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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 June 2013 |
| **Meeting venue:** | Terrace Conference Centre, 114 The Terrace, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 28 May 2013 |
| 12.30pm | 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  3.00-3.30  3.30-4.00 | i 13/CEN/77  ii 13/CEN/78  iii 13/CEN/81  iv 13/CEN/82  v 13/CEN/83  vi 13/CEN/84  vii 13/CEN/86 |
| 4.00pm | General business:  Noting section of agenda |
| 4.15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 01/07/2012 | 01/07/2015 | Apologies |
| 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 12:30pm and welcomed Committee members, noting that apologies had been received from Dr Angela Ballantyne and 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 28 May 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **13/CEN/77** |
|  | Title: | Management of xerostomia following radiotherapy. |
|  | Principal Investigator: | Dr Olivia Apperley |
|  | Sponsor: | Sir John Walsh Research Institute |
|  | Clock Start Date: | 13 June 2013 |

Dr Olivia Apperley, the Co-ordinating Investigator, was not present for discussion of this application.

Note Dr Apperley dialled in later during the meeting and briefly spoke with the Committee.

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 at what stage the peer review process would be completed, noting the application (B.2.2.1) indicates the protocol will be reviewed after its completion.
* The Committee queried the exclusion criteria (F.2.1), noting that there is no mention of participants being excluded if they are taking medications which may cause a dry mouth such as anti cholingerics (inhaled or systemic).
* Please ensure you notify the participant’s GP of study involvement.
* The Committee noted the lack of termination criteria (R.1.4).
* Please clarify if people in the pre-existing database of head and neck radiotherapy patients have consented to be contacted about future research studies (R.2.1.1)
* The Committee requested a justification of study design and sample size. The Committee suggesting a ‘complete block’ design might provide better data as well as reduce the required sample size for the study.
* In future applications please explain how cultural issues are addressed in regards to tissue samples e.g. saliva (P.4.2).
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please provide greater clarity for participants about the study design. The Committee suggested including a diagram in the Information sheet.
* Please provide more information about the study treatment, what the components are and what if any potential side effects, including allergic reactions.
* Provide more information on what the saliva production test involves for the participant.
* Please provide more information about treatment restrictions while participating in the study, including the washout periods.
* Please record ethnicity data.
* Please ensure the Central Health and Disability Ethics Committee contact details are included.
* The Committee suggests reviewing the template PIS/CF found at [http://ethics.health.govt.nz/home](http://ethics.health.govt.nz/home%20) for suggestions of what information to include and how to best format the PIS/CF to ensure the information is accessible to participants.
* Please include information about the possibility that screening will identify health issues unrelated to the study e.g. as a result of the oral examination (R.4.1).
* Please add exclusion criteria for people on existing medication.

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 provide termination criteria for the study (*Ethical Guidelines for Intervention Studies para 6.63).*
* Please provide evidence of Maori consultation (*Ethical Guidelines for Intervention Studies para 4.7).*
* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).
* Please amend the information sheets and consent/assent forms, 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 Dr Dean Quinn and the Chair.

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| **2** | **Ethics ref:** | **13/CEN/78** |
|  | Title: | RELIEF Trial |
|  | Principal Investigator: | Dr Felicity Pugh |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 June 2013 |

Dr Felicity Pugh and Adina (Secretariat to confirm) 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.

* Committee noted the application was well written.
* The Committee asked for clarification on the recruitment process, noting that the participants are consenting on the day of their surgery. Dr Pugh clarified that the process is an opt-out process, adding that participants will be followed up after the surgery.
* In future applications please ensure (P.4.2) includes the main cultural issues for the study, such as the appropriate management of human tissue.
* Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html) (R.2.5)
* Committee noted some participants could be considered vulnerable, due to the context of recruitment. Dr Pugh clarified that day of surgery recruitment had been discussed and researched, concluding that day of surgery recruitment was not more stressful for patients. Dr Pugh added that a personal assessment of patient stress was conducted, and if stress and anxiety was deemed too high the patient would not be recruited.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please clarify which doctor will be contacted in the statement ‘If we are unable to contact you about complications, we will check with your other doctors for this information.’ For example add ‘your GP’.
* Please provide brief exclusion criteria in lay language.
* Please ensure the Central Health and Disability Ethics Committee contact details are included.

Decision

This application was *approved* by consensus.

Please submit an amended PIS/CF for completeness.

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| **3** | **Ethics ref:** | **13/CEN/81** |
|  | Title: | TOTAL Trial |
|  | Principal Investigator: | Dr Gerard Devlin |
|  | Sponsor: | Hamilton Health Sciences |
|  | Clock Start Date: | 13 June 2013 |

Dr Gerard Devlin, Sarah Pilkington and Liz Low were present in person 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 whether the study had been peer reviewed, noting that a critique of literature had been submitted in the place of peer review. The Researchers clarified that the protocol had been peer reviewed by the Canadian Institutes of Health Research (CIHR). The Committee requested that in future applications include this information in (B.2.2.2) to avoid confusion.
* The Committee commended the answering of question (P.4.1).
* In future applications please describe potential cultural issues involved, for instance taking into account human tissue (the removal of the blot clot) and knowledge as a taonga (P.4.2). Information about cultural issues also needs to be included in the PIS
* The Committee requested more information on how the two consent forms will be used. The Researchers explained that the abbreviated PIS will allow patients to make an informed decision when they are in a vulnerable context of recruitment (under duress of a heart attack). As soon as the patient indicates they are well enough, or in a better position to take on board more detailed information, the extensive PIS will be offered, adding that researchers will also discuss the second PIS with the participant.
* The Committee requested the extensive PIS be provided to the family and Whanau at the time the participant consents to the abbreviated form.
* Please add exclusion criteria for M.I
* Please submit CVs for Dr Menon and Dr Liew.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Include Maori contact numbers to both abbreviated and extensive PIS.
* Please add a statement suggesting participants discuss study involvement with family and whanau to both abbreviated and extensive PIS.
* Please ensure it is clear that the blood clot may be removed in the extensive PIS.
* Please include inclusion and exclusion criteria, in lay, in the extensive PIS.
* Please review the language used in the description of risks pg. 2 of extensive PIS. For instance ‘modify’ could be simplified to ‘may increase or decrease’ risk of stroke.
* Please include generic ACC statement in the extensive PIS.
* Please include a list of statements for the participants to consent to in the extensive PIS, each with a yes or no, to ensure participants are consciously and actively consenting.

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 CVs for Dr Menon and Dr Liew (*Ethical Guidelines for Intervention Studies* *para 5.36*).

This information will be reviewed, and a final decision made on the application, by Mrs Gael Donoghue and Mrs Sandy Gill.

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| **4** | **Ethics ref:** | **13/CEN/82** |
|  | Title: | A Phase III study to assess the efficacy and safety of Lebrikizumab in patients with uncontrolled asthma. |
|  | Principal Investigator: | Professor Richard Beasley |
|  | Sponsor: | PPD Global Ltd (NZ Branch) |
|  | Clock Start Date: | 13 June 2013 |

Irene Braithwate and Mark Holiday 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.

Dr Dean Quinn declared a potential conflict of interest, and the Committee decided to let Dr Quinn discuss the application but was exempt from voting in the decision. No other declarations were received.

Summary of ethical issues

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

* Please clarify if the sub-consent form is for unspecified future research or for specific asthma treatment development. Researcher responded they will need to consult with Sponsor.
* The Committee noted that if Sponsor confirms the sub-study is for unspecified future research there is a requirement to submit a separate PIS/CF.
* The Committee queried if participants are assessed against the inclusion and exclusion criteria before enrolment to the study (F.1.2). The researchers clarified that screening for potential participants would have inclusion and exclusion criteria in mind.
* The Committee queried why none of the exclusion criteria were included in the PIS. The Researchers responded that it was difficult to add all of the criteria as it would make the document lengthy.
* Researcher queried whether the PIS/CF should have Maori contacts, noting the template PIS/CF does not have this statement. The Committee responded that it requires Maori contacts be made available.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The word OPTIONAL must be included in the title of the sub study,
* The main inclusion/exclusion criteria must be added using lay terminology,
* Add Maori Contact Details.

Decision

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

* A deadline for participants to respond to the invitation to participate (P.2.1 and P.3.1) must be added (P.2.1 and P.3.1) (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).
* Submit an indication of level of reimbursement for participants (*Ethical Guidelines for Intervention Studies* *para 6.32).*
* 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 clarify if the sub study will be for specified or unspecified future research.

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

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| **5** | **Ethics ref:** | **13/CEN/83** |
|  | Title: | A Phase III study to assess the efficacy and safety of Lebrikizumab in patients with uncontrolled asthma. |
|  | Principal Investigator: | Dr Elaine Yap |
|  | Sponsor: | PPD Global Ltd (NZ Branch) |
|  | Clock Start Date: | 13 June 2013 |

Catherine Howie 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.

Dr Dean Quinn declared a potential conflict of interest, and the Committee decided to let Dr Quinn discuss the application but was exempt from voting in the decision. No other declarations were received.

Summary of ethical issues

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

* Please clarify if the sub-consent form is for unspecified future research or for specific asthma treatment development. Researcher responded they will need to consult with Sponsor.
* The Committee noted that if Sponsor confirms the sub-study is for unspecified future research there is a requirement to submit a separate PIS/CF.
* The Committee queried if participants are assessed against the inclusion and exclusion criteria before enrolment to the study (F.1.2). The researchers clarified that screening for potential participants would have inclusion and exclusion criteria in mind.
* The Committee queried why none of the exclusion criteria were included in the PIS. The Researchers responded that it was difficult to add all of the criteria as it would make the document lengthy.
* Researcher queried whether the PIS/CF should have Maori contacts, noting the template PIS/CF does not have this statement. The Committee responded that it requires Maori contacts be made available.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The word OPTIONAL must be included in the title of the sub study.
* The main inclusion/exclusion criteria must be added using lay terminology.
* Add Maori Contact Details.

Decision

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

* A deadline for participants to respond to the invitation to participate (P.2.1 and P.3.1) must be added (P.2.1 and P.3.1) (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).
* Submit an indication of level of reimbursement for participants (*Ethical Guidelines for Intervention Studies* *para 6.32).*
* 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 clarify if the sub study will be for specified or unspecified future research.
* Please submit the CV for Dr Veal (*Ethical Guidelines for Intervention Studies* *para 5.36*).

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

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| **6** | **Ethics ref:** | **13/CEN/84** |
|  | Title: | An assessment of how the new psoriasis medicine Brodalumab is processed by the body when taken by men and women with psoriasis. |
|  | Principal Investigator: | Dr Christian Schwabe |
|  | Sponsor: | Amgen Australia Pty Ltd |
|  | Clock Start Date: | 13 June 2013 |

Dr Christian Schwabe and Carolyn Harris 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 question (P.4.2) was really well done.
* Please ensure that investigators are screening potential participant’s medical history to confirm participant eligibility (F.2.1).
* Please upload CV and MPS for Dr Wynne.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please include exclusion and inclusion criteria in lay language.
* Please separate the PIS/CF on optional genetic research entirely from the main study.
* Please explain technical terminology for participants where possible. I.e. ataxia.
* Add a declaration that, if participants have any medical or life insurance, the participants should discuss involvement in the study with their provider for this coverage.

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*).
* Submit the CV and MPS for Dr Wynne (*Ethical Guidelines for Intervention Studies* *para 5.36*).

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

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| **7** | **Ethics ref:** | **13/CEN/86** |
|  | Title: | Tibolone 1 x 2.5 mg bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Medigen Pharma Pty Ltd |
|  | Clock Start Date: | 13 June 2013 |

Dr Noelyn Hung, Linda Folland and Dr Tak Hung 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.

* In future applications please acknowledge cultural issues involved in the study (P.4.1 and P.4.2).
* The Committee commended the addition of multiple Maori contacts included on the PIS/CF.
* The Committee queried if the study had been submitted to SCOTT. Dr Hung stated that the study was undergoing review through abbreviated Medsafe pathway.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The Committee noted that cultural issues are not only gender issues. There are Tikanga Maori covering samples and knowledge is Taonga, as well as including Whanau in recruitment and consultation processes.

Decision

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

* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).
* Please provide evidence that SCOTT review is not required, and that the appropriate pathway is the abbreviated Medsafe pathway (*Ethical Guidelines for Intervention Studies* *Appendix One).*

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

## 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:** | 23 July 2013, 12:00 PM |
| **Meeting venue:** | Deloitte House, MEDSAFE, Level 6, 10 Brandon Street, Wellington, 6011 |

The following members tendered apologies for this meeting.

* Mrs Helen Walker
* Committee members Dr Dean Quinn or Mr Paul Barnett will be seconded as Chair for the above meeting.

1. **Problem with Last Minutes**

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

The meeting closed at 3.40pm.