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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 October 2016 |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
|  | Confirmation of minutes of meeting of 27 September 2016 |
|  | New applications (see over for details) |
|  | ii 16/CEN/149  iii 16/CEN/153  iv 16/CEN/155  v 16/CEN/156  vi 16/CEN/157  vii 16/CEN/158  viii 16/CEN/159  ix 16/CEN/160  x 16/CEN/161  xi 16/CEN/162 |
| 5.00pm | Substantial amendments (see over for details) |
|  | i 16/CEN/137/AM01 |
| 5.30pm | General business:   * Noting section of agenda |
| 5.40pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 30/07/2015 | 30/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | 30/07/2015 | 30/07/2018 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |

## Welcome

The Chair opened the meeting at 12.30pm and welcomed Committee members.

The Chair noted that the meeting was quorate, noting that apologies had been received from Dr Patries Herst.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 27 September 2016 were confirmed.

## New applications

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| **2** | **Ethics ref:** | **16/CEN/149** |
|  | Title: | Brain-only metastases in melanoma and the role of EPHB6 mutations |
|  | Principal Investigator: | Dr Peter Ferguson |
|  | Sponsor: | Wellcome Sanger Institute |
|  | Clock Start Date: | 13 October 2016 |

Dr Peter Ferguson 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. This study will look in detail at the molecular features predisposing to brain metastasis in melanoma.
2. The study involves undertaking genome sequencing of brain tumours from melanoma patients alongside matched primary tumour and non-cancerous (germline) DNA.
3. The study aims to identify molecular signatures of primary melanoma that could place a patient at higher risk for brain metastasis and to predict which of these patients may respond to therapy.
4. This kind of analysis is not possible in New Zealand due to the lack of technology.
5. The study involves New Zealand samples because New Zealand has the highest rates of melanoma, and studies have indicated that New Zealand melanoma is genetically different, even between the north and south islands.

Summary of ethical issues (resolved)

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

1. The Committee noted the potential public benefit of this study.
2. The Researcher(s) explained that the study could lead to earlier and more targeted screening, future work with drug trials, regional monitoring etc.
3. The Committee noted the primary ethical issue was the waiver of consent to use tissue. The Researcher(s) stated nearly all patients would be deceased due to their brain metastases and that there are a limited number of patients.
4. The Researcher(s) explained the goal was to have 30 with primary melanoma matched, estimating the need to look 20-30 years back to get the archived samples.
5. The Committee asked whether it is possible to seek consent of those who are alive, can you cross-check samples with mortality data and contact them? The Researcher(s) stated it is certainly possible but does raise ethical issues.
6. The Researcher(s) stated the research involves somatic testing, which could result in incidental findings of clinical significance. This also relates to family related medical findings. The Researcher(s) noted the difficulty in interpreting these results, often requiring genetic counsellors and highly specialist committees that are not available for this study. The Researcher(s) suggested one means to mitigate this ethical risk was to de-identify all samples before analysis, meaning no results could be returned. If consent were sought it would need to be clear to participants that the research would not involve any return of clinical findings due to the de-identification process. The Committee noted that people can then exercise their autonomy by deciding whether or not to allow their tissue to be used for the research, even without receiving clinical relevant findings.
7. The Committee noted contacting participants for research that would not benefit them could cause undue anxiety and sought the Researcher’s views. The Researcher(s) responded that from their experience they did not think that this instance of contact would result in undue anxiety.
8. The Committee queried whether seeking consent would negatively impact the scientific validity. The Researcher(s) noted that those alive would be a small number of an already small number, as most will be deceased it may not be an issue if people did not consent.
9. The Researcher(s) explained that Auckland and Wellington sites were involved at the beginning but if required Dunedin and Christchurch could be considered.
10. The Researcher(s) noted that the researcher stated Maori consultation was not required due to no Maori samples. Please explain how the researcher can be sure that there are no Maori samples. The Researcher(s) stated it was very unlikely that Maori samples will be involved due to experience from prior studies. The Researcher(s) noted in Auckland, it might be possible, but still highly unlikely – 1-2% chance. The Committee asked if they plan to exclude Maori tissue if there are samples available. The Researcher(s) noted no, but could if this was the Committees suggestion. The Committee stated that they did not think Maori should be excluded due to this study aiming to provide a New Zealand melanoma overview, and stated that consultation would need to occur. The Committee noted each DHB would require consultation prior to involving Maori tissue, and requested that the researchers check with the research office at each site to ensure local consultation occurs.
11. The Committee asked about the workshops mentioned in the application. The Researcher(s) stated they held workshops with people who had melanoma to talk to them about the research. They had a large group (12) in Auckland and Wellington had 1 person. Participants were a range of people, patients, carers etc. The Researcher(s) noted while most people didn’t actually know they had tissue stored from their surgery, once they found out, were happy to be used for this research project (in theory).
12. The Researcher(s) noted no cores are taken from tissue blocks, just a section, in order to ensure sample left remains feasible for clinical diagnostics. The Researcher(s) confirmed would not use up sample if it meant none would be leftover.

Summary of ethical issues (outstanding)

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

1. Amend the protocol to outline process to seek consent from those patients who are confirmed to be alive.
2. Amend protocol to state consultation will occur at each site.
3. The Committee stated requested a Participant Information Sheet and consent form is created for those who can consent.

Decision

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

* Amend the protocol to outline process to seek consent from those patients who are confirmed to be alive. The Committee stated requested a Participant Information Sheet and consent form is created for those who can consent. (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Amend protocol to state consultation will occur at each site. (*Ethical Guidelines for Observation Studies* 4.4).

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

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| **3** | **Ethics ref:** | **16/CEN/153** |
|  | Title: | Jazz\_15-007 |
|  | Principal Investigator: | Dr Lochie Teague |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 13 October 2016 |

Dr Lochie Teague and Ms Sonia Alix 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. This trial is a Phase 3, randomized, adaptive study comparing the efficacy & safety of defibrotide prophylaxis vs best standard care in the prevention of hepatic veno-occlusive disease (VOD) in adults and children undergoing HSCT who are at high or very high risk of developing VOD.
2. While the use of defibrotide for the treatment of VOD is a standard approach to care, the use of defibrotide as prophyslaxis prevention is not.
3. A total of 400 participants are planned for enrolment to ensure completion of 360 participants.
4. Randomization will be stratified according to risk of developing VOD (High/very high-risk), age (greater than 16 years or less than/equal to 16 years), and country.

Summary of ethical issues (resolved)

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

1. The Researcher(s) noted current New Zealand treatment is an expensive drug with rigid criteria and is not currently used in a preventative manner. This study addresses whether in high-risk patients this kind of treatment would be beneficial. 15 in New Zealand.
2. The Researcher(s) expect most participants to be children with the occasional adult.
3. The Committee and The Researcher(s) discussed the Participant Information Sheet and confirmed that the participants would have extensive verbal support to understand any information provided.

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

1. Please remove the tick boxes (yes or no) on the consent form unless the statement is truly optional.
2. The Committee commended the tables.
3. Page 14 – local law and reference to Medsafe guidelines. Please remove.
4. Take off option for future unspecified research from main Participant Information Sheet and consent form, and use the optional form only.

Decision

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

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| **4** | **Ethics ref:** | **16/CEN/155** |
|  | Title: | The NeoMonitor trial |
|  | Principal Investigator: | Doctor Bronwyn Dixon |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 October 2016 |

Doctor Bronwyn Dixon Kiran More, Alex Lowings and Richard Dove 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. An apnoea is a pause in breathing that lasts for more than 20 seconds, with change in skin colour – turning blue or paler, or becoming floppy. Apnoea of prematurity (AOP) is an apnoea that occurs in babies who are born before their due date.
2. They occur because the breathing centre in the brain has not yet matured to trigger breaths regularly. In the Christchurch neonatal unit we have used the Graseby MR10 respiratory monitor for newborn infants at risk of apnoeas at home and in the neonatal unit.
3. The Graseby monitor monitors breaths by detecting movement in the abdominal wall. The Graseby MR10 was removed from the market in July 2014 and will not be able to be serviced beyond 2017. The CDHB Department of Medical physics and Bioengineering has designed a new monitor which has the same basic function but with more modern components to provide better accuracy.
4. We would like to do a study to compare the Graseby monitor and the new CDHB monitor and to a pulse oximeter recording (which measures oxygen saturations). The pulse oximeter will note whether any apnoeas detected have caused any disturbance in the baby’s HR or oxygen saturations. We will study 10 babies.
5. The apnoea monitors will be attached to each baby for 10 hours. There will be routine use of a pulse oximeter. Baseline data will be collected about the baby including baby’s gestational age, birth weight, current age, current weight, ethnicity, any medical issues, type of respiratory support and treatments.
6. The objective of the study is to compare the new CDHB apnoea monitor with the Graseby monitor. At the same time we will compare both with the pulse oximeter monitor. Babies enrolled in the study will be between 28-32 weeks gestation at birth and over 24 hours old. We will get formal parental consent. We will not include any babies who are very unwell or have severe life threatening anomalies. Data will be analysed by an appropriate method and stored for 20 years.

Summary of ethical issues (resolved)

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

1. The Researcher(s) confirmed both monitors are worn, as well as an oxygen monitor, adding that the baby would have oxygen monitor ordinarily.
2. P.1.19 – The Committee thanked the researchers for data on Maori.
3. F.1.2 – The Committee noted that this question is about other New Zealanders, not Maori.
4. P.4.4 – The Committee noted that this research does not use kura kaupapa Maori methodology but acknowledged the Maori involvement.
5. The Researcher(s) confirmed they would verbally walk through the Participant Information Sheet with potential participants. The Researcher(s) also leave information with potential participants to read through and they can come back with family or a Maori health worker to discuss again, with lots of time to consider participation.
6. P.4.2 - The Committee noted the question is about cultural issues rather than the consultation process.

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

1. The Committee noted that the section in the Participant Information Sheet under ‘who pays for this study’ – this is about costs for individuals, not about who is funding the study. Please add this information to the Participant Information Sheet.
2. The Committee queried how long the monitor is on, 9 or 10 hours? The Researcher(s) stated 10 hours but only use data for 9 hours. 1 hour at beginning for monitor to settle in, ensure there are no contact problems etc. The Committee requested that this is explained simple language in the Participant Information Sheet.
3. Under withdraw at any time’, remove ‘practicable’. The Researcher(s) stated once data de-identified then can’t remove data. The Committee noted that should be explained, rather than stating ‘practicable’, as participants can withdraw at any time, and should know at what point their data can’t be removed from the study.
4. Please remove the tick boxes (yes or no) on the consent form unless the statement is truly optional.
5. The Committee noted the GP notification in the consent form had suffered a formatting error.
6. Page 2 of 7. ‘Over 24 hours, as long as medically stable’ – just stops. Please add end of sentence.

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 Observation Studies* *para 6.11*).

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

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| **5** | **Ethics ref:** | **16/CEN/156** |
|  | Title: | Study to evaluate the safety and tolerability of GS-5801 in virally suppressed patients with chronic Hepatitis B |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 13 October 2016 |

Prof Edward Gane and Oliva Thame 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. This study will look at how safe and effective repeated doses of GS-5801 are in people with hepatitis B.
2. The researchers also measure the levels of the drug in the blood at different times to determine how quickly it is absorbed from the gut and excreted the body.
3. In total, 60 healthy people will participate in this study in 6 different groups in 2 different parts as follows:
4. Part A: Cohorts 1 and 2 will each contain 10 individuals. Eight receive a daily dose of GS5801 for 7 days and 2 receive a dummy drug. The dose in Cohort 1 is 2mg, the dose in Cohort 2 is 6mg.
5. Part B: Cohorts 3, 4, 5 and 6 is similar to Part A, but the dose in each group will be higher and determined by results of previously completed cohorts.

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

1. The Committee queried if participants can go home between assessments. The Researcher(s) confirmed they could, noting some days were long, but they can go home and come back the following morning. The Committee requested this is added to the Participant Information Sheet.
2. Page 9 – test samples. Insert statement that blood samples stored for future research *if participants provide specific consent in the optional consent form*. Currently lists information only relevant if someone consents for future unspecified research.
3. States study drug has not yet been given to people, but 1a study is underway, so this question now out-dated. Please update.
4. If a male participant father a child, will they be withdrawn? Clarify for HDEC and current wording is ambiguous
5. Page 12 – what contraception methods are being “referred to below”. Please explain for participants.
6. Pharmacogenomic document – make clearer in scope for pharmacogenomic Participant Information Sheet. Either is specified or is unspecified, and if the genomic testing is so broad it should include all of the future unspecified research requirements.
7. Ensure notification of disease is relevant for New Zealand. The Researcher(s) stated will remove statements that are not correct.
8. Allergic drug – clarify the statement, currently implies a person can be allergic to a drug they have not yet taken.
9. Total abstinence – please reword sentence to be clearer for participants.
10. Change ‘your disease’ to ‘this disease’, with regards to what the study may do in helping others.
11. Page 15 – no requirement to withdraw in writing. Can be verbal. Please amend.
12. Countries outside New Zealand – specify countries.

Please ensure all of the following are included in the future unspecified research forms:

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| 1. An indication of the type and nature of the research to be carried out and its implications for the donor, where possible, and an explanation of why the potential donor is being approached for their tissue and specifically what tissue is being sought. |
| 1. Known possible researchers or institutions that might use the tissue sample, if possible. |
| 1. Whether the donor’s sample is going to be, or is likely to be sent overseas, and where possible, to what country or countries. |
| 1. Acknowledgement that all future unspecified research in New Zealand will be subject to ethical review. However, when a tissue sample is sent overseas, unless it is sent in conjunction with a New Zealand research project, future research is likely to be considered by an overseas ethics committee without New Zealand representation. |
| 1. Whether the donor’s identity and details will remain linked with the sample or whether the sample will be de-linked. |
| 1. A statement that if a donor consents to a tissue sample being unidentified or de-linked, they relinquish their right to withdraw consent in the future. |
| 1. Whether the donor may be contacted in the future regarding their tissue sample. Whether or not, and under what circumstances, information about the future unspecified research will be made available to the donor and/or (where relevant) their clinician. |
| 1. Acknowledgement that the donor will not own any intellectual 2. Property that may arise from any future research. |
| 1. Whether there is provision to withdraw consent for the use of human tissue samples in the future. Where there is provision to withdraw consent, only tissue samples remaining at the time of a request to withdraw and any information held for future unspecified research may practically be withdrawn. Tissue samples or information used in research before the request to withdraw is received is unlikely to be able to be returned or destroyed. |
| 1. Acknowledgement that the donor’s decision regarding the consent for use of their tissue sample for unspecified future research will in no way affect the quality of a donor’s current or future clinical care. |
| 1. Where and for how long a tissue sample will be stored, how it will be disposed of and whether there is a cultural protocol for its disposal. For example, information about the institution holding the tissue sample: its aims, research procedures and research governance. |
| 1. Whether or not tissue samples could be provided to other researchers and institutions, and whether or not such provision could include sending samples to other countries |
| 1. Whether or not collected samples will be provided to commercial biomedical companies or will be used in commercial research collaborations, if known. |
| 1. What provisions will be made to ensure patient confidentiality. |
| 1. That different cultural views may inform choice about donation of tissue; for example, for some Maori, human tissue contains genetic material that is considered to be collectively owned by whanau, hapu and iwi. |
| 1. That cultural concerns may arise when tissue samples are sent overseas, including how tissue samples are stored and disposed of. Processes for monitoring and tracking what happens to samples may not be acceptable to donors. |
| 1. That donors may want to discuss the issue of donation with those close to them, for example; family, whanau, hapu and iwi. |

Decision

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

* Please update the 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*).

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

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| **6** | **Ethics ref:** | **16/CEN/157** |
|  | Title: | Right From the Start |
|  | Principal Investigator: | Ms Leith Pugmire |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 October 2016 |

Ms Leith Pugmire and Dr Shane Harvey 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. Right from the Start is an antenatal parenting intervention based on the latest multi-disciplinary theory of child development: the evolved developmental niche (EDN).
2. The evolved developmental niche makes claims about the kind of caregiving infants need based on what our species has evolved to expect, and these claims are consistent with a range of existing evidence.
3. This doctoral research project involves evaluating the intervention, which consists of an evidence-based parenting workshop (6 hours total) and a gifted sling, and is expected, by the researchers, to result in multiple benefits for infants and their families.
4. The project uses a longitudinal, experimental design in which expectant first-time mothers will be randomly assigned to either a control group or an intervention group during pregnancy and followed up over their baby’s first 12 to 18 months of life. We are investigating whether this provision of additional parenting information and resources improves outcomes for a sample of families (up to 200) in the Manawatū region.
5. A ‘waiting-list control’ design means that participants who are assigned to the control group will have access to parenting information and resources at the conclusion of the study, when their babies are one year old. A range of self-report and observational measures will assess infant attachment, birth and breastfeeding outcomes, postnatal depression, and responsive caregiving practices over the babies’ first year of life to see whether the intervention made a difference.

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.4.2 – The Committee noted a potential cultural issue was whakama. Please provide a plan to mitigate any risk for participants who may experience whakama.
2. The Committee queried whether current co-sleeping arrangements that are explained in the workshops run contrary to current advice and policy from Ministry of Health and Plunket. The Researcher(s) stated not sure what Plunkets current views, noting that international literature suggests the basic message of ‘don’t co sleep’ simply doesn’t work. It drives co sleeping underground which leads to unsafe co sleep arrangements occurring.
3. The Researcher(s) explained that they are trying to measure the impact of providing information for women, and understand the follow on impact on health outcomes of these decisions made early in pregnancy. The Committee noted the research needs to make sure it does not come across as if there is a ‘right’ thing to do (as this would both make women feel like they have done something wrong as well as meaning the research was not ethical as if an intervention is already known to be superior it should not be tested by a RCT).
4. R.5.2.1 – page 19. Indicates this is a good intervention, parents will do better etc. This is not balanced starting point that is the norm for health research (equipoise).
5. The Researcher(s) suggested clarifying the two documents, with control being a bit more ambiguous (in order to maintain scientific validity) and the intervention being a bit more detailed (to support informed consent). This would mean information was tailored to explain what would be involved for each group, and balance against priming the participants.
6. The Committee queried will consent be sought again once baby is born. The Committee noted baby must be born before consenting for it, as prior to birth the baby is not an entity. The Committee noted it also related to the inclusion criteria, so re-consent would be appropriate.
7. The Committee noted the title ‘right from the start’ implies there is a right way to parent, potentially causing this reaction in new parents. The Researcher(s) noted ‘from the start’ was an option. The Committee noted that it would be less presumptuous.
8. The Committee queried the study design, in particular how participants are selected and randomised between the two groups. In particular, how is the control arm randomised.
9. The Researcher(s) explained that randomisation occurs before the informed consent procedure. The information provided to each arm is different, depending upon the randomisation. The Committee noted that this is deceptive, and to some extent involves a study related procedure to occur prior to informed consent.
10. The Researcher(s) confirmed they did not upload the control group Participant Information Sheet. The Committee noted that the control Participant Information Sheet needed to be submitted before the Committee could approve the study. The Committee noted that this document should balance the need to allow potential participants to provide informed consent and the need to not prime participants to ensure study validity.
11. The Committee noted that the documents currently do not provide enough information about the control and intervention group, and the design of the study overall.
12. The Researcher(s) stated they had spoken with head of ethics at Massy University about what information should be told to participants, particularly the level of detail about the different arms in the study. The Researcher(s) stated that they felt ‘different experiences’ was sufficient, as to avoid giving the control arms too much information that they would then seek out the intervention arms and would then fail to be a control. The Committee suggested stating the study is about comparing when information is given, or what information, between each arms. The Committee noted that the main differences are the one-day workshop, gifting a sling and the magazines.
13. The Committee noted there was a lot of information in the application that was not in the information sheet, and thought some could be included to facilitate informed consent.
14. The Committee asked why information about what the workshop was is not more explicit (how antenatal class is actually quite different, in particular it is a take on parenting philosophy – attachment theory). The Committee noted by this point they are signed up to the workshop, but do not really know what they are attending. The Committee suggested that participants are able to opt out after the first workshop, and that this is made clear in the Participant Information Sheet.
15. The Committee queried whether people would feel like if they have interventions during birth, they will feel like they have failed. It is important both in workshop and in written material that ‘this may happen and that it is reasonable / acceptable’ etc. Please review documentation and the workshop plan and inform the Committee of any resulting changes.
16. The Committee queried whether there is actually a view that the workshop would reduce chance of being in NICU. The Researcher(s) stated the philosophy implies that if more information is given during pregnancy it will directly impact the birth too, for instance generic public health information, birth plans etc. – all these choices may have impacts on next steps, like breastfeeding, bonding etc. It flows on. Please revise to ensure no guilt or blame.

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

1. Provide a footer, version number and date for all study documents
2. The Committee noted assessment videos would be reviewed by people overseas. Add this to Participant Information Sheet. Add what will happen to the videos after the study, whether extracts will be present in presentations etc.
3. Please add that participants will be screened for postnatal depression. The Researcher(s) noted participants can choose not to take part in that questionnaire. The Committee noted it should be very clear which elements of the research are optional.
4. The Committee suggested that participants are able to opt out after the first workshop, and that this is made clear in the Participant Information Sheet.
5. R.1.2.1 pg. 15 – states no contact with health practitioner. The Committee queried if depression were detected would a health practitioner be contacted. The Researcher(s) stated that there are existing supports mechanisms in the locality to provide support and referral.
6. The Committee noted information on ‘what happens if something goes wrong’ needed to be added in the Participant Information Sheet.
7. The Committee queried what would happen if the woman were at risk, and the baby was at risk, but the participant stated they did not want to be referred. The Committee asked how the researchers would ensure appropriate actions would be taken for them, on their behalf or by them, noting the professional responsibilities.
8. The Researcher(s) explained the process in place, including follow up with our own team to peer review management of a case. The Researcher(s) referred to page 4, notes our duty to keep people safe, in first instance will discuss with participant, but will also need to ensure that appropriate action was taken. The Researcher(s) acknowledged that too much information has been removed from that section. The Committee agreed and stated more information should be added here.
9. Page 2 – ask questions about your parenting – The Committee requested reworded, this could be a first time parent or young parent. The Committee recommended ‘talk with you about parenting’.
10. The Committee suggested rewording the title so that it did not imply there was a single ‘right/correct’ way to parent.
11. The Committee noted there are some women who can’t breastfeed or choose not to, this may make participants feel bad or not participate. Please reconsider how breastfeeding is explained to participants in the study, or explain other options are available.
12. The Committee suggested including more information in the PIS for patients in the intervention arm so they have a clearer idea about the philosophy and content of the parenting workshop before they consent.
13. Add contact numbers for HDC and Maori support.
14. Add ACC statement. See HDEC template.

Decision

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

* Address outstanding ethical issues in a cover letter.
* Primary ethical issue – balancing information while maintaining study validity. Please ensure informed consent is valid. Currently does not meet informed consent standards. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee. Submit the control arm documentation. (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Provide further information on the study design, *in particular the randomisation timing and information given to participants that may involve some deception* (*Ethical Guidelines for Intervention Studies para* 5.4)

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| **7** | **Ethics ref:** | **16/CEN/158** |
|  | Title: | (duplicate) Women Spirituality and Mental Health |
|  | Principal Investigator: | Mr. Noel Tiano |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 October 2016 |

Mr. Noel Tiano and Ms Kath Macleam were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

1. The Committee noted the requested changes had been made.

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

1. ‘Faith’ - remove second line. Use spirituality.
2. Doctor recommend – remove. Change to agree.
3. Move Chaplin conducting focus groups to different heading (what will happen during study).
4. Amend incidental findings to issues or concerns (GP).
5. R.8.1 – positive religious coping screening. The Researcher(s) confirmed the doctors’ do not screening for religious coping mechanisms, but will be consulted to ensure safe for potential participants to participate.

Decision

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

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| **8** | **Ethics ref:** | **16/CEN/159** |
|  | Title: | Cultural Review of Eating Disorder Clientele |
|  | Principal Investigator: | Dr Eve Hermansson-Webb |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 October 2016 |

Dr Eve Hermansson-Webb and Craig Immelman 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. Eating disorders are a serious health problem in New Zealand. They are associated with a significantly impaired quality of life, the highest mortality rates of any psychiatric disorder, and an increased prevalence of comorbidities such as anxiety and depression. Although there is a growing body of evidence on effective treatment methods, most treatments appear to be based on an imbedded view that eating disorders are primarily restricted to European New Zealanders of high socio-economic status. This “stereotyping” is evident in both primary care settings and specialty clinics and impacts on all stages of care, from prevention to diagnosis and treatment. Treatments have been designed to fit with the typical “lifestyle” of this demographic with the principle focus being on regaining control over one’s diet and eating habits.
2. Treatment plans also tend to be generic and inflexible with a “one size fits all” approach. In particular, there is little capacity within the current plans to accommodate the specific needs of patients from differing ethnic backgrounds. For many people, cultural beliefs and traditions strongly influence their eating habits, dietary requirements, lifestyle and social interactions. Differing social contexts of food and eating may well influence the ability of patients to adhere to existing treatment plans and may adversely affect treatment outcomes.
3. A cultural review of patients currently being treated at Auckland’s Regional Eating Disorder Service (REDS) will provide insight into the ethnic diversity, or otherwise, of individuals being referred to the service, and will help inform future research into culturally-specific assessment and treatment options. The study will examine the assumptions being made about the ‘stereotypical patient’ and will include a literature review of existing research about the ethnic diversity of patients with disordered eating patterns in New Zealand and internationally.
4. The study will recruit a summer student to work for 10 weeks.

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 queried why there was no informed consent. The Researcher(s) stated range of clients with different levels of involvement. If we sought informed consent it would detract from treatment goals, and would also not give us a good representation of our cliental as some are not regularly seen.
2. The Researcher(s) noted they also wanted to look at clients that are no longer with the service. Informed consent is not possible as they have been discharged. The Committee asked if they have contact details. The Researcher(s) stated we do, but explained informed consent would cause undue harm.
3. The Committee queried what harm might result if participants found out their data had been used without consent. Would this impact practice, noting that the researchers would be seeing these participants in a treatment context.
4. The Committee noted importance of trust, and stated violating that trust for research could undermine trust in treatment.
5. The Researcher(s) stated they could get informed consent if required.
6. The Researcher(s) noted that it may not be feasible to seek consent and have the student to complete the project within timelines, and that information is being collated only so the risk of harm by contacting people may outweigh the benefit of contacting.
7. The Committee noted that by seeking consent it might help improving cultural input into processes, if the desire was to improve care from a cultural perspective. The Committee noted that the research objective was to improve care provided, and knowing the statistics of the users ethnicity and culture did not result in improved care. If care were to be improved it would require rich data, including information from the users themselves. The Researcher(s) agreed.
8. The Committee noted data would be much richer if it was contextualised by the users. They could speak with the student researcher also.
9. The Committee noted the researchers could provide a Participant Information Sheet just to access data, which can be sent out to users. Later, an amendment can be submitted if interviews and further study related procedures are planned.

Decision

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

* Provide an information sheet and consent form *Ethical Guidelines for Observation Studies* *para 6.11*).
* The study design must minimise risk of harm. Please amend protocol to outline process to consent participants to access their data (*Ethical Guidelines for Observation Studies* *para 5.5*).

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

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| **9** | **Ethics ref:** | **16/CEN/160** |
|  | Title: | Comparison of the blood levels of two forms of voriconazole suspension in healthy male and female volunteers under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 13 October 2016 |

Dr Noelyn Hung, Dr Tak Hung and Mrs Linda Folland were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

1. The Committee queried whether the payment amount of $1,050 should be in Participant Information Sheet. The Researcher(s) stated yes. Please amend.
2. Future unspecified research – R.3.9 – ticked yes. The Researcher(s) confirm this is an error.

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

1. Repetitive, pg. 2 – ‘you are healthy individual’. Just state once.
2. Page 3 – screening – HIV is not a notifiable disease – please ensure correct reportable diseases for New Zealand.
3. You cannot say you are not permitted to leave. Make it ‘if you choose to leave you will withdraw yourself from the study’.

Decision

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

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| **10** | **Ethics ref:** | **16/CEN/161** |
|  | Title: | Obinutuzumab with Idasanutlin and Venetoclax in Lymphoma |
|  | Principal Investigator: | Dr Leanne Berkahn |
|  | Sponsor: | Covance NZ Ltd |
|  | Clock Start Date: | 13 October 2016 |

Dr Leanne Berkahn and Margaret Joppa 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 purpose of the study is to test the safety, efficacy and pharmacokinetics of obinutuzumab in combination with idasanutlin and venetoclax in patients with relapsed or refractory follicular lymphoma (FL) or diffuse large Bcell lymphoma (DLBCL).
2. Up to approx. 140 patients will take part in this study at approx. 25 treatment sites around the world.
3. The study will include an initial dose escalation phase to determine the maximum tolerated dose for idasanutlin and venetoclax in this treatment combination followed by an expansion phase in which idasanutlin and venetoclax will be given at the defined dose from dose escalation phase.
4. In the expansion phase, all patients will receive induction treatment with obinutuzumab, idasanutlin, and venetoclax for six (28 days) cycles. If disease responds to initial treatment and tumour shrinks during the induction phase, patients with relapsed or refractory FL may also be eligible to receive maintenance treatment with obinutzumab for up to 24 months.
5. Obinutuzumab will be given by IV infusion. Idasanutlin and venetoclax will be given by oral tablets either once or twice daily, depending on the dose.
6. The primary efficacy objective will be tumour response determined on the basis of positron emission tomography and computed tomography (PETCT) scans or CT scans alone at the end of Induction. Response will be determined by an Independent Review Committee (IRC) and by the investigator. Study very similar to approved study. Once patients eligible for study can start treatment with 3 drugs. Total of 6 cycles. 28 day cycle.

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

1. Explain who ‘primary doctor’ is for participants. The Researcher(s) stated it means GP. The Committee stated please put GP. Page 3 last bullet point.
2. Update to CEN HDEC.
3. The Committee noted participants could take part in other research, just not during participation in this study. Please increase clarity – whilst you are on the study, during course of the study etc.
4. The Committee queried where samples are sent overseas. Please find out where samples are going. The Researcher(s) stated they would.
5. The Committee noted that a re-consent process is required when a child is born in order for parents to consent on behalf of child for follow up in case of pregnancy. This is due to a child needing to be born in order to provide consent on their behalf. This could be by telephone.
6. The Committee queried what ‘family medical history’ refers to. The Researcher(s) stated whether they have genetic disease in family. The Committee noted this would be health information about another person for health research. If this data is used in health research data, consent should be sought.
7. Legally authorised representative – pregnancy partner Participant Information Sheet. Please remove this statement.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

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| **11** | **Ethics ref:** | **16/CEN/162** |
|  | Title: | Exploring the Economic Causes and Consequences of Child Maltreatment |
|  | Principal Investigator: | Prof Rhema Vaithianathan |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 October 2016 |

Prof Rhema Vaithianathan 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 (resolved)

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

1. The Committee asked for a working definition of maltreatment. The Researcher(s) stated there are a range of definitions. One is substantiated mistreatment by CYFs by confirmation of physical, emotional or sexual abuse. The others the researchers plan to use are marker injuries – i.e. long bone fractures in children aged less than 2 years or intracranial injury in infants and hospital injuries that are registered as intentional.
2. The Committee requested the researcher elaborate on twin section, in particular how was this data not identifiable. The Committee noted the inconsistency in the application regarding identifiably. The Researcher(s) stated the study used twins, or 2 siblings, one who has had substantiated maltreatment or marker etc. and another who has not. Both are from same family, exposed to similar conditions, but one had maltreatment. The paper compares these 2 people to each other to age 17.
3. The Researcher(s) stated the data is entirely anonymous.
4. The Researcher(s) explained process to disseminate results. First presentations, resulting eventually in publication.

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 queried why assume one maltreated but not the other, given they are in the same family. The Researcher(s) confirmed it was likely both were, and this under powers the study, but was not an issue in determining results of the study.
2. R.6.1 – the response does not answer the question about stigmatisation. The Committee noted the research seems to be skewed to assess lower socioeconomic people, Maori and Pacific Island people.
3. The Researcher(s) stated no, on all people who are on working for families programme. The Committee stated that is still a select socioeconomic group.
4. The Researcher(s) stated all administrative data looks at fixed effects, and follows them as working for families rolls in and then back, this is a natural experiment where money is transferred to households to answer the study question. The question is, is it the case that if money is transferred to households, will it increase safety, and improve child welfare, due to lessening the economic pressures in the house hold.
5. The Committee asked why there is specific focus on wellbeing outcome of Maori and Pacific people, noting again the possibility of stigmatisation. The Researcher(s) stated a question is whether there are any implications for Maori from this research, and the answer states we might do a sub group analysis. The Committee stated the application states the current study will focus on Maori, not a potential sub-analysis. The Researcher(s) stated they would only if the data was available, as a result of the first part of the study. The Researcher(s) explained they wanted to know if there was an impact of an increase of income on reduction of marker hospitalisation, was it the same in Maori as in general population. The Researcher(s) explained that if the increased income doesn’t reduce abuse in a general population, the sub-study could see if it does just with Maori or Pacific, and vies versa.
6. The Researcher(s) stated if we do a Maori specific study we will consult with Maori. The Committee stated the original study would require Maori consultation due to relevance of the study outcomes to Maori.

Decision

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

* Provide an overview of the study, its aims and its benefit for society to justify its conduct.
* Issues relating to Māori cultural and ethical values should be addressed in discussion with Māori concerned. Explain Maori consultation processes. (*Ethical Guidelines for Observation Studies* 4.4)
* Peer review is an important aspect of ethical review and is used to assure New Zealand's Health & Disability Ethics Committees of the scientific validity of a research proposal. Please provide independent peer review.
* The study design must minimise risk of harm. Please explain how stigmatisation will be avoided. Please also explain the identifiably of the data during and after the study (*Ethical Guidelines for Observation Studies* *para 5.5*).

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

## Substantial amendments

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| **1** | **Ethics ref:** | **16/CEN/137/AM01** |
|  | Title: | YouthCHAT For All |
|  | Principal Investigator: | Dr Hiran Thabrew |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 October 2016 |

Felicity Goodyear-Smith was present in person for discussion of this amendment.

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 (resolved)

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

1. The Committee noted the amendment and approved the children age 13-15 providing consent as it was likely this group would be competent given their age and the nature of the study. The Committee approved parents having the opportunity to opt out.

Decision

This amendment was *approved* by consensus.

## 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:** | 29 November 2016, 12:00 PM |
| **Meeting venue:** | Room GS.5, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington, 6011 |

The following members tendered apologies for this 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 5.30pm