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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 23 April 2013 |
| **Meeting venue:** | Clinical Trials Unit, Level 8, Ward Services Block, CCDHB |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.10pm | Confirmation of minutes of meeting of 26 March 2013 |
| 12.30pm | New applications (see over for details) |
|  | i 13/CEN/60  ii 13/CEN/59  iii 13/CEN/53  iv 13/CEN/54  v 13/CEN/55  vi 13/CEN/61 |
| 3.30-4.00pm | General business:  Noting section of agenda |
| 4.00pm | Meeting ends |

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

***Welcome***

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

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 26 March 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **13/CEN/60** |
|  | Title: | Acupuncture for Dysmenorrhea |
|  | Principal Investigator: | Mr Mike Armour |
|  | Sponsor: | University of Western Sydney |
|  | Clock Start Date: | 26 March 2013 |

Mr Mike Armour and Ms Cindy Farquhar 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 this study was put before a PhD Committee and accepted but queried whether such review could be considered to be peer review. The committee was satisfied that adequate peer review was given, noting through their own experience that such processes were rigorous and independent.
* The committee asked which women would be interviewed 3 months after participation in the trial and how they would be recruited. Mr Armour advised that they plan to ask all women who participated but that not all women will be interviewed because of resources. Interviews will be stopped once they see themes appearing in the information gained and reach “saturation”.
* The committee noted that some women who could be valid participants might be missing out in participating in research, specifically in regard to one of the listed exclusion criteria of ‘current mental health illness’. The committee asked the researcher to clarify whether or not this was for women who had a current diagnosis only. Mr Armour confirmed that this would be for current diagnosis only and explained that medication for mental health illness can affect experience of pain and therefore could affect the study results. Also, women who are currently depressed may experience pain differently. The committee was satisfied with the response but suggested that the exclusion criteria could be reworded as ‘Any treatment that may interfere with experience of pain’.
* The committee advised that consultation with Māori is required for approval as part of the locality assessment process and asked whether the researchers had consulted with Assoc. Prof. Papaarangi Reid. The researchers advised that they had written to Assoc. Prof. Reid but not received a response to date. The committee suggested approaching the Department of Māori Health at Auckland University generally (rather than Assoc. Prof. Reid specifically) as an alternative and the researchers agreed to do so.
* The committee advised that the researchers store data for 10 years in accordance with the Health (Retention of Health Information) Regulations requirement.
* Participant Information Sheet
* Please correct ‘Hanau’ to ‘Whānau’ on page 2 under the title ‘What would your participation involve?’
* Consent Form
* If you have chosen not to use translators, please delete reference to ‘first language’ in the first sentence on page 1.

Decision

This application was *approved* by consensus

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| **2** | **Ethics ref:** | **13/CEN/59** |
|  | Title: | Topical diclofenac and imiquimod in treatment of periocular actinic keratosis |
|  | Principal Investigator: | Dr Andrea Zarkovic |
|  | Sponsor: |  |
|  | Clock Start Date: | 03 April 2013 |

Dr Zarkovic 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 evaluate two topical agents, Diclofenac and Imiquimod. Both agents are already in use but this is the first time they will be combined.
* The committee noted that surgery is currently ‘gold standard’ treatment but doesn’t work on everyone and this study would look to see if combining the treatment will offer an alternative to surgery.
* The committee considered evidence of peer review submitted with the application was insufficient because it did not show review of what the study involves or the benefits. Dr Zarkovic noted that this is the first time she has submitted an application and that she was not sure what constituted sufficient peer review. The secretariat will include guidance about what is acceptable peer review with the committee’s decision letter.
* The committee asked the researcher to clarify the term ‘fluke’ symptoms at R1.1 on the application form. The researcher confirmed it was a typo and should read ‘flu-like’ symptoms!
* The committee asked whether Dr Zarkovic was able to give a statement about lab protocols in respect of storing tissue. The researcher did not know specific lab protocol but advised that the samples in this study would be treated like any other samples held in a hospital. The committee advised that it would give approval for the study to proceed on basis that tissue is held securely and privately and the committee needs to be assured of this.
* The committee noted that the health information must be retained for 10 years in accordance with the Health (Retention of Health Information) Regulations requirement.
* The committee noted that Dr Zarkovic had not consulted with Māori and had stated in the application that actinic keratosis is likely to affect people with fair skin and is rare in the Māori population. The committee noted that some Māori have fair skin and was particularly interested to learn whether the condition attaches to genetic factors or more simply fair skin when it is diagnosed in Māori. Dr Zarkovic confirmed fair skin and noted that even in the European population it affects those with fairer skin. Dr Zarkovic further advised that the study will be addressed by the ADHB Māori advisory committee and recommendations sought.
* Participant Information Sheet and Consent Form
* Please ensure Māori Liaison contact details are included.
* Please note that Central Ethics Committee has approved this study on page 2.
* Please include the options for tissue destruction and if it will not be destroyed at study conclusion, details of storage and possible future use.
* The committee noted that the study would be funded by research grants but also that Dr Zarkovic might ask the manufacturer for medication free of charge should the grant applications be unsuccessful. The committee was satisfied however, that this would not mean additional benefit for the manufacturer/sponsor.

Decision

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

* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Please amend the information sheet and consent form, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please submit a letter to the committee addressing cultural issues that may arise for Māori participants ([*Guidelines for Researchers on Health Research Involving Māori*](http://www.google.co.nz/url?sa=t&rct=j&q=research%20with%20maori&source=web&cd=3&cad=rja&ved=0CD8QFjAC&url=http%3A%2F%2Fwww.hrc.govt.nz%2Fsites%2Fdefault%2Ffiles%2FGuidelines%2520for%2520HR%2520on%2520Maori-%2520Jul10%2520revised%2520for%2520Te%2520Ara%2520Tika%2520v2%2520FINAL%5B1%5D.pdf&ei=zjpSUYy2BK-QiAfp6oCoCg&usg=AFQjCNER1CqcEuXiwyZFn3Cjbz8ZdIWbZA)).
* Please provide a letter to the committee describing in detail how samples will collected and stored in the laboratory.

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

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| **3** | **Ethics ref:** | **13/CEN/53** |
|  | Title: | A study of Carfilzomib, Melphalan, and Prednisone compared with Bortezomib, Melphalan, and Prednisone in patients with newly Diagnosed multiple Myeloma that are not eligible for stem cell transplant. |
|  | Principal Investigator: | Dr Peter Ganly |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 April 2013 |

No members of the research team were present for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* This study involves a new treatment regime for multiple myeloma and is an open-label study for newly diagnosed who are ineligible for a stem-cell transplant. The standard treatment is VMP (Bortezomib, Melphalan and Prednisone), and participants in this study will be randomised to receive either VMP or CMP (Carfilzomib, Melphalan and Prednisone). Carfilzomib is thought to be more tolerable and have fewer side effects. Participants are therefore more likely to complete treatment.
* The committee noted that although the researchers had answered ‘no’ at application question r .1.3, that should have been ‘yes’ as technically the researchers are withholding standard treatment (VMP).
* The committee also noted that the researchers had answered ‘no’ at application question P3.2.when participants are vulnerable as they have a median life expectancy of 42 months from the time of initial diagnosis. Please refer to the NEAC guidelines for the definition of vulnerability (*Ethical Guidelines for Intervention Studies* para 5.28).
* Participant Information Sheet and Consent Form
* The committee noted the lengthiness and inaccessibility of some of the terminology (Pyrexia, Myocardial Infarction etc.) but agreed that the bulk of terms used are appropriate.
* For a drug with so many side-effects the committee discussed whether it would it be worthwhile having inclusion/exclusion criteria listed. The committee was satisfied that this criteria would not need to be listed as its application would likely be identified by the clinician before the PIS was given to a potential patient participant. It may also be less confusing for patients to have less technical information included when the PIS/CF is lengthy as it stands.
* Pages 3 and 4. It is hard to work out what is standard and non-standard treatment. Please clarify whether there are any additional procedures participants need to carry out as part of being on the trial.
* Page 22. Please cross reference section 5.5. ‘Risk of Loss of Confidentiality’ to the section on study results and confidentiality (section 9 on page 23).
* Genetic Testing Information Sheet and Consent Form
* Please include the word ‘optional’ in the title.
* The committee noted that the mandatory information about cultural considerations for the future use of tissue was not included. Please refer to paragraphs 19, 20 and 21 of the Guidelines for the use of Human Tissue for Future Unspecified Research Purposes and include relevant information.
* Please acknowledge that if data is held overseas then ethics approval will not be required before future studies are conducted (Guidelines for the use of Human Tissue for Future Unspecified Research Purposes, paragraph 8).

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*) and (*Guidelines for the Use of Human Tissue for Future Unspecified Research purposes paras 8 and 19-21)*

This information (above) will be reviewed, and a final decision made on the application, by the Chair, Dr Angela Ballantyne and Dr Dean Quinn.

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| **4** | **Ethics ref:** | **13/CEN/54** |
|  | Title: | A study to compare a new drug to an existing drug in patients with rheumatoid arthritis who are taking Methotrexate and had an inadequate response to a specified prior treatment. |
|  | Principal Investigator: | Dr Alan Doube |
|  | Sponsor: | Covance Asia Pte. Ltd |
|  | Clock Start Date: | 12 April 2013 |

Ms Denise Darlington and Ms Janine Jacobs 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 this study was reviewed and declined by the Northern A ethics committee in March 2013. The committee was satisfied that the researchers had successfully and appropriately addressed the points raised in the Northern A ethics committee’s decision letter.
* The committee noted that some of the documents such as evidence of peer review that were included with the protocol could have been better placed outside of the protocol.
* Participant Information Sheet and Consent Form
* Please simplify into layman’s terms some of the inclusion/exclusion criteria listed at pages 40-45 of the study protocol and include this in the PIS/CF.
* Please include contact details for the Māori Advisor along with culturally-specific information about the use and storage of Māori tissue collected as part of this study, that is cognisant of tikanga Māori.
* The committee noted the patient booklet included with the study protocol had not been included and noted that using syringes could be peculiar and hard for some, particularly first time users. The committee asked how the researchers intended to advise participants about their use. Ms Darlington advised that participants would be shown how to use syringes once they have been admitted to the study. They would also have the option of bringing a caregiver. This would help ensure that the drug is administered correctly. Participants will also be given the option of coming back to the clinic for further instruction if needed. The committee asked that researchers put a sentence to this effect in PIS/CF and also include the instruction guidelines.
* Please include that the study is approved by the Central Ethics committee on page 2.
* Participant Information Sheet for Pharmacogenetic research
* Please clarify whether samples will be held for future rheumatoid arthritis research.
* The committee asked for clarification on the meaning of the first sentence on page 2 about right of access and data correction. The researchers explained that during the period of the main study a participant can change their personal details at any point by contacting their physician. The committee queried how patients would access their own data once it is de- identified. The study codes for 15 years and participants can link back to the sponsor and access data.
* Please include that the study is approved by the Central Ethics committee on page 2.

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 (above) will be reviewed, and a final decision made on the application, by the Chair and Mrs Gael Donoghue.

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| **5** | **Ethics ref:** | **13/CEN/55** |
|  | Title: | Breast cancer tumour profiles and disparities |
|  | Principal Investigator: | Dr Lis Ellison-Loschmann |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 12 April 2013 |

Dr Lis Ellison-Loschmann was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* Dr Angela Ballantyne summarised the study and the accuracy of the summary was confirmed by Dr Ellison-Loschmann. It is a breast cancer tissue analysis study funded by NIH in the United States and has three collaborating sites including two in the United States. The US arm has ethics approval. This study is a pilot. In the pilot Dr Ellison-Loschmann intends to investigate what data is held by the NZ Cancer Registry and in particular to see how many patients on the Registry have cancer tissue blocks that can be accessed. Dr Ellison-Loschmann explained that she intends to look at the health records on the New Zealand Cancer registry to see how many records the registry holds and whether those records contain or identify where patient records and tissue samples are held. In the full study (for which separate ethics approval will be sought) the researchers will conduct tests on the tissue blocks. For the pilot, the researchers are asking for approval to look at patients’ medical files but will not actually conduct research on the tissue.
* The committee advised that getting approval to use health information/data without consent is a different process from getting approval to use tissue without consent and is less rigorous. For future reference, should Dr Ellison-Loschmann apply for approval to access and then use tissue without consent, see Right 7(10)(b) of the HDC Code of Rights.
* The committee asked what information would be held with patient records that would allow Dr Ellison-Loschmann to determine socio-economic status. She explained that address information may be held for many patients but may not be held for early registrations.
* The committee noted that if the required information is not held on the NZ Cancer Registry then Dr Ellison-Loschmann may need to seek review of further medical notes/charts. This would likely relate to the first 25 years of this study where data may be scant.
* Dr Ellison-Loschmann noted the difficulty of obtaining information from earlier registrations and that she may need to contact hospitals to look at earlier records. The committee was concerned that accessing full medical notes would give access to fuller personal information. Dr Ellison Loschmann clarified that she simply wishes to know whether the data and associated tissue specimens exist and can be located. Dr Ellison-Loschmann clarified for the committee that at this stage she would wish to know the following information –
* is the patient registered on the NZ Cancer Registry?
* was there a biopsy?
* if so, does it still remain and where?

No other identifying personal information would be sought in this pilot study.

* The committee asked whether getting consent from the patients would be possible. Dr Ellison-Loschmann felt it would cause unnecessary anxiety when the main study may not go ahead. She drew on past experience in contacting women up to 3 years post diagnosis and noted the need to be mindful of when was an appropriate time to contact women.
* The committee noted that a decision to approve the study would be based on whether the criteria set out at paragraph 6.43 (a – c) of the Guidelines for Observational Studies, 2012 are met

1. the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought, or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and
2. there would be no disadvantage to the participants or their relatives or to any collectivities involved; and
3. the public interest in the study outweighs the public interest in privacy.

* The committee debated whether the criteria set out at 6.43 (a – c) were met and agreed by consensus that both b) and c) were. However, no consensus was reached on 6.43 (a) as the majority did not believe that contacting patients for consent was ‘likely’ to cause unnecessary anxiety. There would be no disadvantage to relatives because the tissue blocks were not being used and therefore a finite resource was not being depleted.
* The committee noted that the public interest in privacy is currently very high given the context of ACC and MSD privacy breeches. The committee held that the public benefit of the study really attached to the main study because breast cancer is a significant health threat to women in New Zealand (both in terms of physical and physiological health) ; but agreed that the main study could not be conducted without the information to be gained from the pilot study. Given the public benefit of the main study the committee decided that criteria (c) was satisfied.
* The committee suggested that the researcher might gain data for the pilot study if that data is for deceased subjects only. The committee believed that gaining informed consent from dead patients would be impossible and therefore criteria (a) would be satisfied. Dr Ellison-Loschmann indicated that she could adjust the methodology to get 10 samples per decade (1940-2010), which would be matched to a mortality database to see if they are alive or not. She would only access the deceased patients’ medical files. The committee has requested a legal opinion from MOH to determine whether consent is required to be obtained for deceased individuals (e.g. from their legal representatives/next of kin). If such consent is not required the committee is satisfied that all three criteria are met in relation to deceased patients whose data is held in the Cancer Registry.
* Dr Ellison-Loschmann noted that in the US approval was given as deceased people are not classified as ‘people’ in law.
* The committee was satisfied that there is no need for Māori Consultation at this point but should the main study go ahead, consultation with Māori would need to be sought.
* The committee was satisfied that there was no conflict of interest arising from the fact that the HRC is both funder and reviewer of this study.

Decision

This application was *provisionally approved* by consensus subject to clarification by way of legal opinion on whether 6.43 (a) dot point 3 (impossible in practice to obtain consent due to the quantity or age of the records) applies to deceased individuals or whether consent should be sought from the next of kin. The approval only applies to accessing data from deceased patients in the Registry. The Committee did not believe the criteria for 6.43 were met in relation to living patients. Therefore if the research wants to access medical files of living patient she must first seek their consent.

This information (above) will be reviewed, and a final decision made on the application, by the Chair and all members.

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| **6** | **Ethics ref:** | **13/CEN/61** |
|  | Title: | SIRROUND T |
|  | Principal Investigator: | Dr Ketna Parekh |
|  | Sponsor: | PAREXEL International |
|  | Clock Start Date: | 12 April 2013 |

No members of the research team were present for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* This study involves the treatment of people with rheumatoid arthritis who are non-respondent to standard treatment for 52 weeks with the additional option of taking part in an open-label study.
* One third of participants will receive placebo and two thirds will receive the treatment drug. The committee was satisfied that the placebo treatment was justified by 18 week ‘threshold’ where participants who do not show improvement from the baseline will come out and be randomised into treatment groups. The study therefore meets the equipoise standard.
* The committee noted that R1.3 on the application form for withholding standard treatment was incorrectly answered as ‘no’ because participants in the placebo arm will not receive standard treatment.
* It was not clear to the committee whether Māori will be given equal opportunity to participate as the application has insufficient evidence to show whether consultation with Māori has taken place. The committee considers that cultural issues that may arise for Māori participants have not been adequately acknowledged. Please submit a letter to the Committee providing comprehensive answers to questions p.4.1 – p.4.3.1. This letter should address tikanga Māori regarding taking tissue samples and whānau involvement, and provide further details of Māori consultation.
* Participant Information Sheet and Consent Form
* Page 3. Please include more information about the study drug other than who the drug has been given to. Please also delete the two tick boxes at the top of the page.
* Please make the fact that participant information is not protected explicit by bold typing the sentence in the second to last paragraph on page 20 “Please be aware that the laws in such countries…being shared with others.”
* Page 18. The committee noted that study medication is not supplied in child resistant form and this may cause problems for participants. The information provided fails to document that drug should be stored at 2-8 degrees i.e. in a fridge. Please clarify whether the onus will be on participants to secure the study medication so that children and others cannot access it and also whether you will supply participants with sharps containers.
* Page 21. ‘What if I change my mind?’ Please be more explicit about whether data that has already been collected at the point at which participants withdraw will remain available to be included in the future analysis.
* Please include the information regarding Whānau support (as stated in the consent form), in the participant information sheet.
* Informed consent form for optional DNA research
* Before granting ethical approval for this study, the committee needs to be satisfied that you have addressed all points in Part Four (paras 26 – 31) of the Ministry of Health Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes in your information to participants.
* Please also include information showing that you have addressed point 13 in Part Two of guidelines about withdrawal of consent and also points 19, 20, 21 about cultural issues around tissue samples and future unspecified use of data.
* The committee was not satisfied that adequate evidence of peer review. Please provide evidence of peer review taking into account the guidelines attached with the committee’s decision letter.
* The committee noted that the name and details of the central US lab where samples will be analysed were not given at R3.8.1 on the application form. Please provide the name and details of the laboratory.

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*) and (*Guidelines for the Use of Human Tissue for Future Unspecified Research purposes paras 13, 19-21 and 26-31).*
* Please submit a letter to the committee addressing cultural issues that may arise for Māori participants ([*Guidelines for Researchers on Health Research Involving Māori*](http://www.google.co.nz/url?sa=t&rct=j&q=research%20with%20maori&source=web&cd=3&cad=rja&ved=0CD8QFjAC&url=http%3A%2F%2Fwww.hrc.govt.nz%2Fsites%2Fdefault%2Ffiles%2FGuidelines%2520for%2520HR%2520on%2520Maori-%2520Jul10%2520revised%2520for%2520Te%2520Ara%2520Tika%2520v2%2520FINAL%5B1%5D.pdf&ei=zjpSUYy2BK-QiAfp6oCoCg&usg=AFQjCNER1CqcEuXiwyZFn3Cjbz8ZdIWbZA)).
* Please provide a letter to the committee describing in detail how samples will collected and managed, if they will be sent overseas and if they will be made available for future research.
* Please include the name and details of the central US lab where samples will be analysed in the letter to the committee.

This information (above) will be reviewed, and a final decision made on the application, by the Chair, Dr Dean Quinn and Dr 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:** | 28 May 2013, 12:00 PM |
| **Meeting venue:** | Deloitte House, 10 Brandon St, Wellington, 6011, Level 6 |

No members tendered apologies for this meeting.

The meeting closed at 4.00pm