|  |  |
| --- | --- |
| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 22 October 2013 |
| **Meeting venue:** | Clinical Trials Unit, Level 8 Ward Services Block, CCDHB, Wellington |

|  |  |
| --- | --- |
| **Time** | **Item of business** |
| 12noon | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 24 September 2013 |
|  | New applications (see over for details) |
| 12.30 – 1.00  1.00 – 1.30  1.30 – 2.00  2.00 – 2.30  2.30 – 3.00 | i 13/CEN/146  ii 13/CEN/150  iii 13/CEN/152  iv 13/CEN/153  v 13/CEN/154 |
| 3.00pm | General business:   * Noting section of agenda |
| 3.15pm | 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 |

## Welcome

The Chair opened the meeting at 12.08 pm and welcomed Committee members, noting that no apologies had been received.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 24 September were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **13/CEN/146** |
|  | Title: | ACCT007: Rap-CV |
|  | Principal Investigator: | Dr Stephen Laughton |
|  | Sponsor: | ANZCHOG |
|  | Clock Start Date: | 10 October 2013 |

Ms Paula Murray 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 acknowledged that this was a well put together application and noted the care that had been put into the participant information sheets.
* This is a stage 1 study, which will add a third drug (rapamycin) to an existing chemotherapy regimen of cyclophosphamide and vinoralbine. Participants will be under the age of 22 whose cancer has returned or has not responded to treatment.
* The Committee noted that rapamycin is not listed in the PHARMAC schedule and is not an approved drug in New Zealand. Rapamune which is a similar drug, is approved in New Zealand in 1mg or 2mg doses. If this is not what the researchers are proposing to use, SCOTT approval is required.
* The Committee noted that as this is a new drug combination, new or worse side effects may ensue and SCOTT approval should be provided. Ms Murray agreed to investigate this.
* The Committee acknowledged that the researchers had recognised the importance of whānau in information and decision making (P.4.2). The Committee recommended for future applications, that reference should be made to the fact that taking tissues (such as blood samples) might pose issues for Māori.
* The Committee queried the discrepancy between the number of participants anticipated to participate in this trial. The participant information sheet states that there will be two to three participants in New Zealand **per year** and the application states that there will be two to three **in total**. Ms Murray will confirm this but thought that it would be two to three in total.
* The Committee queried whether approval for Māori consultation had been received (P.4.3.1). Ms Murray confirmed that this had been received.
* The Committee noted that in order to have informed consent, the participant information sheet should include some of the key exclusion criteria in lay language, particularly the exclusion of pregnant women.
* The following changes were requested to the participant information sheet and consent form:
  + Please state that this study has received ethical approval from the Central Health and Disability Ethics Committee.
  + Please include the relevant exclusions, in lay language, in the participant information sheet, particularly the exclusion of pregnant women.

Decision

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

* Please confirm whether SCOTT approval is required (*Ethical Guidelines for Intervention Studies* *paras 5.50 – 5.51*).
* Please amend the participant information sheet and consent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

The response from the researcher will be reviewed, and a final decision made on the application, by Dr Patries Herst and Mrs Sandy Gill.

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **13/CEN/150** |
|  | Title: | STEP-UP |
|  | Principal Investigator: | Dr Mark O'Carroll |
|  | Sponsor: | Uptake Medical Corporation |
|  | Clock Start Date: | 10 October 2013 |

Dr Mark O’Carroll, Mr Matt Godden and Mr Robert Barry 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 they need evidence of favourable peer review. The Committee queried the status of the submission to the UK MHRA and asked whether MHRA review included a scientific peer review. Dr O’Carroll confirmed that this was at final approval stage, with one more question on informed consent to be answered. The Committee advised that they would like to view documentation of this review once it is complete in order to satisfy the requirement that favourable peer review had been granted.
* Mr Barry advised that ethics approval had been received in Germany and Australia. The Committee explained that there is a distinction between peer review and ethics approval, with ethics approval being given once evidence of peer review, among other things, has been provided.
* Mr Barry queried whether a scientific review is based on the protocol of the study. The Committee confirmed that this is a scientific review based on the protocol and the study design.
* The Committee queried whether there was the possibility of CT scans identifying previously unidentified conditions, such as pulmonary nodules which would potentially require further investigation to exclude malignancy. Dr O’Carroll confirmed that in groups with severe lung disease, that this was a possibility. The Committee agreed that a sentence should be added to the participant information sheet and consent form that following a CT scan, it is possible that a previously undiagnosed condition might be identified that may require further testing.
* The Committee asked for confirmation of the third party’s name as this is currently listed as Novotech Regulatory (A.5.4). Dr O’Carroll agreed to provide this.
* The Committee thanked the researcher for listing the exclusion criteria on the PIS.
* The Committee noted that the question on main cultural issues for Māori was well put together but noted that in future applications, the taking of blood and other tissue samples should be included as a cultural issue. The Committee noted that some statistics such as emphysema rates for Māori should be provided (P.4.1) in future applications and an indication should be given of and what the health benefits for Māori could be.
* The Committee noted the certificate of liability insurance which states that there is limit of medical expenses to any one person of $10,000 and personal injury to up to $1M and queried whether these funds would go to the CRO or the patient.
* The Committee asked for confirmation that the sponsor and PI are comfortable that this insurance fulfils the obligation to provide coverage that is the equivalent of ACC standards. Dr O’Carroll undertook to check this.
* The following changes were requested to the participant information sheet and consent form:
  + Please include “age” and “have received medication management completed pulmonary rehabilitation” as inclusion criteria on the participant information sheet.

Decision

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

* Please provide evidence of scientific review *(Ethical Guidelines for Intervention Studies para 5.11)*
* Please confirm who will receive the insurance funds and whether the insurance provides coverage that is the equivalent to ACC *(Ethical Guidelines for Intervention Studies paras 8.4 – 8.5)*
* Please amend the participant information sheet and consent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

The response from the researcher will be reviewed, and a final decision made on the application, by Dr Angela Ballantyne and Dr Dean Quinn.

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **13/CEN/152** |
|  | Title: | Oxycodone 5 mg bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Mayne Pharma International Pty Ltd |
|  | Clock Start Date: | 10 October 2013 |

Dr Hung and Ms 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.

* This is a bioequivalence study of an oxycodone drug.
* The Committee acknowledged the thoroughness of the participant information sheet.
* The Committee were happy that the content of the peer review was thorough but asked for clarification on the independence of the peer review process. Dr Hung explained that an independent person would be somebody not associated with or on the payroll of the company. He noted however that Zenith did pay Professor Glue for his time. The Committee queried whether Zenith used a range of consultants. Dr Hung confirmed that this was limited to two or three other people as they try to use consultants who are familiar with the protocol, consent and procedures. The Committee noted that it would be helpful to explain this in future applications.
* The Committee congratulated the researcher on their answer to the main cultural issues for Māori (P.4.2).
* The Committee noted that the insurance certificate provided is for another study (metoprolol). Ms Folland advised that the sponsor did not have a certificate ready for the oxycodone study when the application was submitted but that it would be provided before the study starts.
* The Committee queried the format of page 2 of the CF which is for office use only. Ms Folland confirmed that this is the usual form and is for information gathering purpose.
* Ms Folland explained that potential participants come to an information reading, with the consent form also read to them at this time. The investigator will then answer any questions and consent is signed off.
* Ms Folland confirmed that the participant gets a copy of the participant information sheet and consent form before the meeting and can take it away to consider before coming back. The participant also gets a copy of these documents to keep.

Decision

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

* Please provide evidence of sponsor insurance for the oxycodone trial *(Ethical Guidelines for Intervention Studies paras 8.4 – 8.5).*
* On page 10 of the participant information sheet, please add that this has been approved by the Central Health and Disability Ethics Committee.

The response from the researcher will be reviewed, and a final decision made on the application, by the Secretariat.

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **13/CEN/153** |
|  | Title: | Psychotropic Obesity Observational Study |
|  | Principal Investigator: | Dr Mark Huthwaite |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 October 2013 |

Dr Mark Huthwaite was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee noted that this was a worthwhile project.
* The Committee were concerned that there was the potential of stigmatisation to participants from the use of the word obesity in the title. Dr Huthwaite agreed to remove “Psychotropic Obesity Observational Study” from the title on the participant information sheet and consent form.
* Dr Huthwaite acknowledged that this study would involve a vulnerable population but this would be managed by only including participants who have the capacity to give informed consent.
* The Committee asked about consent from caregivers. Dr Huthwaite explained that participants that are unable to give consent will be excluded but there may be some participants who want their family or whanāu involved in the consent process.
* The Committee queried whether there is a sample form for family members. Dr Huthwaite confirmed that they will receive the same information as the participant and that as they will only be involved in the consent discussion, there is no need for them to sign anything.
* Dr Huthwaite confirmed that there will be no children involved in the study and that the participant age range will be from 18 to 65.
* The Committee queried whether there should be contact details for Māori on the participant information sheet. Dr Huthwaite confirmed that Kaumatua and Pacifica contact person are involved with the patient on a day-to-day basis and can be called at any time. There is also a consumer advocate on call.
* The Committee asked if James Stanley had provided a report on the basis of his peer review. Dr Huthwaite explained that this had been done through the University of Otago research grant application. The Committee acknowledged that with UORG grants, the researcher does not receive a report, just a ‘yes’ or ‘no’ decision to fund and that the application would have had at least three reviewers. The Committee asked if it would be possible for UORG to provide evidence in writing of the peer review. This could be sent directly to the Committee to ensure confidentiality. The Committee agreed that they would also be happy to receive a letter of approval from UORG confirming the study as evidence.
* Dr Huthwaite showed the letter of approval from UORG to the Committee who confirmed that they were satisfied with this as evidence of peer review.
* The Committee agreed that the Secretariat would write to UORG about a process for viewing evidence of peer reviews.
* The Committee queried how people would be enrolled in the constipation study. Dr Huthwaite explained that this will be randomised and participants will have taken part in the first study. The Committee recommended that as this is a sub-study that the word “optional” should be included in the title in the participant information sheet and consent form.
* The Committee queried whether there would be any concerns for patients with mental health issues having to wear a monitoring device or swallow tracer capsules. Dr Huthwaite confirmed this would be discussed in the consent process.
* Please provide the name(s) of the person(s) licensed under the Radiation Protection Act 1965 under whose supervision ionising radiation will be administer to participants in the study (R.1.13.2)
* The following changes were requested to the participant information sheet and consent form:
  + Please add that the study has been approved by the Central Health and Disability Ethics Committee to the participant information sheet and consent form.
  + Please add “Because you took part in the first study, you have been invited…” to the participant information sheet for the constipation study (page 1, para 1)
  + Please complete the sentence of the third bullet point, page 3 of the participant information sheet.
  + Please review the first sentence of the bolded paragraph on ACC entitlement on page 4 of the participant information sheet. This should be amended from “you will be covered by the Accident Compensation legislation” to “you may be covered by the Accident Compensation legislation”.

Decision

This application was *approved* by consensus with non-standard approval conditions:

* Please remove “Psychotropic Obesity Observational Study” from the title on the participant information sheet and consent form.
* Please provide the name(s) of the person(s) licensed under the Radiation Protection Act 1965 under whose supervision ionising radiation will be administer to participants in the study.

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **13/CEN/154** |
|  | Title: | Neurocognitive impairment in long term paediatric liver transplant recipients |
|  | Principal Investigator: | Dr Rachael Harry |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 October 2013 |

Dr Rachael Harry 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 asked whether Dr Harry would be prepared to let the Committee see the questionnaires that will be administered to participants. Dr Harry advised that the Psychological Professional Body states that questionnaires are not allowed to be disclosed in order to protect confidentiality.
* The Committee confirmed that they had approved previous applications where questionnaires have been given to the HDEC in confidence and that a closed meeting could be held to ensure confidentiality.
* Dr Harry advised that the questionnaires that will be used are validated tests, which are used world-wide.
* The Committee noted that the peer review did not explain why the study is feasible and whether it had scientific validity. Dr Harry confirmed that she does not know the reviewer and that the application was sent to a colleague who then sent it on to another colleague at Starship Hospital. The Committee noted that this detail should be provided in future applications.
* The Committee were concerned that participants could be stigmatised as the last paragraph of page 1 of the participant information sheet refers to problems with their behaviour and thinking. Dr Harry explained that this was not her intention and that she had worded it in this way as she wanted to use youth language.
* The Committee recommended that the researcher be very careful in the participant information sheet to ensure that there is not an emphasis on wording that could create stigmatisation or a negative picture of young persons who have undergone a liver transplant. Wording that appears to emphasise that young people who have had a liver transplant are more prone to bad behaviour and have lower cognitive functioning than the general youth population is disempowering and potentially stigmatising.
* The Committee noted that it would be useful in future applications to describe how the study may benefit Māori and Pacific people (P.4.1). Dr Harry explained that this would be difficult to give as the study had not yet been done but the Committee advised that what the study hopes to achieve would cover this.
* The Committee noted that the main cultural issues for Māori would be taonga of knowledge and the inclusion of whānau in decision making.
* The Committee noted that they would need to know the qualifications of Lucy Robinson, who will be performing the neurocognitive assessments. This can be done by providing a copy of her CV.
* The Committee queried whether the participant information sheet and consent form has been finalised as there is a draft header on the document. Dr Harry confirmed that this will be removed.

Decision

This application was *declined* by consensus, as the Committee considered the application was incomplete in respect of a material requirement, viz: provision (on a confidential basis) of copies of the questionnaires to be used – see *Ethical Guidelines for Observational Studies para 5.5*.

* When reapplying (as quickly as is practicable) please provide copies of questionnaires that will be used.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee noted ongoing issues with the participation information sheet template which the Secretariat is currently looking at. The following changes were recommended:

* The Committee noted that point one of the consent form template does not take into account differences in literacy levels and cultural norms. At present it reads “I have read, or have had read to me in my first language, and I understand the participant information sheet.” The Committee recommended amending this to read “I have read and been given a verbal explanation and been given a participant information sheet about the research.”
* Revision of the participation information sheet to make it clear that there is a significant element of doubt about whether people will be compensated under ACC.

1. The Committee noted that the participant information sheet template on online forms does not include Māori contact details. The Secretariat will follow this up.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 26 November 2013, 12:00 PM |
| **Meeting venue:** | Deloitte House, MEDSAFE, Level 6, 10 Brandon Street, Wellington, 6011 |

The following members tendered apologies for this meeting.

Dr Patries Herst

The meeting closed at 3.00pm