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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 28 July 2015 |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 23 June 2015 |
|  | New applications (see over for details) |
|  | i 15/CEN/89  ii 15/CEN/93  iii 15/CEN/95  iv 15/CEN/96  v 15/CEN/97  vi 15/CEN/98  vii 15/CEN/99  viii 15/CEN/100  ix 15/CEN/101  x 15/CEN/102  xi 15/CEN/103  xii 15/CEN/104 |
| 5.30-5.45pm | Review of provisionally approved studies |
| 5.45-6.00pm | General business:   * Noting section of agenda |
| 6.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Gael Donoghue | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | 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 Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Apologies |
| Dr Kay de Vries | Non-lay (observational studies) | 19/05/2014 | 19/05/2017 | Apologies |
| Dr Nicola Swain | Non-lay (intervention studies) | STH Co-opt | STH Co-opt | Present |

## Welcome

The Chair opened the meeting at 12.05pm and welcomed Committee members, noting that apologies had been received from Dr Cordelia Thomas.

The Chair welcomed Mrs Philippa Bascand, the HDEC Manager, who was observing the meeting.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Dr Nicola Swain confirmed her eligibility and was co-opted by the Chair as a member of the Committee for the duration of the meeting.

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 June 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/CEN/89** |
|  | Title: | DSD: Navigating decision making |
|  | Principal Investigator: | Professor Sunny Collings |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 09 July 2015 |

Ms Denise Steers and Dr Angela Ballantyne 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 Study

1. The study investigates disorders of sex development (DSD). The study aims to understand how decisions are made and will navigate the experience and treatment pathway that occurs for children who experience DSD in New Zealand, as well as exploring the international context.
2. Earlier research suggests that historical treatment of children with DSD has been problematic. In 2006 there was an international consensus on how children born with DSD should be treated. Since this consensus there remains confusion around how this treatment actually happens. The researchers will assess if care providers adopted the recommendations from this consensus in New Zealand.
3. The study involves three groups - health workers (clinicians), parents of children with DSD and young adults (16+) who have DSD.
4. There has been research conducted with older participants who had experienced the pre-2006 treatment pathways. This study involves a younger group who will be able to comment on more recent treatment methods and will provide a new perspective on current treatment options, giving us a holistic picture.
5. The Otago ethics committee has approved the study.
6. The researchers explained that when they sought locality approval from ADHB their research office requested HDEC review due to the potential vulnerability of the patient population.
7. The Committee commended the study and noted that it was an important project.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried whether there should be a Participant Information Sheet/Consent Form for the doctors due to their involvement as participants. The Researchers explained that the doctors have already been interviewed.
2. The Committee noted this and asked how the interviews went. The Researchers explained there was a mixed response – some were happy to be interviewed but would not refer any patients for the other parts of the study, some were more agreeable to refer.
3. The Committee confirmed funding letter was evidence of peer review.
4. The Researchers explained how they had been developing strong relationships with doctors, families and the young people themselves, noting the importance of trust in this context.
5. The Committee queried whether there are pacific island support groups available, noting DSD may be more prevalent in Pacific Islanders. The Researchers explained that the ‘Rainbow Youth’ have been consulted and will provide support, adding that while DSD participants may not be involved with Rainbow Youth the group has a umbrella support networks in the region.
6. The Researchers explained the number of specialists and advisory and support persons that they had on board for this project.
7. The Researchers explained how participants had explained that being able to discuss their experiences had been cathartic and was so far well received.
8. The Researchers confirmed that there is lots of time to consider participation.
9. The Researcher explained the verbal support that is given with the written information.
10. The Committee queried whether the small sample size and kind of information collected caused a risk of identification when publishing. The Researchers explained that names and places will not be included to ensure anonymity. The Researchers will use quotes but will ensure the individuals can review prior to publishing. A report will also be given to participants prior to publication. We will change anything that looks like it could potentially identify an individual.
11. The Committee queried if Ngai Tahu consultation had been renewed. The Researchers explained that they had applied for renewal.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee requested a copy of the semi-structured interviews, for completeness.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Add a sentence that states that if you have any concerns or experience distress please contact me and I can help you find local support.
2. Please review for structure and grammar.
3. State that Central Health and Disability Ethics Committee approved the document.

Decision

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

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| **2** | **Ethics ref:** | **15/CEN/93** |
|  | Title: | Blinded randomised controlled trial of Oxford Uncemented Unicompartmental Knee Arthroplasty and Total Knee Arthroplasty |
|  | Principal Investigator: | Dr Jonathan Manson |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 July 2015 |

Dr Jonathan Manson 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 Study

1. The Committee noted that the study had been previously declined but stated that the researcher has done a good job in responding to the points.
2. The Researcher explained the intervention and the long-term follow up, post intervention.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried the researcher’s justification to not collect ethnicity information, citing responder burden. The Researcher explained that they could collect ethnicity information if they had to but did not think it was relevant. The Committee stated it was important to collect ethnicity information; some reasons are to identify any ethic disparity, inequality or clinical differences. The Researcher stated he would collect this information from the patient notes.
2. The Committee queried how un-blinding works, citing potential for emergency unblinding. The Researcher explained the treatment could easily be unblinded with an x-ray, there is no issue with emergency un-blinding. The Researcher added that the main issue is more related to keeping people blinded, as one accidental look at an x-ray and the treatment would become obvious.
3. The Researcher confirmed 270 is the correct number of participants.
4. The Committee commended the researcher for acknowledging Maori cultural issues relating to tissue and bone in their application.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. Please submit the evidence of peer review. The Committee accepts that peer review has occurred but notes it was not submitted.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Add ACC statement from HDEC template and replace current ACC wording.
2. Please remove tick boxes and only include those that are truly optional.
3. Remove the consent form statement about understanding compensation – this statement is not relevant for this study.

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **15/CEN/95** |
|  | Title: | CAMERA2 |
|  | Principal Investigator: | Dr Genevieve Walls |
|  | Sponsor: | Menzies School of Health Research |
|  | Clock Start Date: | 09 July 2015 |

Dr Steve McBride 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 Study

1. This application is to involve Middlemore hospital in the CAMERA 2 study.
2. CAMERA 2 is an interventional study comparing standard therapy with a standard therapy + study drug.
3. The Researcher confirmed there had been a pilot study that had microbiological endpoints. The study generated evidence suggesting that the addition of the study drug may have the potential to improve outcomes. This trial aims to generate further evidence to support clinical practice decisions.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried if everyone enrolled will provide written informed consent. The Researcher explained that this varied at sites (internationally). Where it is permissible to enroll participants without consent this will occur but this will not occur in New Zealand. The Committee accepted this response.
2. The Committee queried what would happen if the addition of the study drug indicated that the additional treatment was beneficial. The Researcher explained that it is unlikely that any trial results will be clear during the treatment phase. This relates to the short duration of treatment.
3. The Committee noted study is open label. If a participant is randomized to the single arm (standard care) but then asks for a combined treatment with the study drug – what would occur? To ensure such events do not impact the study we have a 10% drop out rate that is taken into account. We will make it clear in the Participant Information Sheet that the dual therapy does not have any proven benefit – and that it does involve more intensive IV treatment. Patients requesting change of treatment may be an issue but we do not expect it, based on the pilot study.
4. The Committee asked about the time frame to decide whether to participate. The Researcher stated there is up to 72 hours. This timeframe ensures there is no delay in therapy while giving potential participants enough time to consider participation.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. The Committee noted that Maori and Pacific islanders are disproportionately affected, as explained in the application. HDEC to provide cultural statement for the Participant Information Sheet.

Decision

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

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| **4** | **Ethics ref:** | **15/CEN/96** |
|  | Title: | Bowel Cancer Study |
|  | Principal Investigator: | Dr Tinte Itinteang |
|  | Sponsor: | Gillies McIndoe Research Institute |
|  | Clock Start Date: | 09 July 2015 |

Dr Tinte Itinteang & Vicky Cameron 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 Quinn declared a potential conflict of interest, and the Committee decided to have Dr Quinn remain in the room but not take part in discussion or decision of the application.

Summary of Study

1. The Researchers explained they have an HDEC approved tissue bank and are collecting tissue from standard practice surgery. The applications submitted for review are to use banked tissue for the research as outlined.
2. The study will look at cancer stem cells.

Decision

This application was *approved* by consensus.

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| **5** | **Ethics ref:** | **15/CEN/97** |
|  | Title: | Breast Cancer Study |
|  | Principal Investigator: | Dr Tinte Itinteang |
|  | Sponsor: | Gillies McIndoe Research Institute |
|  | Clock Start Date: | 09 July 2015 |

Dr Tinte Itinteang & Vicky Cameron 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 Quinn declared a potential conflict of interest, and the Committee decided to have Dr Quinn remain in the room but not take part in discussion or decision of the application.

Summary of Study

1. The Researchers explained they have an HDEC approved tissue bank and are collecting tissue from standard practice surgery. The applications submitted for review are to use banked tissue for the research as outlined.
2. The study will look at cancer stem cells.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **15/CEN/98** |
|  | Title: | DAP-PEDOST-11-03: Study investigating Daptomycin in the treatment of bone infection in children. |
|  | Principal Investigator: | Dr Tony Walls |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 09 July 2015 |

Suzie Kassess project Manager & Estelle Sachs 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 Study

1. The study will recruit 10 participants in New Zealand.
2. The study is up in running internationally with ethics approval. About 60 patients recruited so far.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried if there had been any declines with other ethics committees. The Researcher stated there had not.
2. The Committee queried if there is any disease prevalence information for Maori. The Researchers will follow up. The Committee requested that in future applications that answers about benefit (P.4.1) do not concern access to research. Instead it would be useful to talk about statistics about the disease that the research is covering and how it may improve Maori health. If there is no increased prevalence for Maori simply state this. Similarly, questions about Maori cultural issues (P.4.2) you should include information on ‘whakama’, which is a Maori cultural issue that needs to be identified and mitigated. Lastly the application asks for information on how the study would impact other ethnicities in New Zealand – this information should be included in applications.
3. The Committee asked for information on reimbursement. The Researchers stated 50 dollars is expected to be provided for parking or travel costs.
4. The Committee noted abstinence is not the usual suggested birth control by the Committee. The Committee noted spermicide is not available in New Zealand. Please review this information in the Participant Information Sheet.
5. The Committee queried if the study drug is being used ‘off label’.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Include cultural statement about value of tissue samples for Maori participants. For example: You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Maori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However it is acknowledged that individuals have the right to choose.
2. Please explain if samples are being sent overseas in the Participant Information Sheet under ‘what will happen to my samples’. The Committee noted this information is in the consent form.
3. Page 7 of the Participant Information Sheet references the New Zealand RMI guidelines. The Committee noted that these are not acceptable in New Zealand as they do not guarantee ACC equivalent compensation. Please use the compensation information from the HDEC template Participant Information Sheet.
4. Please add labels to indicate who the Participant Information Sheet is for – for instance parent or child. The Committee noted there is a footer but please add to title of the document.
5. Please explain that the use of the study drug is off label.
6. On the Participant Information Sheet for 7-11 year olds – please explain that if a participant presents to a hospital they will need to explain that they are taking part in a trial.
7. Please add to the alert card that the study is using an approved drug for off label use.
8. The Committee requested that the first three lines of the Exclusion Criteria on Page 29 of the Application are included in the Participant Information Sheet, in lay language.

Decision

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

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*).

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

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| **7** | **Ethics ref:** | **15/CEN/99** |
|  | Title: | Effectiveness of Face-to-Face Problem Gambling Interventions Clinical Trial |
|  | Principal Investigator: | Professor Max Abbott |
|  | Sponsor: | Ministry of Health |
|  | Clock Start Date: | 09 July 2015 |

Professor Max Abbott, Katie Palmer DuPreez & Maria Bellringer 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 Study

1. The study will compare two proven interventions that treat problem gambling.
2. The Researchers explained that a 3-year follow up study has recently finished and is currently unpublished, with the Ministry of Health. This study has further informed the current research project. The Researchers explained that the bulk of the established research is about cognitive interventions that compare effectiveness of face to face, telephone and online.
3. The Committee commended the protocol.

Summary of ethical issues

The main ethical issues considered by the Committee:

On the peer review, efficacy and interventions

1. The Committee asked for information on the two peer reviews provided, noting they raised a number of issues with the project. The Committee noted that the peer review stated that one of the interventions only had one face to face meeting, with the remainder being on the telephone - was this appropriate for those who had a higher level of problem gambling status? The Researchers stated that groups who had received this form of intervention in prior studies were high risk gamblers who were at the extreme clinical end and who also had mental health risks and other co-morbidities. The evidence from these studies suggests that the face-to-face with telephone follow up is appropriate. The Researchers stated the peer reviewer did not appear to know about these prior studies.
2. The Committee queried whether the cognitive interventions had proven efficacy? The Researchers stated there has been a trial conducted in Australia that suggested it did, adding the cognitive behavior component for this study has been trailed in other studies. The part that has not been studied very much (in problem gambling) but has been used in other psychological treatments such as anxiety is the exposure component. The Committee asked what exposure treatment is. The Researchers stated this is when you expose people to real life gambling experiences. This can either be done in the imagination or it can be done physically. The Committee restated the question – do you think that the cognitive intervention in this study has some level of efficacy. The Researcher stated yes.
3. The Committee queried the peer reviewer’s sample size concerns. The Researchers stated that the peer reviewer stated that the sample was too large. The Researcher explained that this was not something to be concerned about – having a too small sample was bad not too large.
4. The Committee noted that for a research study you don’t want to over recruit as this causes unjustifiable risk for participants. This is an ethical risk because participant sample size should be enough to answer the research question.

On ethnicity and accessibility of the study

1. The Committee asked about the involvement of Maori and Pacific people in this study. The Committee noted that currently participants are recruited through the Salvation Army Oasis system. The Researchers confirmed this was correct. The Committee queried, knowing that Pacific people are less likely to access this system and therefore be enrolled, how will the Researchers include Pacific populations? The Researchers explained it is key to the study to recruit people who are seeking help (through Oasis). It would not be appropriate to recruit by other means. The critical thing is to make sure the Maori numbers are high enough. The Researcher is confident that he will meet his ethnicity targets for Maori as half the people in Oasis will be Maori, but noted that Pacific levels are going to be a challenge. The Researchers explained that they will likely keep the study running until they meet the Pacific peoples target.
2. The Researcher stated they could recruit through people seeking help from the helpline. They have considered this as a contingency plan.
3. The Committee queried whether the Asian population was an ethnicity that would be analysed. The Researchers stated ‘no’ because it would be too costly, potentially adding millions to the cost of the study. The Researchers explained that Maori and Pacific have highest rates of developing problem gambling – they are also a health priority for the Ministry of Health.
4. The Researcher explained that participants must speak English as their first language to participate. The Committee noted this condition would potentially exclude a vulnerable population who should be involved in the study.

On the counsellors and training

1. The Committee queried how counsellors are involved. The Researcher explained that therapists, who provide ‘treatment as usual’ along with motivational interviewing, will be delivering the care / intervention for the study. This mitigates bias from therapists. However it may mean that there is a bias for treatments provided. The Committee noted that this risk was raised by one of the peer reviewers, terming this ‘therapy leakage’.
2. The Committee asked if any therapists would not be on board with this research. The Researchers stated it is possible. The Researchers explained that the therapists must be interested in evidence-based care and there are plans for developing national level training – the national level managers are on board, however there may be individuals who do not want to participate. These therapists can abstain from participation.
3. The Committee asked if there will be any literacy issues experienced – do the researchers have translators? The Researcher explained that the Participant Information Sheet have been crafted in conjunction with stakeholders (Oasis and consumer representatives) and are confident that participant will be able to understand it.
4. The Committee queried who the expert is for adapting Cognitive Behavioral Therapies for Maori. The Researchers advised Dr Simon Bennet.
5. The Committee queried who would conduct the training for Cognitive Behavioral Therapy and Motivational interventions. The Researchers explained the lead trainers will be Australian and Canadian teachers who are world leading. The Committee queried how it would take place? The Researcher stated they will come to New Zealand to conduct training.
6. The Committee queried the process for MI. The Researcher explained it was one face to face and then continued telephone follow up.
7. The Committee queried who would conduct the review to determine whether the participant has a clinical gambling problem. The Researchers explained they will use standardized measures that are internationally accepted.
8. The Committee queried whether court ordered clients would be included. The Researchers explained that they would – unless they meet other exclusion criteria.
9. The Committee queried how participants are screened for exclusion criteria. The Researchers stated that therapists are going to help screen and are well experienced to determine if a person is eligible. Through normal practice they will check for any risks. The Researcher clarified that they will not exclude people who are depressed.
10. The Committee queried the use of data for future research. The Researchers explained that the Ministry received de-identified data but confirmed that the data would not be used for any other work.
11. The Researchers confirmed that a counselor could withdraw a participant if they have particular or individual needs. Participants can also withdraw at any time.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee requested further justification of the randomizing.
2. The Researchers explained that the peer reviewers must have not been aware of the status of these interventions or the latest research. The Committee asked how the researchers responded to the peer reviewers. The Researchers explained that they provided a response to the peer reviews. The Committee requested evidence of the response or rebuttal to the peer review responses, noting it was important to address these concerns.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Confirm that no identifying data is recorded.
2. Add Maori contact details and HDEC contact details.
3. F.2.1 – please add the three ‘willing to’ eligibility criteria to the Participant Information Sheet.
4. Add basic ACC information - check HDEC for the correct terminology template.

Decision

This application was *provisionally approved* by vote, with 5 for and 2 against (1 voted for decline, 1 voted for approve) 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*).
* An intervention study meets the equipoise standard if the evidence is ‘equally poised’ as to the overall balance of risks and benefits of each of the interventions offered in the study, so that it cannot be determined in advance which of the groups in a proposed study will be better off. Please explain how your study meets this standard. (*Ethical Guidelines for Intervention Studies* *para 5.18*).
* Please provide evidence of favourable independent peer review of the study protocol or provide a response to the points raised in your existing peer review (*Ethical Guidelines for Intervention Studies* Appendix 1).

This following information will be reviewed, and a final decision made on the application, by Dr Patries Hearst and Mrs Helen Walker.

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| **8** | **Ethics ref:** | **15/CEN/100** |
|  | Title: | 3-DHB Youth AOD Exemplar Project |
|  | Principal Investigator: | Dr Jessica Allen |
|  | Sponsor: | 3 DHB (Capital and Coast, Hutt Valley and Wairarap |
|  | Clock Start Date: | 09 July 2015 |

Dr Jessica Allen 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 Study

1. The study investigates the patient journey for young people who are taking part in the AOD Exemplar project. This project deals with youth alcohol and drug use.
2. The Committee queried age range. The Researcher stated age group for focus groups will be 13 to 24 year olds. For interviews it was 12-24. The Committee asked what was occurring for the 10-11 year olds. The Researcher stated that these participants would likely not be involved due to the practicalities (both no treatment options available for them and seeking consent may be difficult).
3. The Committee requested that in future the Participant Information Sheet/Consent Form documents are identifiable documents by including a footer (date and version number) and header (title of the information sheet / consent form) to help differentiate them.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. Please provide assent forms for children who do not have capacity to consent. Parents provide consent and children provide assent (where there is no capacity for consent). The Committee acknowledged that the children could likely consent for participation in focus groups themselves.
2. There should be a range of patient information sheets. HDEC suggests 10-14, 15-16 and then 16+.
3. The Committee queried how participants would be deemed competent to consent. The Researcher explained they would talk to health professionals to ensure researchers approach the right patients.
4. The Committee queried if these patients in the system (on file)? The Researcher stated for the interviews yes, as we will identify through counselors. For the focus groups they will be identified from health providers.
5. The Researcher explained that while the participants are vulnerable they should have a voice too. The Committee agreed.
6. The Researcher explained parental consent is on the interview Participant Information Sheet but not on the focus group. The focus groups have no requirement for individuals to participate, they can be present but silent if that is what they want to do.
7. The Committee confirmed that participants could participate in the focus group with consent (even young children) provided they are Gilllick competent.
8. The Committee queried what process is followed if participants are identified as under the influence during the focus group? The Researcher explained the researchers are trained in identifying this behavior. If the participant seem different from their normal self we will assess whether they should participate. If they seem like their usual self, which may involve being under the influence, we will include them as their voice is important. If they are putting themselves in a situation where they may disclosure something that they may regret, or disrupt the group, we will gently remove them from the group and discuss further.
9. The Committee queried whether a social worker (youth worker) would be available at all times? The Researcher confirmed social workers would be present adding her own experience with CYF care and at risk children generally.
10. The Committee requested that safety information was added to Participant Information Sheet that explains the need to potentially notify an appropriate person if information that places the child at risk arises.
11. Please add prevalence of Maori with respect to the focus of the research, in future applications (P.4.3.1)
12. (P.4.2) The Committee noted that this question is not so much about participation; rather it is about cultural issues, such as whakama.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).
2. The Committee queried if there were other scenarios other than the one provided in the protocol. The Researcher confirmed there were 5. The Committee requested they are submitted to HDEC for completeness.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please add confidentiality clause for 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, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Please submit other scenarios for completeness.

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

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| **9** | **Ethics ref:** | **15/CEN/101** |
|  | Title: | ASLAN001-003 |
|  | Principal Investigator: | Professor Bridget Robinson |
|  | Sponsor: | ASLAN Pharmaceuticals |
|  | Clock Start Date: | 09 July 2015 |

Professor Bridget Robinson was not 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 (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. (P.4.1) Please include prevalence statistics for Maori. If there are none please state this.
2. (F.1.2) Please use statistics to show whether or not study will reduce inequalities, or state that the study will not impact on existing inequalities.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Page 2 – arm B study drug paragraph, last sentence – refers to the study drug being well tolerated – should this be the comparator drug?
2. Page 11 – please be clear about what ‘study drug’ is being referred to throughout the document.
3. Specify where sample is going overseas (optional Participant Information Sheet).
4. Please copy cultural statement about tissue from optional study to the main Participant Information Sheet.
5. Specify ACC information – please use the HDEC template information.
6. Add confidentiality clause (general protections for data) in the optional Participant Information Sheet.
7. See PIS page 13 under What are my rights? On the paragraph that starts ‘Any Information obtained etc’. ---See second line after the word -- permission, or as required by --and the sentence is not finished. Please review.
8. Please include any important inclusion or exclusion criteria, such as having ingested illegal drugs.
9. P/DM1 – please explain funding status of this therapy. This should be explained in the Participant Information Sheet/Consent Form on the section outlining alternative treatment options.
10. The Committee noted the grapefruit restrictions and queried if there are any other lifestyle restrictions? If so please include them in the Participant Information Sheet.

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 address in a cover letter 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*).

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

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| **10** | **Ethics ref:** | **15/CEN/102** |
|  | Title: | Bariatric Embolization for morbidly obese patients |
|  | Principal Investigator: | Dr Martin Krauss |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 July 2015 |

Dr Martin Krauss 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 Study

1. The Committee surmised the study.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried whether tissue necrosis was a risk. The Researcher explained that this treatment had been used regularly for other indications (for example upper GI bleeding or ulcers in the stomach). It is a well-established treatment option. The risk of clinical necrosis is very low. There are some reports that cover single cases, worldwide. The risk is very minimal compared to the risks of surgery.
2. The Committee queried the consent, and time for consent. The Researcher explained the participant had substantial time to consider participation.
3. (P.4.1) The Committee requested statistics that are available that relate to Maori (for future applications).
4. (P.4.2) – for future applications please identify cultural issues such as whakama.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. (P.3.1) The Committee asked for clarification on the kind of patient being approached, noting that if patients are excluded due to them being too high risk for surgery but must be morbidly obese to participate, how do you balance these inclusion and exclusion criteria? The Researcher stated that the class 4-5 is quite obese and would likely be excluding 5. More likely looking at 3-4 classifications. The Researcher will clarify the level.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. The Committee queried if under risks, under rare, should it include the possibility for tissue necrosis. The Researcher agreed. The Committee also requested a quantification of these figures (such as 1 in 1000).
2. F.2.1 – The Committee requested that some basic, important inclusion and exclusion criteria should be included. Particularly anything that might not be in patient notes.
3. Please explain what level of radiation occurs in the scans. Please explain what kinds of CT scan is administered.
4. Page 5 under rare side effects – please remove malignancy.
5. Page 6 – please add Maori support contacts and HDEC contact details.
6. Page 7 has a typo – please review.
7. Review the tick boxes on the consent form – only leave an option if it is truly optional.
8. HDEC to send the ACC template Participant Information Sheet.

Decision

This application was *approved* by consensus, with non-standard conditions.

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| **11** | **Ethics ref:** | **15/CEN/103** |
|  | Title: | Incidence and clinical significance of anti-DFS70 in a New Zealand population |
|  | Principal Investigator: | Mrs Stacey Lucas |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 July 2015 |

Mrs Stacey Lucas was not 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 Study

1. The Committee noted that this is an audit involving human tissue. The study will add one additional test that may be added to routine testing if it assists with diagnosis and the identification of false positives.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. Please store data generated from the study for 10 years as per health information privacy code.
2. The Committee requested that in future applications that answers about benefit (P.4.1) should include prevalence of Maori. It would be useful to talk about statistics that the research is covering and how it may improve Maori health. If there is no increased prevalence for Maori simply state this.
3. Similarly, questions about Maori cultural issues (P.4.2) you should include information on Maori and their value of human tissue.

Decision

This application was *approved* by consensus.

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| **12** | **Ethics ref:** | **15/CEN/104** |
|  | Title: | LONG TERM INVESTIGATIVE FOLLOW-UP IN TRIALNET (LIFT) |
|  | Principal Investigator: | Professor Russell Scott |
|  | Sponsor: | TrialNet Co-ordinating Center |
|  | Clock Start Date: | 09 July 2015 |

Dr Jinny Willis 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 Study

* Trialnet is an International clinical trials network that involves a number of interventional studies. This new study proposes follow up of people who have been diagnosed with diabetes in other Trialnet studies.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried why oral insulin was given. The Researcher explained that it was to stop the immune system from reacting against insulin. It is a preventative intervention rather than treatment.
2. (R.2.4) The Researcher confirmed that data is available for future research.
3. The Researcher confirmed samples would be stored in registered tissue bank.
4. The Committee noted the child patient group are used to a medical context and may be able to understand more information than is currently in the youth Participant Information Sheet.
5. The Committee queried the length of follow up. The Researcher stated they are not sure. It will likely vary per participant.
6. The Committee queried whether the study was sponsored? The Researcher explained that while there are funding arrangements in place the study is not commercially sponsored.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee requested a separate Participant Information Sheet and Consent Form for the Future Unspecified Research. This separate document must comply with the Ministry of Health Future Unspecified Use guidelines.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Amend wording for blood samples volume – remove ‘a safe amount’.
2. Please move any information about the optional future unspecified research to separate Participant Information Sheet/Consent Form for example on page 5 of the adult sheet.
3. Please add more information for 7-11 year old. The Committee suggested using pictures.
4. Change ‘mad’ to ‘upset’ on the youth Participant Information Sheet.
5. Small modification to ACC statement – please refer to the HDEC template Participant Information Sheet.
6. Data confidentiality should be acknowledged in the consent form.
7. Please explain offshore institutions location (i.e. in the USA).
8. The Committee requested what is reimbursed. The Researcher explained that there are a number of Trialnet gifts. For children there are cuddly toys. For adults this will be a 50 dollar petrol voucher, to reimburse time and inconvenience. The Committee requested that this information is included in the Participant Information Sheet.

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* 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 provide age appropriate information sheets and assent forms for younger participants and amend the existing information sheets and assent/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 Mrs Gael Donoghue.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee discussed the 15/CEN/41. The Committee noted that the CI has not met the conditions requested at the April meeting. The Committee noted that the HDEC had tried to help the researcher but these attempts did not resolve the outstanding issues. The Committee agreed by consensus to decline the application. Secretariat to action.
3. The Committee discussed the ENZAMET study. The Committee discussed the request of the CI in relation to not separating the optional Future Unspecified Research from the main Participant Information Sheet. The Committee rejected the request and asked the Secretariat to respond to the researcher explaining their reasoning.
4. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 25 August 2015, 08:00 AM |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington, 6011 |

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 4.45pm