|  |  |
| --- | --- |
| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27 August 2013 |
| **Meeting venue:** | Deloitte House, MEDSAFE, Level 6, 10 Brandon Street, Wellington |

|  |  |
| --- | --- |
| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.10pm | Confirmation of minutes of meeting of 23 July 2013 |
| 12.30pm | New applications (see over for details) |
|  | i 13/CEN/109  ii 13/CEN/111  iii 13/CEN/118  iv 13/CEN/119  v 13/CEN/120  vi 13/CEN/112  vii 13/CEN/113  viii 13/CEN/114  ix 13/CEN/115  x 13/CEN/116  xi 13/CEN/117  xii 13/CEN/110 |
| 4.30pm | General business:  Noting section of agenda |
| 4.45pm | Meeting ends |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 | Present |
| 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 | Apologies |

## Welcome

The Chair opened the meeting at 12.12pm and welcomed Committee members, noting that apologies had been received from Dr Lynne Russell.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 23 July 2013 were confirmed subject to the following amendments:

Page 18, bullet point 4. Please amend the sentence the “Committee would like this letter cc d to Mark Brunton to read “The committee would like the letter to Dr Alister Neill cc d to Mark Brunton”.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **13/CEN/109** |
|  | Title: | Swallowing safety and efficacy with the Swallow Expansion Device (SED) |
|  | Principal Investigator: | Dr Jacqueline Allen |
|  | Sponsor: | Waitemata District Health Board |
|  | Clock Start Date: | 15 August 2013 |

Dr Jacqueline Allen 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 is a phase I, pilot study to test the safety of a new non-invasive device in participants with aspiration and oropharyngeal dysphagia who have difficulty swallowing food. Dr Allen explained that invasive surgical procedures have been used in the past and this device is “small, simple” and will be sutured onto the cricoid cartilage. The participant can manually activate the device to take food away from the airway.
* Dr Allen confirmed that the device will initially be used in patients who have no other option for swallowing. If found to be safe, the device may be used in the broader population and could have benefits, especially for the elderly.
* The committee complimented Dr Allen on a well-written participant information sheet, especially information for Maori participants.
* The committee noted that the consent form appeared to be an additional participant information sheet and queried whether this would be a doubling up of information for participants. Dr Allen noted the forms were developed for the American system and agreed there may be crossover of information. Discussion was had about whether a shortened form of the consent form and or transferring the information to the participant information sheet would be a useful alternative. The committee was satisfied that the crossover of information would not hinder participants and agreed to retain current format.
* Page 15 r.1.72 of the application form. The committee sought assurance that participants in the study would be covered by insurance and queried whether private insurance is provided at this stage. The committee noted that the University of California Davis is applying for a patent and that this could lead to commercial exploitation of the device. Dr Allen confirmed that participants are not covered by private insurance at this stage and explained that the University of California Davis has the patent and could commercialise the device but this would be some way down the track. Because device would not be used more widely than in 5 patients for this study, there are no plans to commercialise device at this stage.
* The committee asked Dr Allen to clarify prior to starting the trial whether participants are covered by ACC when there is a device that will be potentially commercially available.
* The timeline envisaged for treating participants was queried. Dr Allen advised that will be an interval between treating patients in line with her clinical schedule and she will treat one at a time depending on her patient list. The committee suggested that because this is a ‘first in man’ study Dr Allen may wish to perform a treatment and then monitor the sentinel person before repeating in other participants.
* Dr Allen confirmed for the committee that she will initially treat 5 patients. If the device is shown to be safe, the aim is to recruit a further 15 patients. The committee asked to see the study results and Dr Allen agreed although it was confirmed this would be done initially through progress reports.
* The committee asked Dr Allen to clarify whether the device was ‘high’ or ‘low’ risk or ‘novel’ as each was stated in the application. Dr Allen explained that both the device and procedure are simple as complex surgery is not involved in treatment. The reason Dr Allen was unclear about whether the device is ‘low’ risk is because this is the first time this study will be done in live subjects. She noted the potential for risk as the device is a foreign body but thought it unlikely that reactions will be severe. The device has been tested in animals without any serious reaction. Previous studies gave the researchers confidence that the device is safe for use.
* The committee noted that Dr Belafsky may receive honorarium if the device is commercialised and queried whether this would constitute a conflict of interest in terms of remuneration. The committee was satisfied that there was not conflict as Dr Belafsky would not receive honorarium for this study or recruitment of participants.
* Participant Information Sheet and Consent Form
  + Please include in lay language, the exclusion and inclusion criteria set out at question f.2.1 on page 22 of the application form.
  + Please advise participants that health information generated in this study will be stored for 10 years as you have stated at question r.2.5 of the application form.

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.

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **13/CEN/111** |
|  | Title: | E-cigarette acceptability |
|  | Principal Investigator: | Dr Penelope Truman |
|  | Sponsor: | University of Auckland, School of Population Health |
|  | Clock Start Date: | 15 August 2013 |

Dr Penelope Truman and Dr Jeff Robinson were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The researchers explained that the primary objective of this study is to test whether e-cigarettes will be accepted (i.e. will patients use them?). The secondary objective is to compare other forms of nicotine supplementation with e-cigarettes.
* The committee queried why consultation with Māori had not been done after the researchers confirmed that a percentage (around 15%), of Māori will participate this study and the study will potentially help reduce health inequalities. Dr Truman explained that because they were not specifically targeting the Māori population in this study that it may have been too early to consult.
* The committee noted the requirement for cultural issues to be discussed and advised that because Māori were going to be part of the study, consultation is needed. The committee advised the researchers on the consultation process they can take.
* Locality assessment has been gained but consultation with Māori was not addressed as part of this process. Both Dr Robinson and the committee expressed surprise that this was not addressed as part of locality assessment and noted that they would look into the broader locality process.
* The committee queried how the researchers intended to follow up with participants about how they found using the e-cigarettes once they have completed the study. For example would they carry out semi-structured interviews? Dr Truman advised that she had allowed space for clinicians to record impressions. The committee noted that participants may feel more able to express their impressions themselves in a neutral setting and suggested the researchers provide a focus group facilitated by someone who is not a clinician. This may allow participants to respond more openly.
* The committee noted that participants won’t have access to e-cigarettes at the end of the study and queried how ethical this was. The researchers noted they had also considered this and the obligation to assist participants once the study has finished. They noted the possible ways that participants may still have access to e-cigarettes; GPs can prescribe e-cigarettes and nicotine cartridges can also be bought over the internet.
* R3.10. Would this (answer) skew study? The only reason blood test is taken is to measure blood nicotine levels and is not compulsory.
* Participant Information Sheet and Consent Form. Please:
  + Provide contact details for the Māori advisory/support person
  + Note the legal requirement for health information to be stored for 10 years and advise participants of this.
  + Expand on the information about compensation, noting more specifically what compensation participants will be covered for.
  + Spell out acronyms in full. For example, NRT.
  + Revise and set out more clearly the information given at dot point 6 on page two under ‘What will my participation in this study involve?’.
  + Delete the sentence advising participants that they will receive a summary of study results as this is not the case.
* Consent Form
  + Please correct your footer
  + If you are intending to provide an interpreter, this information should be included in the participant information sheet in the participant’s first language. If you aren’t intending to provide an interpreter, please remove sentence from the consent form.

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, Sandy and Patries.

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **13/CEN/118** |
|  | Title: | Investigation of the use of Kanuka honey to treat rosacea |
|  | Principal Investigator: | Professor Richard Beasley |
|  | Sponsor: | Honeylab |
|  | Clock Start Date: | 15 August 2013 |

Mr Mark Holliday and Ms Anna Hunt 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 researchers had submitted three similar applications and all were relatively uncomplicated and of low risk. The issues discussed were in relation to all three studies.
* Insurance has been issued by QBE in all three studies. The committee noted that there may be a potential difference in the detail of cover insurers provide under a general umbrella term or description of cover. Therefore, the committee asked that the researchers check that cover for participants in each of the three studies encompasses the entitlements listed at r.1.9 on page 16 of the application form.
* The committee noted that the researchers had stated that Standard treatment would not be withheld at r.1.3 on page 14 of the application form when it appears that some participants will have standard treatment withheld while they are using kanuka honey preparation. Mr Holliday confirmed this is the case and the need to define this more clearly in the study protocol.
* The committee noted that the timeframe for participants to consult with family and friends before agreeing to participate in the study was open-ended (p.2.1, page 21), and recommended that the researchers define and specify a timeframe to participants.
* P.4.2 on page 23. The researchers have not specified any cultural issues for Maori other than “the use of flora and fauna that are significant to iwi or hapu identity”. The committee noted however that studies 118 and 119 will involve the use of the head, which is tapu for Maori and this may have significant cultural issues that the researchers will need to take into account.
* The committee asked the researchers how patients be randomised to the study. Randomisation will be coordinated by the sponsor who will allocate a number of envelopes to each site. There will be periods of non-competitive recruitment then recruitment will be open across all sites.
* Mr Holliday noted that at page 9 of protocol states an interim analysis of safety data is planned but analysis will be now performed at the end of the study. Mr Holliday asked whether the committee could approve this as an amendment during the discussion or whether the committee required submission of a substantial amendment to the HDEC secretariat. The committee advised that if the researchers are going to write to sponsors and amend the protocol then they need to submit as a substantial amendment to the HDEC secretariat after a decision has been made (i.e. as a post approval item).
* The committee noted that the Rosacea (118) study protocol states Inclusion/Exclusion criteria includes that participants can’t be on any steroids during the study. The protocol did not specify any washout interval for these treatments prior to enrolment in the study. Mr Holliday advised that he will raise this with the sponsor and if necessary the modified exclusion criteria should be carried forward to the participant information sheet.
* Participant Information Sheet
  + Please include contact details for the Maori support/advisory person.
  + Please include exclusion criteria beyond general allergy listed on page 3. If there are other exclusions, they should be included so that participants can make an informed decision.
  + Please include information about what restrictions will be in place while the kanuka preparation is being used.
* Consent Form.
  + If you are intending to provide an interpreter, this information should be included in the participant information sheet in the participant’s first language. If you aren’t intending to provide an interpreter, please remove sentence from the consent form.

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 ensure that compensation for participants will be covered to at least ACC- equivalent standard (*Ethical Guidelines for Intervention Studies* *paras 8.4-8.5*).
* Please ensure that all cultural issues of significance to Maori are addressed. (*Ethical Guidelines for Intervention Studies* *paras 4.7 and 4.9*).

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

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **13/CEN/119** |
|  | Title: | Investigation of the use of Kanuka honey to treat Acne |
|  | Principal Investigator: | Professor Richard Beasley |
|  | Sponsor: | Honeylab |
|  | Clock Start Date: | 15 August 2013 |

Mr Mark Holliday and Ms Anna Hunt 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.

* Please refer to discussion noted for application 13/CEN/118.
* Participant Information Sheet
  + Please include the use of OCs and systemic retinoids in the exclusion criteria so that participants have all the information needed to make informed consent.

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 ensure that compensation for participants will be covered to at least ACC- equivalent standard (*Ethical Guidelines for Intervention Studies* *paras 8.4-8.5*).
* Please ensure that all cultural issues of significance to Maori are addressed. (*Ethical Guidelines for Intervention Studies* *paras 4.7 and 4.9*).

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

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **13/CEN/120** |
|  | Title: | Investigation of the use of Kanuka honey to treat Nappy Rash |
|  | Principal Investigator: | Professor Richard Beasley |
|  | Sponsor: | Honeylab |
|  | Clock Start Date: | 15 August 2013 |

Mr Mark Holliday and Ms Anna Hunt 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.

* Please refer to discussion noted for application 13/CEN/118.
* Participant Information Sheet
  + Page 4. Please note approval from the Central Ethics Committee.
  + Please revise the content to show that consent is for the infant rather than the caregiver who is consenting on the infant’s behalf. For example, on page 4 under confidentiality “your personal information” should be “your child’s personal information”.
  + Please include the exclusion criteria listed at question f.2.1 of the application form e.g antibiotics, antifungals and corticosteroids.
* Consent Form
  + Page 6 of 6. Please replace “I consent to my GP being informed of my involvement in the study” to “I consent to my child’s involvement in 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*).
* Please ensure that compensation for participants will be covered to at least ACC- equivalent standard (*Ethical Guidelines for Intervention Studies* *paras 8.4-8.5*).
* Please ensure that all cultural issues of significance to Maori are addressed. (*Ethical Guidelines for Intervention Studies* *paras 4.7 and 4.9*). 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)).

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

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **13/CEN/112** |
|  | Title: | Clinical Utility of Cognitive Screening Tools (CUTCOST) |
|  | Principal Investigator: | Dr April Clugston |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 August 2013 |

Dr April Clugston and Mr Gary Cheung 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 aim of this researcher is to gather data on commonly used cognitive screening tools. The screening tool being trialled in this study is a relatively new tool that has not been trialled in New Zealand before.
* The committee noted that it is good to see a tool that will be looked at in a New Zealand context.
* Dr Clugston confirmed that 70 patients will be recruited for each group – with dementia and without dementia in this study and that there is currently no information sheet for patients without dementia. The committee asked the researchers to submit an information sheet for this group.
* The committee noted that a simplified participant information sheet and assent form are provided some studies involving groups who cannot consent for themselves and asked whether the researcher would consider providing some of the information in a similar form to dementia patients. Dr Clugston advised that dementia patients in this study have mild dementia and it is expected that these patients can assent for themselves. The committee noted that the current form doesn’t have a place for participants to sign and asked Dr Clugston to provide this. The committee noted the importance of providing ways for participants to be empowered as much as possible.
* The committee thought the response at p.4.1 noting benefits to Maori was well written but noted the researcher expected no cultural issues that might need managing. The committee noted that this study would involve the use of the head, which is tapu for Maori and also taonga of information and asked that the researchers rethink this section.
* Dr Clugston noted for the committee that funding for the Auckland and Hamilton sites is approved and additional money will be available for other areas. The power of study will therefore be sufficient.
* Participant Information Sheet and Consent Form
* The committee noted that the way in which the information sheet is currently written makes it appear as though the person signing on behalf is taking part. Please revise the content and make consistent.

Decision

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

* Please revise and rewrite the participant information sheet and consent form so that they are cognitively appropriate. 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 following information will be reviewed, and a final decision made on the application, by the Chair and Sandy.

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **13/CEN/113** |
|  | Title: | Testing biomarkers for diabetic complications |
|  | Principal Investigator: | Dr Renwick Dobson |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 August 2013 |

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 ethical issues

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

* The committee noted that the researchers did not include participant information sheets or consent forms for future unspecified research. (Please refer to the attached copy of the Ministry of Health *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes*).
* Given the discrepancy in answers r3.8 (p 15) and b4.53 (p13) on the application form, it was not clear to the committee whether tissue samples collected in this study will be sent overseas.
* The committee noted that while peer review had been conducted within the team, evidence of independent peer review was not submitted. (Please refere to the attached copy of: *Appendix 1: Joint Health Research Council and NEAC guidance on features of robust peer review for assessing the scientific validity of research*)
* The committee noted discrepancy about how participants will be informed of study results. The participant information sheet states that samples will be stored ‘anonymously’ and at r.4.1.1 of the application form the researchers state the nurse will inform participants of study results. The committee questioned how participants could be informed if study results/samples were anonymous.
* Application form question b.4.3 states the project will produce valuable intellectual property. Question r.5.6 states no conflicts of interest. The committee queried who owns the intellectual property and what the relationship between university and the researchers is. The committee noted that the participant information sheet should inform participants that valuable intellectual property might be produced as a result of the study and that participants will not be entitled to payment.
* At question p.4.3.1 the researchers state “the ethnicity of blood donors is not important”. How do the researchers know this in advance; is it not possible that the biomarkers are differentially expressed in different ethnic groups?
* At question r.2.3.1 the researchers did not answer this question but a questionnaire has been attached. The answer should therefore be ‘yes’.

Decision

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

The committee is unclear about the study design and therefore is unable to judge whether the protocol and information provided best answers the study question. (*Ethical Guidelines for Intervention Studies* *para 5.4, page 11).*

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **13/CEN/114** |
|  | Title: | A study to evaluate the efficacy, safety and tolerability of topically applied tretinoin formulated with TPM as an anti-acne preparation in human subjects with acne vulgaris. |
|  | Principal Investigator: | Dr Marius Rademaker |
|  | Sponsor: | Phosphagenics |
|  | Clock Start Date: | 15 August 2013 |

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 ethical issues

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

* The committee requests justification for enrolling 12 – 15 year olds in a Phase II clinical trial when the research question can be adequately answered in an adult group 16 years of age and older.
* The committee noted a problem with the study methodology. The researchers state the study is blinded and participants must not tell researchers about their treatment. The committee thought this could be hard to achieve i.e. if participants forget and accidentally tell the researchers. The committee is concerned that this will compromise the blinded nature of the research.
* The answer given at question p.4.1 did not address the question of how the study might benefit Maori. However, the committee was satisfied that the answer given at question p.4.2 addressed the question at p.4.1
* The committee asked that the researcher specify how much time participants would have to consider participation in the study (p.4.2, page 24) and clearly state the timeframe for participants.
* Participant Information Sheet and Consent Form
  + The committee noted the tone was regimented and not accessible and requested that you revise and soften the tone. The content should be structured to reflect the age of the participants.
* If there is adequate justification for enrolling 12-15 year olds please revise the PIS/CF for adolescents.
  + Simplify the language to make it appropriate for the age group.
  + Please provide Maori contact details.
  + Please state that cream is “applied” not “taken”.
  + Please include reference to the Central Ethics Committee.
  + Please correct contact information for the Chairperson of the Central Ethics Committee.

Decision

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

* Please provide justification for enrolling 12-15 year olds in a Phase II clinical trial when you can adequately perform this trial and see the effect in an adult group 16 years of age and older. [*NEAC Ethical Guidelines for Intervention Studies, Appendix 2, page 46, 3rd bullet point under ‘Principles’*].
* 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, Dean and Patries.

|  |  |  |
| --- | --- | --- |
| **9** | **Ethics ref:** | **13/CEN/115** |
|  | Title: | A study to evaluate if the study drug refametinib works and is safe in patients with liver cancer carrying a specific gene mutation (RAS mutation). |
|  | Principal Investigator: | Prof Ed Gane |
|  | Sponsor: | Bayer New Zealand Limited |
|  | Clock Start Date: | 15 August 2013 |

Mrs Jane Biddulph 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 phase II study will evaluate how Refametinib works and whether it is safe in patients with liver cancer who carry the RAS gene mutation. 15 people who have RAS will take part and the researchers have been allocated 10 patients to screen. There will be 95 participants worldwide.
* The committee noted that the researchers had stated participants will be given “as much time as necessary” to consider whether to take part in the study at question p.2.1 on page 22 of the application form. The committee requested that the researchers decide and specify a time frame for participants rather than keep it open-ended.
* The committee complimented the researcher for the fact that one of the investigators will also explain the information in the participant information sheet and consent form to participants.
* The committee noted that question p.4.1 on page 24 of the application form about benefits to Maori has not been answered as there is no health information included. What the potential benefits health wise for Maori?
* The committee advised that cultural issues at question p.4.2 include the fact that the researcher will take bloods and transfer the samples overseas. The committee pointed out that for traditional Maori, this is important to know so that they can agree to this and ask that the researcher please provide evidence that this answer is amended and that this information is provided to participants in the information sheets and consent form.
* The committee wants to ensure that compensation cover for participants relates to the five bullet points listed at r.1.9 on page 16 of the application form. The committee stressed the importance of the researcher checking the overarching terms to know the exact details and that equivalent ACC cover will be provided.
* The committee noted that remaining blood samples available for future unspecified research and advised that a separate PIS/CF will be needed for this purpose. (Please refer to the attached copy of the Ministry of Health *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes*).
* The committee noted that all participants in this study will be over the age of 18 and therefore no consent from a legal guardian is needed.
* The researcher confirmed for the committee that the collection of data for pregnancy is in the unlikely event that a participant falls pregnant.
* Participant Information Sheet and Consent Form.
  + Please include main exclusion criteria from protocol in lay language eg. pregnancy. Make it directive to participants who are left in the study. It is important that this is criteria is listed as part of informed consent.

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 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 separate PIS/CF for the future unspecified research use of human tissue. (Please refer to the attached copy of the Ministry of Health *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes*).

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

|  |  |  |
| --- | --- | --- |
| **10** | **Ethics ref:** | **13/CEN/116** |
|  | Title: | Filaggrin mutations in atopic dermatitis in Māori |
|  | Principal Investigator: | Professor Peter R. Hull |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 August 2013 |

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 is specific to Māori and will identify specific genetic mutations. The researchers intend to take a sample of saliva so there are cultural issues specific to Māori.
* The committee was satisfied that the research is not damaging but that there are outstanding issues relating to Māori cultural aspects.
* The committee was not satisfied that the researcher had explained why the risks of the study will be proportional to the benefits at question r.8.1 on page 18.
* No specific timeframe for study commencement was given in the application form (question p.2.1, page 19).
* The committee were unclear about how participants will be identified/selected in a way that ensures they can give informed consent free of undue influence as the answer given at question p.3.1, page 20 on the application form was ‘not applicable’. The committee would like to know how potential participants are going to be identified.
* The committee noted that the researcher recognises cultural ownership issues and that it is impressive that he has already met with Te Puna Oranga at Waikato DHB and is committed to ongoing consultation. However the researcher does not record how common eczema is in Māori. The New Zealand Health Survey (2006/7) indicates a high prevalence (Māori 14.9% vs. non- Māori 9.9%), so it is a significant Maori health issue that is overlooked.
* The committee was unclear about what additional genetic information the researcher will collect. The committee noted that the researcher addresses the common concerns raised in genetic research (what additional genetic information is being collected and what that information will be used for). The researcher says that a single gene will be examined and the DNA will then be destroyed (question a.1.6, page 4). But at question b.4.5 the researcher indicates that that tissue will be made available for use in future research without consent.
* The committee was unclear about where the samples would be stored. Page 3 of the participant information sheet states that DNA samples will be stored at the University of Saskatchewan. But on page 5 there is a bolded statement that advises once testing is complete the samples will be destroyed.
* The committee would like clarification about whether the researcher does in fact plan to undertake further unspecified research with these samples. If so then a separate participant information sheet and consent form is needed. (Please refer to the attached copy of the Ministry of Health *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes*).
* The researcher stated that an additional number of children will be screened for mutation at question b.2.1 on page 10 of the application form. The committee was unclear as to how additional numbers would fit into this application. If the researcher intends to screen children then an additional application will be required. The Committee would not give approval for children as part of this application.
* The committee noted that no independent peer review was submitted. The committee requires evidence of independent peer review so that it can check that the scientific validity of the study has been assessed.
* Participant Information Sheet and Consent Form
  + Given this study is for Māori only, please use the word ‘Whānau’ alongside family
  + Please include a paragraph that acknowledges Māori cultural issues. The committee suggests the following: *“The collection of tissue samples (saliva) and health information is considered tapu for many Māori. Removing these taonga or handing them on without approval may be culturally harmful to those who hold these views. You are, therefore, encouraged to consult with your whānau and hapū who share your whakapapa about the potential impact of this, before entering the study.”*
  + The committee suggests that the researcher may find it useful to refer to the Canadian research guidelines on research with indigenous people as many of the issues are the same.
  + Please remove language that could be perceived as stigmatising such as: “If there is anything ‘wrong’”, “if you have a mutation that can be corrected”.
  + The consent form has a drafting note about the use of an interpreter. Please determine whether you are offering interpreter and if not, please state this in the participant information sheet and modify the consent form.

Decision

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

The committee was satisfied that the research is not damaging but that there are outstanding issues relating to Māori cultural aspects that need to be addressed. (*Ethical Guidelines for Observational Studies* *para 4.3, page 8).*

The committee asks that you please address the points noted in the discussion and reapply as soon as possible. The committee notes that there are time restraints but recognises that the research is valuable.

|  |  |  |
| --- | --- | --- |
| **11** | **Ethics ref:** | **13/CEN/117** |
|  | Title: | Free lymph node transfer in the treatment of lymphoedema |
|  | Principal Investigator: | Mr Winston McEwan |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 August 2013 |

Dr Elizabeth Travis and Dr Sarah Shugg 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 queried the researcher’s answer of ‘no’ to unexpected clinically significant findings at question r.4.1 on the application form. It may be unlikely but there is a small possibility of finding an abnormal donor lymph node that would not found if the patient was not participating in the study. If that was case then the chief investigator would use clinical judgment.
* The committee noted that transferring body tissue will be a cultural issue for Māori but this did not appear to have been addressed by the researchers. The committee advised that participants may wish to have a karakia or talk to a kaumatua for instance. The researchers confirmed that discussion of cultural issues did take place but after submission of this application.
* The committee complimented the researchers on having an investigator talk through the participant information with potential participants noting that this approach safeguards those who may not be able to read.
* The committee asked the researcher whether written peer review by a senior colleague was uploaded or just discussed. The researcher has email records of discussion and will provide to the committee. The committee noted that the researcher might the NEAC guidelines on independent peer review useful and will send a copy to the researcher with the committee’s decision letter.
* The committee was concerned that no independent monitor was in place for this study. The researchers explained that this study is small and an independent monitor may not be necessary. The committee was satisfied that patient safety will be protected regardless.
* Participant Information Sheet and Consent Form
  + Please state the number of visits participants will make as this is not clear currently.
  + Under ‘risks’ because no bandaging is there a possibility that their l could get worse.
  + Please expand sections 2 and 3. For example, whether it is a day procedure, how long the recovery period is and whether the site will be painful.
  + Please put the benefits and risks into lay language.
  + Please state the study is approved by the Central Ethics Committee.
  + Please include the exclusion factors listed at question f.2.1, page 21 on the application form.

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)).

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

|  |  |  |
| --- | --- | --- |
| **12** | **Ethics ref:** | **13/CEN/110** |
|  | Title: | Levonorgestrel 1 x 1.5 mg tablet bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Medigen Pharma Pty Ltd |
|  | Clock Start Date: | 15 August 2013 |

Dr Tak Hung and Mrs Linda Folland 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 complimented the researchers on a well presented application.
* The committee complimented the researchers on the use of inclusion/exclusion in the participant information sheet and consent form including the inclusion of recreational party pills as often participants do not realise such substances pose a risk.
* The committee noted that the researchers appear to have put a lot of work into building up networks with Māori and that these networks are available for participants in this study.
* The committee noted that equivalence to ACC cover needs to be ensured for participants. The committee suggested the researcher check the statement of cover with the insurer to ensure that the five types of risk listed at question r.1.9 on the application form are covered for researchers’ own safety.
* The committee noted that the certain lines on pages 4, 5, 11 of the Participant Information Sheet make sense when read out by the researcher but are not included on scanned copies available.

Decision

This application was *approved* by consensus.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. Clarify template changes and forward templates to the committee.
3. Check the requirement for Maori consultation within locality assessment process. HDECs do rely on locality assessment covering the issues adequately.
4. Clarify why a full day can be claimed for 10 or more applications when previously a full day could be claimed for 8 or fewer applications.
5. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 24 September 2013, 12:00 PM |
| **Meeting venue:** | Terrace Conference Centre, 114 The Terrace, Wellington, 6011 |

The following members tendered apologies for this meeting.

Dr Angela Ballantyne

The meeting closed at 5.00pm.