noted that the researcher will need to obtain locality assessment from DHBs and GP practices.

Decision

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

1. Please create a new future unspecified use of human tissue consent form. Please ensure that the new PIS/CF meets the requirements of the guidelines. (<http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>) and OPTIONAL in capitals. The PIS/CF should state that samples will be sent overseas and may be used in animal models, which would be subject to ethical review and approval by an overseas ethics committee (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
2. As the connection between the whenua and mother, the pito is particularly significant for many Māori. Both the pito and whenua are buried in a place of meaning to the whānau to reinforce the link between the pēpi and Papatuanuku. Removal of blood from this tapu body part is, therefore, of some significance. The PIS should acknowledge this tikanga and associated need to talk to whānau about participation in the study and should include information about who to contact for further discussion (*Ethical Guidelines for Intervention Studies* *para 4.7*).
3. Please list all exclusion criteria in lay language the PIS.
4. The PIS should refer to the Central Ethics Committee not Southern.
5. Please obtain locality assessment from DHBs and GP practices.

This information will be reviewed, and a final decision made on the application, by Angela Ballantyne and Gael Donaghue.

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| **6** | **Ethics ref:** | **13/CEN/104** |
|  | Title: | LeAPP study |
|  | Principal Investigator: | Dr Sophie Chien-Hui Wen |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 July 2013 |

Dr Walls and Dr Wen and Dr David Murdoch 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 would like to see evidence of independent peer review. The researcher agreed to seek additional peer review from an overseas expert.
* The research aims to improve knowledge about rates of Legionella in children. The recruitment numbers are based in what the researchers believe they can realistically sample, they stated that they cannot do a power calculation.
* The Committee sought further information about future use of tissue. The PIS talks about storing material for future use. The researchers would seek approval for future use.
* Please provide a separate PIS/CF for future unspecified use of human tissue (<http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>).
* There needs to be a consent form for an adult consenting on behalf of a child.
* Please also prepare an assent form for any older children who are capable of understanding and assenting or consenting to the study.
* Please develop assent/consent forms for the following ages: 5-8, 9-12, 13-16.
* The Committee commended the researchers for their application which acknowledged that Māori regard the head as tapu. However, the PIS contains no information about cultural issues and no contact details for Maori support available. Please provide contact details on the PIS for participants who wish to contact ~~someone~~ an appropriate person to discuss cultural implications of the research.
* The researchers clarified that for children under two years of age the researchers will use percussion to obtain a sputum sample and that this would be standard practice to obtain such a sample.
* Please state exclusion criteria (in lay terms) in the PIS.

Decision

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

1. Please provide evidence of independent peer review (*Ethical Guidelines for Intervention Studies* Appendix 1).
2. Please provide further information about the future use of tissue collected as part of the study. Please provide a separate PIS/CF for future unspecified use of human tissue (<http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>).
3. Please prepare a consent form for an adult consenting on behalf of a child(*Ethical Guidelines for Intervention Studies* *para 6.22*).
4. Please also prepare an assent form for any older children who are capable of understanding and assenting or consenting to the study(*Ethical Guidelines for Intervention Studies* *para 6.22*).
5. Please develop assent/consent forms for children in the following age groups: 5-8, 9-12, 13-16 (*Ethical Guidelines for Intervention Studies* *para 6.22*).
6. The Committee commended the researchers for their application which acknowledged that many Māori regard the head as tapu. However, the PIS contains no information about cultural perspectives or issues and no contact details. Please provide contact details for participants who wish to contact someone to discuss cultural implications of the research (*Ethical Guidelines for Intervention Studies* *para 4.7*).
7. Please state exclusion criteria (in lay terms) in the PIS.

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

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| **7** | **Ethics ref:** | **13/CEN/105** |
|  | Title: | Acetazolamide as an adjunct to non-invasive ventilation in the treatment of obesity hypoventilation syndrome |
|  | Principal Investigator: | Dr Alister Neill |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 July 2013 |

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.

* Committee noted that the peer review submitted was extremely brief. The committee would like to see more comprehensive peer review. Please refer to the NEAC/ HRC guidance on peer review. (see Ethical Guidelines for Intervention Studies , Appendix One, http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research).
* The PIS should provide Māori contacts.

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| * Please include the standard ACC clause, i.e. “If you were injured in this study, which is unlikely, you would be able to apply for compensation from ACC just like if you were injured in an accident at work or at home. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.” |

* The Committee noted that the CPAP device used as part of standard care straps around the head and that the head is tapu for many Māori. Collecting blood samples also raises cultural issues for Māori participants. (Committee would like this letter cc d to Mark Brunton).
* The PIS should include information about exclusion criteria.
* Please submit investigator cvs.

Decision

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

1. The Committee noted that the CPAP device used as part of standard care straps around the head and that the head is tapu for many Māori. Collecting blood samples also raises cultural issues for many Māori participants. Please provide Māori contacts in the PIS (*Ethical Guidelines for Intervention Studies* *para 4.7*).
2. Please submit evidence of comprehensive independent peer review. (Please refer to the NEAC/ HRC guidance on peer review Ethical Guidelines for Intervention Studies , Appendix One, http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research).
3. The PIS should include information about exclusion criteria (*Ethical Guidelines for Intervention Studies* *para 6.22*).
4. Please submit cvs for the investigators.

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| 1. Please include the standard ACC clause, ie “If you were injured in this study, which is unlikely, you would be able to apply for compensation from ACC just like if you were injured in an accident at work or at home. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.” |

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

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| **8** | **Ethics ref:** | **13/CEN/106** |
|  | Title: | Identity in a community rehabilitation service for acquired brain injury |
|  | Principal Investigator: | Dr. Maxine Bevin |
|  | Sponsor: | Stewart Centre @ EIT |
|  | Clock Start Date: | 11 July 2013 |

Maxine Bevin and Alexa Hantler 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 considered that even if material is anonymised, given the small patient population, some of the participants may be recognisable. The Committee noted that the PIS discusses this possibility.
* Committee commended the PIS for its design for use with this patient population.
* The Committee questioned whether the participants would have capacity to consent and whether a proxy would also have to consent on their behalf. If participants lack the ability to consent would proxy consent be sought or would participants be excluded from the research? If proxy consent may need to be sought, the researchers will need to prepare a PIS/CF for proxy consent.
* A study specific PIS and CF for staff is needed.
* The Committee noted that the researchers had not discussed what the benefits of the research might be for Māori.
* The Committee noted that the researcher did not identify any particular cultural issues for Māori. The Committee identified the tapu of the head, taonga of knowledge and participation of whānau in treatment as pertinent issues for Māori. The Committee noted that a high percentage of the participant population are likely to be Māori (15-20%).
* The Committee would like to see evidence of consultation with Huia Beattie.
* The PIS needs a cultural component, including contact details for someone with whom a participant could discuss the cultural implications of the study.
* The researcher needs to clarify how long patients have to decide whether or not to participate.
* The researcher needs to provide evidence of independent peer review.

Decision

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

1. The Committee questioned whether the participants would have capacity to consent and whether a proxy would also have to consent on their behalf. If participants lack the ability to consent would proxy consent be sought or would participants be excluded from the research? If proxy consent may need to be sought, please prepare and submit a PIS/CF for proxy consent (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. Please provide a study specific PIS and CF for staff is needed.
3. The Committee would like to see evidence of consultation with Huia Beattie.
4. Please include in the PIS contact details for someone outside the study and who is culturally appropriate with whom a Maori participant could discuss the cultural implications of the study (*Ethical Guidelines for Intervention Studies* *para 4.7*).
5. Please clarify how long patients have to decide whether or not to participate.
6. Please provide evidence of independent peer review (*Ethical Guidelines for Intervention Studies* Appendix 1).

This following information will be reviewed, and a final decision made on the application, by Patries Herst and Lynne Russell.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 27 August 2013, 12:00 PM |
| **Meeting venue:** | Deloitte House, MEDSAFE, Level 6, 10 Brandon Street, Wellington, 6011 |

1. **Other business**

The Secretariat will circulate a contact details list amongst committee members.

The meeting closed at 4.05pm.