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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 29 November 2016 |
| **Meeting venue:** | Room 3N.3, Third Floor, Ministry of Health, 133 Molesworth Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 25 October 2016 |
| 12.30pm | New applications (see over for details) |
| 12.30-12.55  12.55-1.20  1.20-1.45  1.45-2.10  2.10-2.35  2.35-3.00  3.00-3.25  3.25-3.50  3.50-4.15  4.15-4.40  4.40-5.05  5.05-5.30 | i 16/CEN/165  ii 16/CEN/167  iii 16/CEN/169  iv 16/CEN/173  v 16/CEN/177  vi 16/CEN/179  vii 16/CEN/184  viii 16/CEN/187  ix 16/CEN/188  x 16/CEN/189  xi 16/CEN/190  xii 16/CEN/191 |
| 5.30pm | General business:   * Noting section of agenda |
| 5.45pm | 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 | 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) | 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 12.00pm 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 25 October 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/CEN/165** |
|  | Title: | AAML1531: Risk-stratified Therapy for Acute Myeloid Leukaemia in Down Syndrome. |
|  | Principal Investigator: | Dr Siobhan Cross |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 17 November 2016 |

Ms Sara Parkin was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

1. The committee complimented the research team on a well put together application. The committee did not have any significant ethical concerns about the intended study but made the following points in regard to the information sheets and consent forms for potential participants.
2. The committee noted that the main issue it sees for some studies that have many information sheets is that it is often not easy to work out what is going on. One way around this is for researchers to provide a cover sheet that outlines what each of the information sheets are for. The committee stated its preference for researchers to submit a coversheet or email when this is the case.
3. The generic short form for non-English speaking participants is used in conjunction with the specific study information sheet and consent form. It has been agreed with the committee that the main information sheet and consent form will be signed first and then the generic short form.

The committee requested the following changes to the participant information sheets and consent forms:

1. Main study information sheet, page 1 under the heading ‘What is a Clinical Trial?’: the committee noted the statement “It is common to enrol children and adolescents with cancer in a clinical trial that seeks to improve cancer treatment over time.” And commented that this may give the impression to parents/caregivers that there is an expectation that their child will be enrolled. The committee suggested that this statement could be rephrased. The researcher explained that the content in this form is from a COG template and that they are required to adhere closely to the template for audit purposes.
2. The committee queried the consistency of information stated on pages 3 and 5 about the allocation of participants into Arm A of the study after they have had a Minimal Residual Disease (MRD) test. Information on page 3 states that participants who have “minimal or no traces” of leukaemia cells in their bone marrow after the first course of treatment will be placed in Arm A of the study and information on page 5 states that “If there is no leukaemia in the bone marrow” allocation will be to Arm A of the study. Please correct this contradiction so that information is consistent.
3. Page 11 of the main information sheet: the committee noted the instructions for receipt of the study results and queried whether the research team could make it easier for participants to get the study results and suggested that someone from the study team could provide participants with the results. The researchers agreed to add here that someone from the Christchurch team can give additional instruction on how the participants can receive the results or could send results out to them.
4. Page 7 of the main information sheet under the heading ‘Biobanking’: the committee noted that this section sets out for participants that the researchers would like to get extra bone marrow samples and do extra testing on these samples. The committee requested that in this case that the researchers provide an extra form for participants to read and sign on reaching 16 years of age (the legal age of consent) so that as an adult they can make the decision about whether they agree to and give permission for this. To facilitate an ‘approved’ decision the committee noted the researcher may wish to email this information sheet to the HDEC inbox for circulation to the committee for comment before submitting it with the provisional approval response. The reason for this is that the committee can only make a provisional approval decision once.
5. The committee pointed out that the researchers can’t assume that people in this population group are not competent to make this decision but if they are deemed to be not competent once they reach the age of 16 then the research team cannot re-consent them once they are adults and they will need to take the samples out of the study.
6. The committee sought clarification on the relationship between the information stated in the section about biobanking on page 7 of the main information sheet with that stated in the Optional Future Unspecified Use of Tissue information sheet. The researcher confirmed that the information stated on page 7 is a summary of the information given in the optional form and refers to same thing. The committee noted that it would be useful to say in the section on page 7 that this is covered in more detail in the optional FUR information sheet and consent form.

Decision

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

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

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

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| **2** | **Ethics ref:** | **16/CEN/167** |
|  | Title: | COG ARST1431 |
|  | Principal Investigator: | Dr Mark Winstanley |
|  | Sponsor: | Children's Oncology Group (COG) |
|  | Clock Start Date: | 17 November 2016 |

Dr Mark Winstanley 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. The committee noted that this is an interesting study that will attempt to improve long term survival of patients with Rhabdomyosarcoma. The researchers will first do a dose escalation to find out what dose is tolerated and safe and then run the trial. They will compare standard treatment against standard plus. There is a third arm of the study where some participants (who are diagnosed with ‘low risk’ and not as aggressive cancer after pathology review), will be transferred to another (less aggressive) regimen prior to the start of week 4 of therapy. The researchers noted that the treatment is the same for the first 4 cycles.
2. The researchers noted that an ongoing question for Rhabdo is to find quicker endpoints to more quickly assess whether therapy works. One of the options they are looking at in this study is how good PET scans are for diagnosis and for showing how a tumour is responding to therapy.

The committee requested the following changes to the participant information sheets and consent forms:

1. The committee noted that there were many participant information sheets and consent forms submitted with this application and complimented the researchers on a well-written, informative cover letter that set out what each of the information sheets and consent forms were for. The committee also noted the inclusion of flow charts was helpful.
2. The committee commended the researchers on their responses to the cultural questions in the application form.
3. The committee complimented the researchers on the information provided about genetic information and potential risks on data linkage and privacy noting it was accessible and future proofed.
4. The committee sought clarification on the future use of tissue. Optional research tests – 1 future research and 2 FUR use of tissue. The committee asked what happens if a participant signs ‘yes’ for future related research and then ‘no’ on the future unspecified research form. Please include a note on the information sheet to cross reference to the future unspecified research information sheet for more information. (On the optional research test form at item one – please put a cross reference there)

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **16/CEN/169** |
|  | Title: | EuroEwing 08 |
|  | Principal Investigator: | Dr Mark Winstanley |
|  | Sponsor: | Australasian Sarcoma Study Group |
|  | Clock Start Date: | 17 November 2016 |

Dr Mark Winstanley and Ms Paula Murray 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 were as follows.

1. The committee had no significant ethical concerns about this application and agreed to approve the study. The committee discussed a couple of minor points relating to the information for participants as part of the informed consent process which were clarified by the researchers present and do not require checking by the committee following approval.
2. The committee noted the information sheet sets out for participants that the study will be done in three phases and noted the use of the word ‘adjuvant’ early on in the information sheet. The committee queried whether people will understand this term as it is complicated and specific. The researchers agreed that they can replace this term with a more accessible one throughout. The committee suggested that a more simple way to say adjuvant could be that it comes after the second round of chemotherapy.
3. The committee queried the use of the patient references R1, R2 and R3 and the researchers explained that this is a European way of stratifying the disease, that three separate streams have been agreed: R1 for small, localised tumours, R2 for no metastatic disease or disease only to the lungs and, have better outcomes or mass has not responded to chemotherapy. R3 is for patients who have extensive metastatic disease or more aggressive disease and everyone in this group does poorly and there is more room for improvement in treatments. The committee asked the researchers to explain this in detail in the information sheets.
4. The committee commended the researchers on the inclusion of information in the 11-15 year old information sheets about taking precautions if sexually active while taking the study medication as it acknowledged the reality that some adolescents in this age group are sexually active.

Decision

This application was *approved* by consensus.

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| **4** | **Ethics ref:** | **16/CEN/173** |
|  | Title: | Data Registry. |
|  | Principal Investigator: | Dr Swee T Tan |
|  | Sponsor: | Hutt Valley District Health Board |
|  | Clock Start Date: | 17 November 2016 |

Dr Swee Tan was present by teleconference for discussion of this application.

Potential conflicts of interest

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

Dr Dean Quinn declared a potential conflict of interest, and the Committee decided that he would not take part in the discussion or decision making for this application.

Summary of ethical issues

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

1. The committee queried whether when getting consent from the parent for prospective use of the data the researchers would get assent from the child. The researcher advised that for vascular birthmarks they ask the child when they come with the parents and consent is gained then. The committee noted in research involving children that a simple assent form is often given so that the child can sign it and say they agree to participation in the research. The committee would like to see and assent form for the child and noted that the HDEC website has some examples of assent forms: <http://ethics.health.govt.nz/guidance-materials/assent-guidance>
2. The committee noted that when a child comes of age (16 in New Zealand) they are given the opportunity to give their full consent for continued participation (including ongoing use of their data) in a study. Dr Tan noted that if they have moved away it could be difficult to track them. In that case, would the committee require ‘reasonable’ efforts be made to locate the young person. The committee thought the researchers should track the whereabouts of participants. The committee noted that if the researchers are going to prospectively collect data then they would likely know when the patient is moving away.
3. Dr Tan noted the specific example of someone going overseas without consenting to ongoing use of the data and asked the committee whether they could continue to keep this data in the database. It was noted that if data is deleted it would not be a representative sample of the population. The medical condition in question affects 1.5 percent of the population.
4. Dr Tan explained that the information collected is from when the patient comes to see the research team, it will be specific to their medical problem. The committee noted that it would be helpful to clarify this in the participant information sheets. The researcher noted that the only reason more information would be collected for someone over the age of 16 would be when they come in for clinical care, or when other specialists seek advice from the researchers for an opinion on what to do with a patient. The committee noted that in that case when another specialist contacts the researchers they could get consent from the patient for their continued inclusion in the data registry.
5. The committee noted that it is happy to approve the study for the use of prospective data in the database where parents have consented and the child has assented.
6. In terms of the retrospective data: the researcher explained that routine practice is to collect patient data for analyses and audit purposes. The data held is about a patient’s medical condition and what the treatment was. The researchers would wish to transfer this historical data to the registry rather than destroy it.
7. The committee noted that the retrospective use of data without consent needs to meet regulations and asked the researcher to explain why they can’t get consent to use the retrospective data. Dr Tan stated that some of the patients will have died and if they trace the person back to their next of kin this could create some anxiety for them and, locating patients also requires lots of resource. The researcher reiterated that the information collected is about the patient’s medical condition and the outcome, NHI and age and sex and the research team would not be collecting any other personal information. This registry collects information about the person, age, sex and condition, treatment and outcome.
8. The researcher advised that a spreadsheet of patients with vascular anomalies established in 1996 would be accessed rather than patient clinical records. For Head and Neck patients a spreadsheet established in 2005 and there are around 1400 people in each population.
9. The committee discussed whether an opt-out option could be done where the research team send the information sheet to patients whose data is held in the historical database and they can contact the research team if they wish to opt out of being in the registry. On balance the committee decided against this option.
10. The committee asked how long the research team were anticipating storing and using the retrospective data. Dr Tan stated they would like to store the data indefinitely. The committee agreed that it would approve retention of and access to the data for 10 years and ask that the researchers then come back and apply to extend storage.
11. The committee asked the researchers how they anticipate using the data given that they wish to store it indefinitely. Dr Tan stated that any use of the data for research would need to be approved by an ethics committee through an application to access and use the data. He would only send de-identified data to third party researchers. The data they will keep may be shared with other researchers but only in anonymised form and use would need ethics approval.
12. The researchers intend to collect ethnicity data.
13. The committee agreed that on balance it approved entering the retrospective data into the research database without patient consent as there was sufficient public good in the use of health information for future research and to inform clinical care for these patients. The committee noted that any research use would need specific ethics approval.
14. The committee noted that the peer review submitted with this application was from colleagues within the research team and requested that the researchers submit further peer review from an independent expert who is qualified to comment on the design, methods and feasibility of the intended research.

The committee requested the following changes to the participant information sheet and consent forms:

1. The committee asked that the researchers include Yes/No boxes on the consent form only for the statements that are truly optional.
2. The committee asked that the researchers include the standard contact numbers for the independent bodies that the participants can contact. Examples of these can be found on the HDEC website: <http://ethics.health.govt.nz/home>

Decision

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

* Please provide scientific peer review of your intended research from someone who is independent of the research team and who is qualified to comment on the design, methods and feasibility of the intended research. *(Ethical Guidelines for Observational Studies, para 5.8 and Appendix: Joint Health Research Council and NEAC guidance on features of robust peer review for assessing the scientific validity of research)*
* Please submit an age appropriate participant information sheet and assent for children consenting to the prospective collection of data. *(Ethical Guidelines for Observational Studies, para 6.11)*
* Please submit a participant information sheet and re-consent form for young persons who turn 16 and seek additional care or advice from the research team and therefore generate additional health information that will be entered into the database. *(Ethical Guidelines for Observational Studies, para 6.11)*
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Observational Studies, para 6.11)*

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

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| **5** | **Ethics ref:** | **16/CEN/177** |
|  | Title: | Gratitude journal for adolescents with type 1 diabetes |
|  | Principal Investigator: | Dr Anna Serlachius |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 17 November 2016 |

Dr Anna Serlachius 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 the Study

1. The researcher gave a brief outline of the study. The research team intend to recruit adolescents who have been diagnosed with type I diabetes and trial a gratitude journal, which is a “gentle” intervention where participants in the intervention group will fill in journal and write down 3 three things they are grateful for. The study is a randomised controlled trial design. Half of the participants will have standard care and the other half will have standard care and use the journal for 8 weeks. The researchers are looking to see whether the intervention can improve mood, self-care behaviour and glycaemic control. The researchers will aim to recruit 40 adolescents and 40 parents.

Summary of ethical issues (resolved)

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

1. With regard to the questionnaires that will be used in this study the committee queried why the questionnaires included a request for information about parental income. The researcher explained that the inventory for parents is validated and deemed to be reliable for this cohort. This questionnaire is used most and gives data for scores to compare data in this cohort. The researcher noted that the questionnaires were developed in the US where it can be expensive for care – they could leave this question out of the questionnaire but that could possibly make it difficult to compare data.
2. The committee asked the researcher how the team planned to recognise and accommodate cultural differences in the way people would answer questions and in turn for capturing accurately the information they wish to measure/analyse. In other words, the researchers are looking for accurate data but that may be skewed by cultural norms. For example, question 22 on the inventory for parents asks whether the person has disagreed with a member of the health team and the committee noted that in some cultures e.g Pacific Island, they so not disagree with people who are in positions of authority. The researcher acknowledged that is a difficulty associates with using standardised questionnaires in general, especially those piloted and used with a western (USA) society. The standardised questionnaire they wish to use is the best that they have access to currently. The researcher explained that parents will complete the questionnaires at the clinic and parents will be welcome to ask any questions of the health team that they may have including about the questionnaire. The student researcher can say that if a person doesn’t feel a question is applicable to then they can let the researcher know. The researcher suggested that another way to get around this is that they could talk with staff at the University of Auckland about having individual questions with cultural groups. The committee noted that they are only taking a global score so it may not be helpful to add additional questions. This issue could alternatively be addressed this in the limitations section of the research.
3. Questionnaire for adolescents looking at state of mind: the committee asked what plans the researchers have in place if they find that a participant is at risk. The researcher explained that this questionnaire is one used mostly in research and is not a diagnostic tool. If there were such questions then they would need to have a different protocol in place. They have discussed the issue with the diabetes health team. A sensible approach would be if the person scores high on depression measure then the research student would call family and ask them if they would like additional support and referral to another specialist. Also send something in the post outlining where they can go for further confidential support. The committee queried whether this would be a breach of a participant’s privacy. The researcher explained that their consenting process involves usually speaking to the individual in the presence of their parents. After signing consent the young person would know that they would bring in the family. The committee asked that this be outlined clearly in the participant information sheets that this is a possibility if any information comes to hand that the researchers think warrants it. Please include in the PIS that this is a possibility if anything comes out. The committee also noted that the researchers decide on alternatives to whanau support as the young person may not wish to seek support from family especially if the family dynamic is dysfunctional. The researcher noted that the student researcher will have liaised with a team psychologist to look at inclusion/exclusion criteria and person not at risk. The committee suggested that the researchers don’t use the word ‘depression’ and state something along the lines of if any concerns come up that there is a possibility they will share information with other health professionals.
4. Procedures in place for screening. Access to support is well thought out for families who might need different types of support.

The committee requested the following changes to the participant information sheet and consent forms:

1. The committee asked the researchers to include the study’s purpose up-front in the information sheets for the young people. i.e why they are doing the study and why they are being asked to complete the journal.
2. Please identify and include a Maori support person who potential participants can contact if they have any questions about being in the study.
3. Consent forms – please include yes/no boxes only for the statements that are truly optional.
4. The committee suggested that the researchers use one participant information sheet for 10 to 15 year old participants and noted that any participants who turn 16 during the study are required to be re-consented using the main information sheet and consent forms. The committee also asked that the fact that parents/caregivers will be asked questions should be included in the information sheet for the young person.
5. The researcher explained that their consenting process involves usually speaking to the individual in the presence of their parents. After signing consent the young person would know that they would bring in the family. The committee asked that it be outlined clearly in the participant information sheets that any information that comes to hand that the researchers think warrants referral with the young person’s family or another specialist that this is a possibility.

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 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:** | **16/CEN/179** |
|  | Title: | Whole body vibration training in DMD |
|  | Principal Investigator: | Dr Lisa Power |
|  | Sponsor: | Liggins Institute |
|  | Clock Start Date: | 17 November 2016 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

1. The committee noted the peer reviewer’s comments about whether the study is powered enough to have statistical relevance and noted that the researchers had included an extra assessment in response to this point.

Summary of ethical issues (outstanding)

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

1. Question p.4.1 on page 25 of the application form: please clarify for the committee what the following statement means – “Maori boys with DMD will be eligible for the study. However, if they are eligible all attempts to overcome financial and geographic concerns will be made to include them”.

The committee requested the following changes to the participant information sheets and consent forms:

1. Please review the document for grammatical consistency. e.g. You will/we would please make consistent.
2. Please include clearer information about what the body vibration programme is and what participants are required to do. A graph or flow chart that sets out the different stages visually would be a helpful addition and is recommended.
3. Information and assent forms for the children and adolescents should be in line with the recommended age groups 7-11 years of age and 11-15 years of age. The committee noted that one information sheet is for 13 to 18 years old and requests that you change it to 11-15 years of age. Young people 16 years old and over can legally consent as adults to be in the study and should use the main participant information sheet and consent forms.
4. Please provide a re-consent form for children who will turn 16 during the study and therefore will be able to agree to be in the study as consenting adults.
5. Please include age group headings (e.g 7-10 and 11-15) on the participant information sheets and consent forms.
6. Please state that the study has ethical approval by the Central Health and Disability Ethics Committee.
7. Vibration training: the committee noted that the application form states that an exercise physiologist will be present during this time but could not find any information that explains whether supervision will be provided by an exercise physiologist if the child trains at home. Page 4 of the parent/caregiver information sheet states that training will occur at a child’s school or at their home with the help of a research assistant and the committee would like clarification as to whether this person will be an exercise physiologist. The committee would like to be assured, from a participant safety perspective that they will not fall over as they will be supervised by an appropriate person.
8. Please make clear where the blood testing will take place and who will do it in between clinic visits.
9. Page 2: the committee would like the researchers to clarify how much benefit is to be expected. The information makes reference to a previously conducted study in 40 adolescents with cerebral palsy but doesn’t state how much longer they were able to walk and whether that result was significant. The committee would like to see further information on what the benefit might be e.g. improved muscle strength and function? Please clarify on page 2 specifically how much improvement the earlier study showed in the CP group or alternatively remove reference to the CP group as it might be misleading to this group of participants. The researchers could state that your child may experience an improvement or may remain the same and that they can’t guarantee any improvement as a result of participation in this study.
10. Page 6, under the heading ‘Data and Results’: please state who will keep the data and bloods and be responsible for their secure storage, for how long, how they will be destroyed/discarded, and who will have access to the data and how the study findings will be communicated on completion of the study, including to participants.
11. The committee noted that question b.2.1 on page 12 of the application states that the study design effectively allows for the participants to act as their own controls and that any patients unable to travel to Auckland for the full assessments, who would like to participate, will be included as a control group with assessments at T0 and T2. The committee would like to see a separate participant information sheet for the participants in the control group.
12. Consent Form: Please include Yes/No boxes for the statements that are truly optional only.
13. Please include information about whether participants will have access to the study device after the study has finished.

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 information will be reviewed, and a final decision made on the application, by Dr Patries Herst and Dr Cordelia Thomas.

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| **7** | **Ethics ref:** | **16/CEN/184** |
|  | Title: | M15-942 HCV (MAGELLAN-3) |
|  | Principal Investigator: | Dr. Michael G. Schultz |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 17 November 2016 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (outstanding)

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

1. The committee noted the main issue as one it had before with the sponsor about the use of work ‘archival’ samples. Specifically in previous studies, the use of the term archival related only to tissue consented to be used for future unspecified research. The committee would like clarification about what “archival samples” refer to. For example, does it refer to pharmaco-genetic samples or to all samples being collected in the study?

The committee requested the following changes to the participant information sheet and consent forms:

1. Please revise the page numbers and correct them as they are currently inconsistent and some are repeated.
2. Page 2 (first one): the committee noted that the volume of blood to be taken at the blood sample collection visits is not specified. Please give a range.
3. Page 4 (first one) under the heading ‘HIV/AIDs Testing’: the committee noted the statement “If your test results are positive, the study doctors are required by law to notify government health authorities.” Please remove this statement as while AIDS is a notifiable disease in New Zealand, HIV is not.
4. Pages 4 (second one), 6 and 7: please review the reference to “local label” and delete or reword to a term that is relevant to a New Zealand audience.
5. Page 4 (second one): please include the emergency number 111 under the heading ‘Allergic Reactions’.
6. Page 10 under the heading ‘Rights to your information’: the researchers are asking participants to agree not to review or make a copy of some of their records related to the study until after study has been completed. This is an open label study, how would early disclosure of health data alter the integrity of this data?
7. Page 5 (first one): please explain what the term ‘Flow Cytometry’ means
8. Page 7, 2nd bullet point under the heading ‘Male Participants’: please remove the words “when this is in line with the preferred and usual lifestyle of the participant and instead include wording along the lines of: *Please refrain from heterosexual intercourse or intercourse that might lead to pregnancy.*
9. Page 8 under the heading ‘Participant reimbursement of travel expenses’: please specify what a “reasonable” amount of reimbursement is.
10. Page 9: examples of health information – biological samples aren’t health information. Please remove.

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 information will be reviewed, and a final decision made on the application, by Dr Dean Quinn and Mrs Helen Walker

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| **8** | **Ethics ref:** | **16/CEN/187** |
|  | Title: | CID Genome wide investigation |
|  | Principal Investigator: | Prof Jon Skinner |
|  | Sponsor: | ADHB |
|  | Clock Start Date: | 17 November 2016 |

Prof Jon Skinner, Dr Kathryn Waddell-Smith and Dr Klaus Lehnert were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

Summary of the Study

1. The researchers wish to perform a genome wide study with the aim of detecting new genetic mutations that contribute to cardiac disease in inherited cardiac conditions. The researchers will collect bloods that will be sent overseas for whole genome testing where standard testing has failed to identify a mutation.
2. The researchers confirmed that the patients they wish to enrol in this study are already enrolled in the registry, some will have bloods stored and the researchers will collect bloods from those who do not.
3. The researchers outlined the consenting process for patients when they were enrolled in the registry – they would have consented to participating in the registry and given their permission for the use of their clinical data and blood samples and for research into cardiac inherited disease. Their identity will be anonymous to any third party researchers. The committee noted that in future it would be useful for the committee to see the original consent form in order to access how the proposed research confirms with and/or differs from the original 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 asked whether consent is for future unspecified research or are they just giving permission to store the data/tissue and then get specific consent for each study.
2. The researchers stated their understanding is that they gain consent from people to do any research directed toward the condition on that DNA but if they do something new like get more tests then they will seek approval form the ethics committee. They are seeking consent in this case because the genome wide investigation is outside of the original consent given and because they need extra samples.
3. The committee asked whether the research team has completed their consultation with their local Maori research group. The researchers stated that they had not and were still in the process. The committee noted that often in these types of studies the Maori research body will suggest wording for the statement around the ongoing use of tissue and information from a cultural perspective. If the research team does amend the wording in the participant information sheet then the committee would like to see this change submitted as an amendment with changes tracked.
4. The committee noted that the researchers had answered ‘yes’ to question p.4.4 on the application form that asks whether the study involves Kaupapa Maori methodologies. The researchers advised that this was in error and that they would seek advice from Maori advisors as part of their consultation process.
5. The researchers noted that the study protocol submitted with this application stated in its aims section that the study is “To pilot a whole genome pedigree…” when it should say “perform”. The committee agreed that the proposed study was a full study and not a pilot.

The Committee requested the following changes to the participant information sheet and consent forms:

1. The committee noted that the researchers had stated in their application that children and adolescents under the age of 18 may be enrolled in the study and consent would be sought from the parents. The committee advised that 16 years of age is the legal age of consent in New Zealand and participants who are 16 years of age and older can consent for themselves. With this in mind the committee would like to see age appropriate information sheets and assent forms for participants who are under 16 years of age. Assent forms are needed so that the young person has the chance to say whether they agree and are happy with taking part in a study. The committee noted the age ranges for information sheets and assent forms are generally accepted as 7-11 and then 11-15, (which is a bit more sophisticated), and then full participant information sheets and consent forms for those who are 16 and over. The committee would also like to see a re-consent form for anyone who turns 16 during the course of the study. The HDEC website has examples of assent forms on its website that you may wish to refer to for guidance: <http://ethics.health.govt.nz/guidance-materials/assent-guidance>
2. The committee reminded the researchers that the law in New Zealand allows for a parent/guardian to consent to their child taking part in research but that incompetent adults cannot have someone else consent on their behalf.
3. Please provide contact details for a Maori Health Support person and the Health and Disability Ethics committees
4. Please update details for the approving ethics committee to the Central Health and Disability Ethics Committee.
5. The committee noted that the researchers may have incidental findings as they would like to look for heart and heart rhythm gene markers and that they will not review all of the genes in detail. The researchers added that they will be guided by policy from the American College of Genetics for when there is no treatment available for an identified condition then the information may not be helpful to the patients. The committee noted that question r.8.1 on page 19 of the application form states that people will be given the opportunity to talk to a genetic counsellor about incidental findings. The committee accepted that there will be a number of incidental findings that don’t need to be communicated but thought that it would be appropriate to give people the option of signing in to receiving news of incidental findings even if there is no treatment for the condition. Not informing participants of the results and procedures could be contrary to Right 6 of the HDC Code of Health and Disability Services Consumers’ Rights Regulation as they are entitled to information that they would reasonably expect to receive. The committee noted that people might, for example, alter their reproductive choices as a result of incidental genetic results (e.g. Huntington’s).
6. The committee suggested that the researchers include optional tick boxes that include the options of participants choosing whether they would like to know about all incidental findings or only those that the American college of genetics recommends. The committee asked that the researchers expand on information in the participant information sheet about the fact that if a person has a mutation that it does not mean that they will automatically have the disease and that they can talk to a genetic counsellor.
7. Page 3: the committee noted the statement about the researchers needing samples from three or more family members. The researchers confirmed for the committee that each family member will have to consent for themselves, that there will be three independent family members and they may include people who don’t have the condition to act as a positive control. The family members do not have to recruit other family member.

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 Observational Studies, para 6.11)*

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

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| **9** | **Ethics ref:** | **16/CEN/188** |
|  | Title: | Mycoplasma genitalium and antimicrobial resistance |
|  | Principal Investigator: | Dr Sally Roberts |
|  | Sponsor: |  |
|  | Clock Start Date: | 17 November 2016 |

Dr Sally Roberts 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 the study

1. Until recently mycoplasma gentalium has been recognised as a cause of sexually transmitted disease but it has not been able to be tested for. It can be detected in urine but can’t be grown in agar and most laboratories don’t routinely attempt to isolate it. Around the world it has been shown that the organism develops resistance to the standard treatment quite quickly. The researchers wish to use retrospective stored DNA specimens extracted from urine and to compare the performance of a new multiplex PCR assay with that of the current in house assay. It is hoped that this could be used as standard test in future.

Summary of ethical issues (resolved)

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

1. The committee asked whether there is any chance of getting consent from those who have given the specimens. The researchers explained that the samples go back to the year 2009 and have a coded name and they would then have to go back to the sexual health service to contact the patients. Patients gave consent for the original test on the sample, and the proposed research test is very similar. The researchers want to look at DNA of bacteria from the sample. In this case, the committee agreed that given length the length of time since the sample was provided; the sensitive nature of the information regarding sexual health; and the nature of the proposed research contacting patients might cause unnecessary anxiety and was therefore unnecessary in this case.
2. The public good of the study is that if this test is successful then clinicians could be better informed about the most appropriate treating regimen to use in their patients taking antimicrobial resistance into account. Patients would be less likely to come back for further treatment.

Decision

This application was *approved* by consensus.

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| **10** | **Ethics ref:** | **16/CEN/189** |
|  | Title: | Metastatic breast cancer outcomes project |
|  | Principal Investigator: | Dr Marion Kuper |
|  | Sponsor: |  |
|  | Clock Start Date: | 17 November 2016 |

Dr Marion Kuper and Ms Jenni Scarlett 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 were as follows.

1. This study has come to a full committee meeting as the researchers will be accessing identifiable patient data that will be linked and published. The data will be de-identified and will be published as anonymous data.
2. The committee noted that a summer student will be contracted who will have access to identifiable data and will do the linking. The committee queried what supervisory training arrangements are in place for the student especially around privacy and confidentiality of information. The researchers advised that training is provided and that the student will be required to sign a confidentiality project before carrying out this work.
3. The committee asked whether the student will have information on his or her personal laptop and the researchers confirmed no and that any work will be done on the DHB computers and held there.

Decision

This application was *approved* by consensus.

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| **11** | **Ethics ref:** | **16/CEN/190** |
|  | Title: | BLIS-OM: Preventing Upper Respiratory Tract Infection in Infancy |
|  | Principal Investigator: | Prof Julian Crane |
|  | Sponsor: |  |
|  | Clock Start Date: | 17 November 2016 |

Prof Julian Crane 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 the study

1. In this study the researchers would like to give an oral probiotic to infants aged from 6months to 2 years in an attempt to stop upper respiratory tract infections in particular those that give rise to AOM. Such infections are common in this age group and the basic outcome measure will be records from the GP.
2. The researchers also wish to look at possible future research in terms of samples collected from child’s mouth. The researchers are also interested in dentition as probiotics are thought to interfere with dental decay. If the research team sees something that looks interesting in this study they would proceed to get some funds.

Summary of ethical issues (resolved)

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

1. The committee queried whether the researchers feel confident that mothers will give this probiotic to their babies every day for two years. The researcher gave the example of a previously conducted study where it was found that 85 percent of mums gave the probiotic to their infants. The researchers were surprised at that and noted a possible reason for compliance as because mothers who take part in these studies are keen to contribute. The study population may not be as representative of the general population as mums who like natural products might volunteer to take part but the researchers are reasonably confident that the mothers will comply.
2. Try to deliver the probiotic in a way that is more like the real world as mothers may not give it to their infants every day. The infant can take it in various different ways, for example, mixed with food in their feeder dummies. The longer the probiotic dwells in the mouth the better so that could be a bit of a challenge.
3. Recruitment with GP – practices that take part in studies will give access to their patients. GPs who have patients with infants who have presented with an infection will hand out information to their patient who will then choose whether to get in touch with researchers to find out more about the study.

The Committee requested the following changes to the participant information sheet and consent forms:

1. It appears that the researchers don’t intend to do future unspecified research on the tissue samples taken but as the samples are to be collected and may or may not be analysed the committee requested that information on the storage and possible analysis of the samples should be included in the participant information sheet for the study. Please revise the participant information sheet to include information about the possible uses of the swabs and include this also in the consent form. If future unspecified research is to be done with the samples then a separate optional and distinct consent would need to be obtained.
2. Consent form – please include tick boxes only for the statements that are truly optional.

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

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| **12** | **Ethics ref:** | **16/CEN/191** |
|  | Title: | Blood flow restriction training for hand osteoarthritis |
|  | Principal Investigator: | Mr Nico Magni |
|  | Sponsor: |  |
|  | Clock Start Date: | 17 November 2016 |

Mr Nico Magni, Prof Peter McNair and Dr David Rice 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 were as follows.

1. The committee noted the answer stated at question r.1.5 on page 13 of the application form about every adverse event being reported to the AUT ethics committee. The committee reminded the researchers that they are also obliged to report serious adverse events to the Central HDEC.
2. The researchers advised that they have revised an aspect of the study to increase the sample size to 66 participants in order to give power to the study to detect statistically significant changes.

The committee requested the following changes to the participant information sheet and consent forms:

1. The committee queried the involvement of GPs in this study. It noted a statement on the consent form that stated a GP had deemed the person suitable to take part in the study. Given this statement the committee presumed that the GP has been given an information sheet and or discussed the study with the researchers. The GP should be told about anything that comes up in the study. The committee noted that the participant information sheet should explain what the GPs part in the study will involve and include information about what they are expected to discuss with the GP including discussion of any issues that would make it impossible for the individual to participate.
2. Please explain that the koha participants will receive for taking part in the study will be 40 dollar petrol vouchers.
3. The committee would like to see more information included about what will happen to the participant data, including where it will be stored and for how long, who will access to the data. Please refer to the HDEC template on its website: <http://ethics.health.govt.nz/>
4. Please include contact details for a Maori support person.
5. Information from statements 6, 8 and 9 on the participant consent form also need to be included with information in the participant information sheet.
6. Page 2 under the heading ‘What will my participation in the study involve?’, last paragraph: please replace the word “do” with the word “have” in the sentence that reads “If you have hand osteoarthritis but you do not have hand x-rays taken [..]”.
7. Please include how many people you are hoping to recruit into the study.

Decision

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

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

## 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:** | 31 January 2017, 08:00 AM |
| **Meeting venue:** | Room GN.6, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington, 6011 |

The following members tendered apologies for this meeting.

Dr Angela Ballantyne

The meeting closed at 5.30pm