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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 15 December 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 24 November 2015 |
| 12:30pm | New applications (see over for details) |
|  | i 15/CEN/212  ii 15/CEN/213  iii 15/CEN/216  iv 15/CEN/217  v 15/CEN/218  vi 15/CEN/219  vii 15/CEN/222  viii 15/CEN/224  ix 15/CEN/230  x 15/CEN/231  xi 15/CEN/214  xii 15/CEN/215 |
| 5:15pm | General business:   * Noting section of agenda |
| 5:30pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| 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) | 01/07/2015 | 01/07/2018 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 01/07/2015 | 01/07/2018 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 24 November 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/CEN/212** |
|  | Title: | AAML1331: Acute Promyelocytic Leukaemia |
|  | Principal Investigator: | Dr Siobhan Cross |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 03 December 2015 |

Mrs Meredith Woodhouse 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 study will recruit children and teenagers with APL.
2. The purpose of the study is to reduce, or completely remove, the need for anthracycline and other conventional chemotherapy.
3. 10 participants in New Zealand will be allocated to different study arms based on their presenting white blood cell count.
4. This study uses a historical control from a similar Italian study that showed promising results.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether participants 16 years old and over would consent for themselves. The Researcher confirmed that all participants 16 years old and over would consent for themselves.
2. The Committee questioned whether this study would be approved by SCOTT. The Researcher confirmed that it has been submitted for SCOTT approval.
3. The Committee noted that the application form did not indicate that the study involved Future Unspecified Use of Tissue. The Researcher confirmed that this was an optional aspect of the study and that its omission from the application was an error.
4. The Committee noted that the application stated that participants would have ample time to consider their participation in the study, however many of the participants may be in an acute condition before they are able to be enrolled in the study. The Researcher explained that their consent process first involved thoroughly going through the Participant Information Sheet and Consent Forms with potential participants and then, when possible, potential participants were left with the information overnight before they signed the consent form.
5. The Committee questioned whether there were any statistics regarding the rates of APL in Maori. The Researcher explained that there are currently no statistics regarding prevalence in Maori or other ethnic groups. The Committee requested that this kind of information was included in future applications.

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

1. Please ensure that the Participant Information Sheet specifies that the study was approved by the Central HDEC, rather than ‘an ethics committee’.
2. The Committee noted that there is a number of optional aspects of the study, as well as Future Unspecified Use of Tissue. Although these optional aspects of the study have separate Consent Forms they also require a separate Participant Information Sheet for the Future Unspecified Use of Tissue to ensure it is clear that this aspect of the study is fully optional.
3. Please reformat the contact numbers in the Participant Information Sheet to ensure they are clear and stand out to participants.
4. The Committee noted that although the researchers understood that all participants 16 years old and over must consent for themselves their information sheets and consent forms seemed to allow for the possibility of parents consenting for their children until the age of 18. Please ensure this is rectified.

Decision

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

1. Please amend the information sheet and consent forms, 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 Patries Herst and Mrs Sandy Gill.

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| **2** | **Ethics ref:** | **15/CEN/213** |
|  | Title: | AALL1331: Blinatumomab in First Relapse of Childhood B-ALL |
|  | Principal Investigator: | Dr Peter Bradbeer |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 03 December 2015 |

Dr Peter Bradbeer and Mrs Jenny Harrison 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 Committee noted that they were overall satisfied with the application and the study, however they requested some changes in the Participant Information Sheet for clarity. The Committee noted that the study’s sponsor, Children's Oncology Group (COG), are reluctant to modify their Participant Information Sheets and Consent Forms unless required, however they suggested that a number of issues were reoccurring with COG studies and it may be beneficial for COG to reconsider their templates to align with the HDEC expectations.
2. The Committee noted that with so many Participant Information Sheets and Consent Forms it would be useful for future applications to include a cover letter to the HDEC explaining the differences between the forms. The Committee noted that it would also be useful to have these collated when they are submitted as having a large number of individual documents makes them difficult to navigate.
3. The Committee noted that the study drug is very expensive and that it is a good opportunity for participants to access this drug for free as it may otherwise be out of reach.

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

1. The Consent form specifies that participants have read the ‘English’ form, the Committee requests that the word ‘English’ is removed as New Zealand is an English speaking country and therefore this is superfluous.
2. Please modify the Consent Form that will be given to children who turn 16 during the study as they must be provided with a full Participant Information Sheet when they are reconsented as they are now considered adults in terms of their ability to consent to their involvement in research and should be given all of the information an adult participant would be given.
3. Please simplify the Participant Information Sheet for participants aged 7-11 years as it is currently difficult for this age group to understand. The Committee suggests pictures or cartoons be used to help explain the study.
4. The Committee appreciates the Flow Charts in the Participant Information Sheet to help participants understand the series of related studies, however, they suggest that they could be more user friendly, such as indicating what criteria is fulfilled or not (e.g. at “evaluation”) for the participant to then be directed down one treatment route or another.
5. The pharmacodynamics testing information sheet states that extra blood will be taken, however this is not specific enough. Please include a specific measurement regarding how much extra blood will be taken.
6. Please ensure a separate Participant Information Sheet is included for the Future Unspecified Use of Tissue aspect of the study.
7. The Participant Information Sheet refers to the NCI website, please modify this to refer to a New Zealand website.
8. The Committee noted that the statement in the main consent form that participants can discuss the study with the ‘ethics department’, they requested that it is made clearer that this refers to the study research office rather than the HDECs.

Decision

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

1. Please amend the information sheet and consent forms, 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 Dean Quinn and Dr Angela Ballantyne.

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| **3** | **Ethics ref:** | **15/CEN/216** |
|  | Title: | The CRISP study |
|  | Principal Investigator: | Associate Professor Anne Camille La Flamme |
|  | Sponsor: | Capital and Coast District Health Board |
|  | Clock Start Date: | 03 November 2015 |

Associate Professor Anne Camille La Flamme 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 Committee commended the application and Participant Information Sheet and noted that they enjoyed reading this proposal.
2. The Committee expressed that they felt that the high quality of the Participant Information Sheet would ensure that participants would be fully able to understand 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 questioned whether this study would be approved by SCOTT. The Researcher explained that although the study drug is available through PHARMAC the specific formulation used in this study is not marketed in New Zealand so they will get SCOTT approval.
2. The Committee questioned the statement in the Consent Form that if participants withdraw from the study their data collected before they withdraw would be kept in the study. The Researcher explained that it would not be possible to withdraw an individual participants study data from the results if they withdraw part way through the study, therefore, this was an exclusion criteria, if participants were not willing for their data to be included even if they withdrew they could not participate in the study.
3. The Researcher noted that since submission for HDEC approval a minor change had been made to the study protocol as they had discovered that they were unable to do one of the proposed tests in a meaningful way and therefore had removed this from the study. The Committee noted this was acceptable and asked that it be confirmed in writing for their records.

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

1. The Committee noted that the Consent Form stated that a participant has been able to discuss the study with their family, whanau, or legal representative. However, the Committee suggested that using the term ‘legal representative’ may be misleading and suggest that it is left out as it suggests some participants may be incompetent and have a legal representative (such as a EPOA or Welfare Guardian). In that case the participant could not be in the study.
2. Please ensure the ACC statement is accurate.
3. The Committee noted that although MS is very uncommon in Maori genetically it is still important to include Maori Cultural Support Contact Details as some participants may identify as Maori.
4. The protocol indicates that future research would be done on tissue samples, and the application form indicated that samples would be retained for 5 years. The Committee questioned whether Future Unspecified Use of Tissue would occur, and if it will occur requested a separate Future Unspecified Use of Tissue information sheet and consent form as per the guidelines and template.
5. The protocol lists a number of prohibited medications, please ensure that at least the MS related medications are included in the Participant Information Sheet.
6. Please clarify in the Participant Information Sheet whether any drug of abuse testing would occur.
7. Please clarify in the Participant information Sheet any contraception requirements or pregnancy testing that will occur as part of the study.

Decision

This application was *approved* by with non-standard conditions to be checked by the secretariat.

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (Ethical Guidelines for Intervention Studies para 6.22)
2. Please confirm the change in protocol in writing and provide an updated protocol and Participant Information Sheet if necessary.

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| **4** | **Ethics ref:** | **15/CEN/217** |
|  | Title: | T Cell Receptor Therapy of Liver Cancer |
|  | Principal Investigator: | Dr. William Abbott |
|  | Sponsor: |  |
|  | Clock Start Date: | 03 December 2015 |

Dr. William Abbott 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 study involves a single participant with hepatitis B virus-induced liver cancer being treated with an experimental treatment.
2. The inclusion criteria for this study is very rarely fulfilled and they do not expect any other possible participants in New Zealand as they required a liver transplant and to be infected again after the transplant.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether this was research and required ethical approval. The Researcher explained that Medsafe requested they obtain HDEC approval. The Committee noted this appeared to be compassionate treatment rather than research. The Researcher explained that although the primary purpose of this treatment was compassionate reasons they also had a research component.
2. The Committee noted the possibility of side effects on other organs being mentioned and questioned whether this was a possibility. The Researcher explained that they thought this was highly unlikely but included the information to ensure every possible adverse outcome was described.
3. The Committee noted that the participant identified as Cook Island Maori, however, the application stated that there would not be able Maori participants. The Researcher explained that they intended to mean that there was no New Zealand Maori participants in the study. The Committee noted that if the participant identified as Maori they would require a Maori Cultural Support Contact Number in the Participant Information Sheet and Maori Consultation. The Researcher explained that they had already had informal Maori consultation and would consult with the participant regarding their cultural self-identification and whether they would like any specific cultural support. The Researcher also explained that the participant would be provided with a number of contact details and could access a range of support if required or requested.
4. The Committee questioned how long study data would be kept. The Researcher explained that all study data would be stored indefinitely as part of the participant’s health information in the patient files.
5. The Committee questioned whether there was an intention to publish the study results. The Researcher confirmed that they intended to publish the results as this technique is still very novel and experimental.

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

1. The Committee noted that the language in the Participant Information Sheet may be slightly misleading as it states that the treatment ‘will’ guide them to cancer cells and destroy them, the Committee suggested that it may be more appropriate to state that this ‘may’ happen as it could not be guaranteed.
2. The Committee questioned whether the participant would be able to be identified from any publication as he is the only participant. The Researcher agreed that this may be possible. The Committee requested that a sentence is added to this effect in the Participant Information Sheet to ensure the participant is aware of this.
3. Please rephrase the sentence ‘when you sign the consent form’ to ‘if you sign the consent form’ as the participant does have an option to not sign.

Decision

This application was *approved* by with non-standard conditions to be checked by the secretariat.

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

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| **5** | **Ethics ref:** | **15/CEN/218** |
|  | Title: | My Baby's Movements |
|  | Principal Investigator: | Dr Katie Groom |
|  | Sponsor: | Mater Research Institute – The University of Queen |
|  | Clock Start Date: | 03 December 2015 |

Dr Katie Groom and a co-investigator 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 is a Multicentre trial with study sited in Australia and New Zealand.
2. The purpose of this study is to investigate whether increased information and awareness of foetal movements reduces the rate of still births.
3. Many women wait several days after detecting reduced foetal movement before presenting to a doctor or midwife and it is believed that if they did not wait to present this change their still birth may be able to be prevented.
4. The researcher in this study are investigating how the information that is presented to pregnant women influences the likelihood that they will report reduced movement to their doctor.
5. Part of this study involves the use of smart phone application to monitor changes in foetal movement. The researchers will investigate whether the use of this app changes whether participants are likely to report changes in foetal movement.

Summary of ethical issues (resolved)

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

1. The Committee questioned what will happen if participants report reduced foetal movement. The Researcher explained that each hospital has difference processes but that they expect that the woman would be seen by a doctor or midwife who would decide if a CTG scan was required and possibly an ultrasound if necessary. The Researcher explained that part of this study was to encourage hospitals to have protocols in place for reports of reduced foetal movement.
2. The Committee questioned whether a rise in the number of women presenting to clinics would have resourcing implications. The Researcher stated that there may be resourcing implications but it the rates of still birth were reduced this benefit would outweigh the cost.
3. The Committee questioned the length of some of the questions in the questionnaire and noted that some participants may find them difficult to understand. The Researcher explained that a midwife would be available to go through the questionnaire with participants if requested.
4. The Committee questioned the purpose of the 6 month follow up questionnaire as it appeared to relate to the participants anxiety levels or possible depression rather than focusing on their experiences with the smart phone application. The Researcher explained that the questions in this questionnaire were those standardly used to assess new mother’s wellbeing as they wanted to determine whether the application had an impact on maternal wellbeing and anxiety levels.
5. The Committee questioned how many women would be completing the questionnaires. The Researcher explained that the questionnaires would be done over a 4 week snapshot in each hospital so the exact number of participants completing questionnaires was not certain.
6. The Committee questioned what would happen if a potential participant did not have a smart phone or lived somewhere without mobile coverage. The Researcher explained that as a pragmatic consideration access to a suitable phone is part of the inclusion criteria.
7. The Committee questioned how the researchers would avoid sending follow up questionnaires to women who had adverse outcomes, such as a still birth. The Researcher explained that they have a system in place to identify these women and stop their follow up.
8. The Committee noted that the researchers intended to collect information from the hospitals without the consent of each woman, they questioned whether this information would be anonymous. The Researcher confirmed that they would only be collecting aggregate hospital outcome data such as the number of deliveries and the number of still births, not information about individual patients.

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

1. The Committee noted that the Participant Information Sheet, as currently presented, makes it appear that if a woman has a still birth it is their fault as they could have prevented it by reporting reduced movement to their doctor. The Researcher explained that this was not their intention and that they would work to improve the Participant Information Sheet wording to help prevent women feeling responsible for a still birth if it eventuated. The researcher explained that hospitals have protocols in place for aftercare if a woman has a still birth that include counselling for the woman. The Committee noted that this was good to know but that it was essential that the Participant Information Sheet did not give the impression that the woman was at fault if she had a still birth.
2. The Committee noted that the researchers intended to collect information from clinicians about their views on foetal movement and requested that the Participant Information Sheet and Consent Form for clinicians is provided to the Committee for their consideration.
3. The Consent Form states that the study will be done in accordance with the national statement, however, this is an Australian statement please remove this.
4. The Participant Information Sheet stated that participants ‘may not benefit’, however, it is very unlikely to benefit from completing a questionnaire at all. Please consider rephrasing this to state that participants ‘will not benefit’ from their participation in the study.

Decision

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies para 6.22)*
2. Please confirm what information hospitals will be providing to the researchers.

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

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| **6** | **Ethics ref:** | **15/CEN/219** |
|  | Title: | A Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ACH-0144471 in Healthy Volunteers |
|  | Principal Investigator: | Dr Rod Ellis-Pegler |
|  | Sponsor: | Clinical Network Services (CNS) Ltd |
|  | Clock Start Date: | 03 December 2015 |

Dr Rod Ellis-Pegler and a co-investigator 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 noted that the application seemed to suggest that tissue would be stored after the end of the study and requested that this is clarified. The Researcher explained that the non-genetic blood samples would be stored after the end of the study. The Committee questioned whether this required a separate information sheet and consent form in line with the Guidelines for Future Unspecified Use of Tissue. The Researcher stated that they would confirm if this was required as they were unclear at this stage whether this aspect of the study meets this criteria as it was not unspecified as they knew what tests would be conducted on this tissue.

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

1. Please include the inclusion and exclusion criteria in the Participant Information Sheet as although this may be discussed with participants it should also be provided in writing.
2. Please include in the Participant Information Sheet that participants will have a drug screening.
3. Please rephrase the statement in the Participant Information Sheet that participants will be ‘confined’ for 3 days as this suggests that they will be held against the will.
4. The Committee questioned the statement in the Participant Information Sheet that participants must not use any ‘controlled substances’ as they do not think this is clear to participants what this means. Please specify in the Participant Information Sheet what substances can and cannot be used by participants.

Decision

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

1. Please clarify whether your study has Future Unspecified Use of Tissue and if so please provide the required information sheets and consent forms for this.
2. Please amend the information sheet and consent forms, 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 Dean Quinn and Mrs Helen Walker.

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| **7** | **Ethics ref:** | **15/CEN/222** |
|  | Title: | A Phase I/II trial of MK3475(pembrolizumab) in children's solid tumours and lymphoma |
|  | Principal Investigator: | Dr Timothy Prestidge |
|  | Sponsor: | MSD (Australia) Pty Limited |
|  | Clock Start Date: | 03 December 2015 |

Dr Timothy Prestidge, Dr Sarah Hunter, and two representatives from the study sponsor 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 investigates a new study drug for treating children with lymphoma.
2. The study drug has been used in adults to treat melanoma with promising results.
3. This is a phase II follow up to a dose escalation international trial.
4. The study involves an optional Future Unspecified Use of Tissue aspect.
5. The Committee noted that the adults Participant Information Sheet is well written, however, the forms for children need some work.

Summary of ethical issues (resolved)

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

1. The Committee questioned if there was any statistics regarding the incidence of lymphoma in Maori. The Researcher explained that they believe the rates are very similar between Maori and Non-Maori. The Committee noted that this kind of information would be good to include in future applications.

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

1. Please rephrase the term ‘poke’ in the Participant Information Sheet for children as this does not mean that a hole will be made, please rephrase this to ensure clarity.
2. The Committee questioned the appropriateness of the statement in the Participant Information Sheet for 7-11 year olds regarding the risks associated with pregnancy. The Committee suggested that this statement is reduced to lessen the impact on younger children.
3. The Committee noted that currently children who turn 16 during the study will only be provided with an abbreviated information sheet, however, as a 16 year old is legally able to give consent as an adult they must be provided with all of the necessary information. The Researcher explained that they were concerned that if the full study information arrived to the participant when their parents were not home they may find it distressing. The Committee suggested that the researchers directly contact the participant, such as by phone, to discuss the study before the full Participant Information Sheet is provided to them to reduce the risk of shock and distress. The Committee stressed the importance of providing participants who turn 16 during the study with all of the necessary information, including a full Participant Information Sheet to ensure they can give fully informed consent to their continued participation in the study.
4. Please ensure it is clear in the Future Unspecified Use of Tissue information sheet and consent form that this aspect of the study is completely optional.
5. Please include the Maori Cultural Statement in both the main Participant Information Sheet and the Future Unspecified Use of Tissue Participant Information Sheet as it is currently only in the main form.
6. Please include a diagram or table to explain what happens at each study visit. The Researcher suggested adding it as an appendix.
7. Please work on simplifying the Participant Information Sheet for children to ensure ease of understanding.
8. Please consider rephrasing and reducing the statements regarding the risk of pregnancy in the Participant Information Sheet for children 7-11 to ensure it is appropriate for the age group.
9. Please consider rephrasing the safety and survival follow up information in the Participant Information Sheet as it currently appears that participants will be rung to determine if they are still alive.

Decision

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

1. Please amend the information sheet and consent forms, 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 Patries Herst and Dr Cordelia Thomas.

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| **8** | **Ethics ref:** | **15/CEN/224** |
|  | Title: | School readiness |
|  | Principal Investigator: | Dr Alison Leversha |
|  | Sponsor: |  |
|  | Clock Start Date: | 03 December 2015 |

Dr Alison Leversha 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 study will investigates the reasons that children in the Tamaki region are reportedly not prepared for school in terms of their social and developmental level.
2. The researchers propose that the health of these children has an impact on their school readiness.
3. 450 participants from the Tamaki area will be involved.
4. This study will investigate both new school entrants and children attending early childhood education.
5. Potential participants will be identified by their teacher who will approach their parents about the study. If the parents are interested they will agree to have their contact details given to the researchers who will contact them to obtain informed consent.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether the researchers and those approaching the parents are of Maori or Pacific ethnicities as most of the participants will be. The Researcher explained that the person who makes the initial contact with participants is of Maori descent and from the local community. The Researcher also explained that they will recruit another investigator and hope to recruit a Tongan speaking person for this role.
2. The Committee noted that the risk of stigmatisation from this study is quite high and questioned how this would be mitigated. The Researcher explained that currently parents of these children are not identifying the same developmental delays that the school reports when they enrol their children in school, they believe that this may be to do with a lack of understanding in the community about normal child development. Because of this the Researcher is sensitive to the possible stigmatisation surrounding this and intends to mitigate this by working directly with the parents to help work out the reasons these delays are not reported as well as helping to inform the parents about normal child development to improve understanding in the community.
3. The Committee questioned whether health information would be accessed to recruit participants. The Researcher explained that they did not need to access health information to recruit participants.
4. The Committee noted that the Participant Information Sheet is quite complex and questioned whether someone would go through this with the parents. The Researcher explained that they have used a similar Participant Information Sheet in another study and because they discuss it in detail with the parents in their main language they did not find any issues with it.
5. The Committee noted that some of the answers given in the application form are quite blunt and suggest that future application may benefit from more sensitive wording to ensure the Committee is aware that the researchers understand the potential complexities and sensitives surrounding the research topic. The Committee noted that it was clear from speaking to the researcher that they understood the sensitivities surrounding this topic and were well prepared to handle them.
6. The Committee questioned the statement in the application that if an unacceptably high rate of unmet need was identified in the first year they would terminate the study. The Researcher explained that if the children in the education only arm are not doing well they will move all participants to the health and education arm if this arm is getting better results.
7. The Committee questioned whether the services would be able to cope with the potential unmet need. The Researcher explained that they are in discussion with a range of agencies regarding ways to manage resourcing issues and are developing strategies to meet this need.

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

1. Please proof read the Participant Information Sheet to remove spelling and grammar errors.
2. Please reword the Participant Information Sheet to soften the language as it currently appears that the researchers are stating that the child is unintelligent or poorly cared for and this may cause offence to parents and not assist with recruitment. The Committee stresses that whakama is an important issue to be aware of in this study and requested that the Participant Information Sheet is rephrased to be more sensitive to this and to avoid parents feeling like they are being judged.
3. Please remove the tick boxes from the consent form for any aspects of the study that are not truly optional.

Decision

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

1. Please amend the information sheet and consent forms, 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 Sandy Gill.

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| **9** | **Ethics ref:** | **15/CEN/230** |
|  | Title: | ARROW |
|  | Principal Investigator: | Dr Hilary Blacklock |
|  | Sponsor: | Onyx Therapeutics, An Amgen Subsidiary (referred t |
|  | Clock Start Date: | 03 December 2015 |

Dr Hilary Blacklock and Mrs Catherine Howie was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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 application stated that participants would be sent a copy of the results of the study, they questioned if this meant that all participants would get a copy of the information. The Researcher clarified that this would be an opt-in aspect of the consent form that was mistakenly left off the copy provided to the Committee.
2. The Committee questioned whether participants would have access to the study drug after the study ended. The Researcher confirmed that if they were doing well on the study drug they would have access after the study.

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 questioned whether there was a separate Participant Information Sheet and Consent Form for pregnant participants. The Researcher explained that no participants would be pregnant during this study. The Committee noted that there was a section in the Participant Information Sheet referring to if participants, or their partner, because pregnant. The Committee requested clarification regarding this, including whether there is a risk to a male participant’s female partner is she becomes pregnant.

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

1. The Committee noted that the Consent Form provided is very brief and suggest that it is considered against the HDEC template to ensure all of the necessary information is included.
2. Please confirm in the Participant Information Sheet that participants will be able to access the study drug after the end of the study if they are doing well on it.
3. The Committee noted that the Participant Information Sheet states that if the researchers cannot contact participants they will use their health information and other information to determine their health status. The Committee requested that it is clarified in the Participant Information Sheet what kind of information will be accessed.
4. The Participant Information Sheet has information regarding the American approval of the study drug. Please also include information about its approval status in New Zealand.
5. Please ensure it is clear in the Participant Information Sheet that if participants withdraw from the study their samples and data already collected will only continue to be used with their consent.
6. Please rephrase the statement that an ethics committee ‘will’ review the study information as the committee ‘may’ do this but it is not certain.

Decision

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (Ethical Guidelines for Intervention Studies para 6.22)
2. Please clarify whether there is a risk to a male participant’s female partner if she becomes pregnant.

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

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| **10** | **Ethics ref:** | **15/CEN/231** |
|  | Title: | Investigation of the antibody Sirukumab in patients with Giant Cell Arteritis |
|  | Principal Investigator: | Dr Ketna Parekh |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 03 December 2015 |

Mrs Helen White and Marina Dzhelali 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. Giant Cell Arteritis is generally treated with steroids that have a number of side effects.
2. This study will investigate and alternative treatment that is hoped to have fewer side effects.
3. The first part of the study will randomise participants to one of 5 groups, 2 placebo arms and 3 study arms that involve different concentrations of the study drug.
4. Part 2 of the study will extend the most successful study arm for part 1 for 2 more years.
5. Participants will be evaluated at the end of part 1 and reassigned to allow participants who were on a placebo arm to be in an active study arm if it is showing positive results.
6. The study hopes to recruit 8 participants in New Zealand.
7. There are two optional sub studies and tissue samples will be sent overseas.

Summary of ethical issues (resolved)

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

1. The Committee commented that the questions in the application form regarding the use of tissue were not all completed correctly. The Researcher explained that this must have been an error.
2. The Committee questioned whether tissue samples would be kept beyond the end of the study. The Researcher stated that all remaining samples would be destroyed.
3. The Committee questioned whether there are any statistics regarding the prevalence of Giant Cell Arteritis in Maori. The Researcher stated that national data does not show any prevalence in any ethnic group. The Committee noted that in future it would be beneficial to state this in the application.

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

1. Please ensure that the cultural statement is included in all of the Participant Information Sheets as it is currently only included in the main Participant Information Sheet.
2. Please specify in the relevant information sheets that the sub study is for an optional biomarker test.
3. The Committee noted that currently pregnant participants are being asked to consent before birth to their child being enrolled in the study, however, it is not possible to consent on this child’s behalf before they are born. Please amend the consent forms and information sheets to reflect this, please also provide an appropriate consent form and information sheet for after the woman has given birth.
4. Please ensure any concerns regarding a male participant’s female partner becoming pregnant are included in the Participant Information Sheet.
5. Please check the titles of the Participant Information Sheets and Consent Forms to ensure accuracy.
6. Please consider rephrasing the statement regarding the use of medicines and remedies to state ‘over the counter medication’ to assist with clarity to participants about what is included.
7. The Committee questioned the statement in the Participant Information Sheet that not many people had been treated with the study drug. They request that this is rephrased to specify how many people have been treated with it, including if it is used to treat any other conditions.
8. Please ensure that if the optional genetic study is Future Unspecified Use of Tissue that the Information Sheet and Consent Forms must meet the requirements for this kind of research.

Decision

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

1. Please amend the information sheet and consent forms, 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 Patries Herst and Mrs Helen Walker.

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| **11** | **Ethics ref:** | **15/CEN/214** |
|  | Title: | M13-545 Rheumatoid Arthritis |
|  | Principal Investigator: | Dr Daniel Ching |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 03 December 2015 |

Daniel Ching 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 study was discussed alongside 215 as they are related studies.
2. These studies are investigating new therapies for Rheumatoid arthritis. Treatments for this population group must be tested in a number of groups with this condition, these two studies are investigating the same study drug in different groups of patients with Rheumatoid arthritis.

Summary of ethical issues (resolved)

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

1. The Committee questioned the frequency of this condition in Maori. The Researcher explained that they believe the rates are similar in all ethnic groups. The Committee requested that this kind of information is included in future applications.

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 noted that the answer given in the application to the question regarding how participants will find out about the study does not answer the question. The Committee requested further information regarding how participants will be recruited for the study.
2. The Committee noted that the Participant Information Sheet stated that tissue samples could be disposed of with a karakia, however they are being sent overseas. Please confirm whether disposal with karakia is available for samples disposed of overseas.

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

1. The Committee noted that they appreciated the weekly chart in the Participant Information Sheet.
2. The Committee noted that the cultural consideration section in the Participant Information Sheet for 15/CEN214 was much better than the section in the Participant Information Sheet for 15/CEN/215 and suggested that this wording from the Participant Information Sheet for 15/CEN/2014 is used of both studies.
3. Please consider the sentence in the Participant Information Sheet regarding the purpose of the study as the Committee found this confusing.
4. Please do not refer to the placebo as a ‘fake drug’, it may be more suitable to refer to it as ‘inactive’.
5. The statement in the Participant Information Sheet that the researchers will access ‘certain’ health information is confusing, please rephrase this. The Committee suggested removing the word ‘certain’.
6. The Participant Information Sheet states that the questionnaire may bring up bad memories for participants or make them uncomfortable. Please provide more explanation in the Participant Information Sheet regarding this, for example specifying that they may discuss the participant’s experiences of pain.
7. The statement under the heading ‘what do I have to do’ that states that some procedures may prevent you from being a participant in the study should be moved to another section of the Participant Information Sheet as this is an exclusion criteria.
8. The Participant Information Sheet lists biological samples as health information, please revise this statement.
9. The Committee noted that currently pregnant participants are being asked to consent before birth to their child being enrolled in the study, however, it is not possible to consent on this child’s behalf before they are born. Please amend the consent forms and information sheets to reflect this, please also provide an appropriate consent form and information sheet for after the woman has given birth.
10. The Information Sheet for the participant’s pregnant partner refers to their ‘legally authorised representative’, please remove this reference as no one is able to consent on their behalf.
11. The Committee noted that the Optional Pharmacogenetic sub study is Future Unspecified use of Tissue and suggested that the researchers compare their Information Sheet and Consent Form to ensure it contained all of the information required in the HDEC template.
12. Please ensure that the study titles, protocol numbers, and headings in all Participant Information Sheets are accurate.
13. Please clarify in the Participant Information Sheet whether the study drug is a standard treatment.

Decision

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

1. Please respond to the Committees outstanding ethical concerns detailed above.
2. Please amend the information sheet and consent forms, 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 Peter Gallagher and Dr Cordelia Thomas.

|  |  |  |
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| **12** | **Ethics ref:** | **15/CEN/215** |
|  | Title: | M14-465 Rheumatoid Arthritis |
|  | Principal Investigator: | Dr Daniel Ching |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 03 December 2015 |

Daniel Ching was present 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 was discussed alongside 215 as they are related studies.
2. These studies are investigating new therapies for Rheumatoid arthritis. Treatments for this population group must be tested in a number of groups with this condition, these two studies are investigating the same study drug in different groups of patients with Rheumatoid arthritis.

Summary of ethical issues (resolved)

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

1. The Committee questioned the frequency of this condition in Maori. The Researcher explained that they believe the rates are similar in all ethnic groups. The Committee requested that this kind of information is included in future applications.
2. The Committee questioned if there is a safety net in case participants start to deteriorate. The Researcher explained that if participants start to deteriorate they will be moved to a different treatment group or pulled from the study.

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 noted that the answer given in the application to the question regarding how participants will find out about the study does not answer the question. The Committee requested further information regarding how participants will be recruited for the study.
2. The Committee noted that the Participant Information Sheet stated that tissue samples could be disposed of with a karakia, however they are being sent overseas. Please confirm whether disposal with karakia is available for samples disposed of overseas.

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

1. The Committee noted that they appreciated the weekly chart in the Participant Information Sheet.
2. The Committee noted that the cultural consideration section in the Participant Information Sheet for 15/CEN214 was much better than the section in the Participant Information Sheet for 15/CEN/215 and suggested that this wording from the Participant Information Sheet for 15/CEN/2014 is used of both studies.
3. Please consider the sentence in the Participant Information Sheet regarding the purpose of the study as the Committee found this confusing.
4. Please do not refer to the placebo as a ‘fake drug’, it may be more suitable to refer to it as ‘inactive’.
5. The statement in the Participant Information Sheet that the researchers will access ‘certain’ health information is confusing, please rephrase this. The Committee suggested removing the word ‘certain’.
6. The Participant Information Sheet states that the questionnaire may bring up bad memories for participants or make them uncomfortable. Please provide more explanation in the Participant Information Sheet regarding this, for example specifying that they may discuss the participant’s experiences of pain.
7. The statement under the heading ‘what do I have to do’ that states that some procedures may prevent you from being a participant in the study should be moved to another section of the Participant Information Sheet as this is an exclusion criteria.
8. The Participant Information Sheet lists biological samples as health information, please revise this statement.
9. The Committee noted that currently pregnant participants are being asked to consent before birth to their child being enrolled in the study, however, it is not possible to consent on this child’s behalf before they are born. Please amend the consent forms and information sheets to reflect this, please also provide an appropriate consent form and information sheet for after the woman has given birth.
10. The Information Sheet for the participant’s pregnant partner refers to their ‘legally authorised representative’, please remove this reference as no one is able to consent on their behalf.
11. The Committee noted that the Optional Pharmacogenetic sub study is Future Unspecified use of Tissue and suggested that the researchers compare their Information Sheet and Consent Form to ensure it contained all of the information required in the HDEC template.
12. Please ensure that the study titles, protocol numbers, and headings in all Participant Information Sheets are accurate.
13. Please clarify in the Participant Information Sheet whether the study drug is a standard treatment.
14. Please ensure it is clear that as the participants in this study have not responded well to other treatments there is a risk that their condition may worsen if they are placed on the placebo arm.

Decision

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

1. Please respond to the Committees outstanding ethical concerns detailed above.
2. Please amend the information sheet and consent forms, 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 Peter Gallagher and Dr Cordelia Thomas.

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 28 January 2016, 12:00 PM |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington, 6011 |

The following members tendered apologies for this meeting.

* Dr Patries Herst
* Dr Melissa Cragg

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.