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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 28 April 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 March 2015 |
| 12.30pm | New applications (see over for details) |
|  | i 15/CEN/41  ii 15/CEN/43  iii 15/CEN/46  iv 15/CEN/47  v 15/CEN/48  vi 15/CEN/50  vii 15/CEN/51  viii 15/CEN/52 |
| 3.50pm | General business:   * Noting section of agenda |
| 4.10pm | Meeting ends |

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

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Mrs Sandy Gill.

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 March 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/CEN/41** **(CLOSED)** |
|  | Title: | Phase I Study of MK3475 in Combination with Trametinib and Dabrafenib |
|  | Principal Investigator: | Dr Rosalie Fisher |
|  | Sponsor: | Merck Sharp & Dohme (Australia) Pty Limited |
|  | Clock Start Date: | 16 April 2015 |

Dr Rosalie Fisher and Ms Vivian Sun 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.

Decision

This application was *provisionally approved* by consensus.

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| **2** | **Ethics ref:** | **15/CEN/43** |
|  | Title: | Treatment of Hepatitis C in injecting drug users- SIMPLIFY Study |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | UNSW Australia |
|  | Clock Start Date: | 16 April 2015 |

Professor Ed Gane and Victoria Oliver 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

* The researcher explained that most studies exclude injecting drug users. This study specifically aims to generate information for oral treatments in this patient population.
* This treatment is well tolerated. The study treatment should clear the virus and reduce the risk of re-infection.
* Most Hepatitis C infections are from horizontal transmission of injecting drug users.
* The Committee noted there is an optional sub study that looks at the efficacy of finger prick compared with venous blood draws.

Summary of ethical issues (resolved)

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

* The researchers confirmed a SCOTT application has been submitted.
* (R.7.1) The Committee asked if there are any risks to researchers or third parties. For instance, is the patient population aggressive? The researcher explained that there is a reasonably large population of injecting drug users who have Hep C. The screening process will identify any criminal charges and or mental health disorders which will identified to reduce risks, adding that the researchers were experienced with the patient population.
* (P.4.1) the committee noted that for this question it is appropriate to add statistics in relation to Maori and any information about Maori benefits. For example information on the number of Maori who were intravenous drug users would be useful to know. The researchers explained that very recent data suggests that rate of injecting drug use is the same in Maori as non-Maori. The Committee noted this kind of information is useful, thanked the researchers for addressing the question and asked that such information be added to future applications.
* The Committee queried how you can trust the patient population with respect to adherence, taking their tablets correctly and also how study will monitor drug interactions, including illicit drug use. The researchers explained that the study population has demonstrated that they have good track records in taking methadone. The researcher explained that there are electronic blister packs which help tell the researchers when the patients are taking their tablets which can increase adherence information. These are a brand new technology which is being piloted by the sponsor. Education as well as a short duration of treatment will help, as well as the fact that these participants are seeking treatment. The researchers explained that they do realise that adherence will not be 100%. The drugs have a reasonable half-life so missing 1 or 2 treatments will not be too detrimental.
* The researchers explained that there is low risk of drug interaction. There have not been any adverse findings with heroine and the study drug.
* (P.4.2) Committee noted this response is a good example of potential cultural issues relating to the study.
* The Committee asked what samples are optional or additional. The researcher explained that the participants will have an additional sample for the sub study, because the participants do not have any blood draws on week 1.
* Will main study blood samples be stored in a tissue bank that is also used for the sub study future unspecified research samples? The researchers explained that all samples will go to the registered tissue bank. If consent is not given to store the samples will be disposed.
* The Committee queried whether there was any element of coercion because they are not able to participate in many other studies. The researcher noted that unfortunately we are in a situation in New Zealand where no one is able to access these study treatments free of charge, irrespective of drug use. Almost every other country in the world, including Australia, will be funding treatment with oral treatment for Hep C. The researcher agreed that there was a degree of coercion in that regard, but it applied to all Hep C research in New Zealand. The researcher added that treatment was available post study but would cost participants.

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

* Please add ‘OPTIONAL’ in the title of the sub study (PIS and CF).
* Add a statement early in the PIS that this is voluntary and optional.
* Please remove the written withdrawal requirement as it is not required by New Zealand Law.
* (P.2.9) is it possible for participants to receive a lay language summary of study results? The researcher confirmed it was possible. The Committee requested adding a yes no option on consent form to receive a lay language summary.
* Pg.4 ‘what are my rights?’ – Please specify who ‘authorised’ persons are for participants.
* Pg.5 – ACC statement. 4th line. Please amend ACC statement to:

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.  
  
If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

* Pg.5 – anticipated that you will not be identified ‘except with your express permission’. The Committee queried what this referred to? The researcher stated it would be very unlikely and was not sure why this was in the PIS. Please clarify with sponsor and remove if incorrect.
* Please add in a cultural statement about tissue use:

You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Maori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However it is acknowledged that individuals have the right to choose.

**Or when GENETIC analysis being done use the following**

You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas, storing your tissue samples and or undertaking genetic analysis on them should be discussed with your family/whanau as appropriate. There are a range of views held by Maori around these issues; some iwi disagree with storage of samples and genetic testing citing whakapapa and advise their people to consult prior to participation in research where this occurs. However it is acknowledged that individuals have the right to choose.

* Pg.2 – please include, in lay language, some basic inclusion and exclusion criteria. Particularly those that may not be in medical records. The Committee suggest adding ‘who can take part in the study’ as a header. See page 28 of the ethics application for some examples.
* Screening on page 3 – about drug and criminal history. What process is in place if participants don’t want to answer these questions in the questionnaire? The researcher explained that nothing in the questionnaire will be compulsory, though it is a condition of entry that they have been an injecting drug user. Committee requested adding a statement saying ‘you don’t need to answer all questions in this questionnaire and you can still participate in the study’. The researcher will clarify with the sponsor and add a statement.
* Add confidentiality clause to the consent form.
* (A.1.6) data won’t be disclosed unless as required by law. Committee queried if it was actually possible for the researchers to maintain confidentiality of participant information, noting that if there is a court case or criminal conduct it could lead to private information being released. This is a risk, particularly with the patient population. Please further explain the chances or circumstances where information would be released for participants so they understand the risks.

Decision

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

* Please amend the separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

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| **3** | **Ethics ref:** | **15/CEN/46** |
|  | Title: | New ways to deliver oxygen to children. |
|  | Principal Investigator: | Dr Stuart R Dalziel |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 April 2015 |

Dr Stuart R Dalziel 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

* The study will recruit 0-12 month old children.
* Committee noted that the application clearly outlines the potential benefits, including treatment benefits as well as cost savings.
* The study aims to generate evidence to lead global treatment of bronchiolitis in children.
* 25-50% of infants with bronchiolitis are exposed to steroids adrenaline and hypertonic saline which have failed to demonstrate effectiveness.
* The study is funded by the NHMRC and emergency medicine foundation.
* 2/3 of participants of children with bronchiolitis will need emergency oxygen and will receive treatment. For those who are not requiring oxygen they will be recruited prospectively with informed consent prior to treatment.
* The Committee commended the researcher for their PIS/CF.

Summary of ethical issues (resolved)

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

* The Committee asked about the two treatments and their current use. Dr Dalziel explained that evidence regarding what one works better lacking. Timing of intervention for treatment vary in practice across New Zealand. There is a lack of consensus on how and when to use the treatment.
* Committee confirmed that study participation was in the best interest of the children who will in some cases require emergency care.
* The Committee queried Fisher and Paykel’s involvement in the study. Dr Dalziel explained that Fisher and Paykel is providing the machines for the study but is not involved in design of the study.
* Committee noted delayed consent, provided that it was emergency treatment in children, was acceptable.
* Committee noted it is the parent who can give consent on behalf of the child, not a caregiver.
* The researcher confirmed that clinical equipoise exists between the two study treatments. There is no evidence that either arm of children would be at a disadvantage for study participation.

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

* Please amend the consent form check boxes to only provide a yes no option if it is truly optional.
* Please note that the participant is the child not the parent, so ‘you participate’ is not correct. Please amend.
* Pg.8 consent form – please add ‘consent form for parent and or legal guardian’ as a header.
* Please amend ACC statement to:

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.  
  
If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

Decision

This application was *approved* by with non-standard conditions for Secretariat to check.

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| **4** | **Ethics ref:** | **15/CEN/47** |
|  | Title: | Risk factors for multi-drug resistant bacterial infections |
|  | Principal Investigator: | Dr Jacqueline Benschop |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 April 2015 |

Dr Jacquie Benschop with co-investigators Zoe Grange and Leah Toombs-Ruane 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

* Study will recruit 700 participants.
* Study aims to demonstrate if multi drug resistant bacterial infections have a relation to family pets in the home.
* Study involves human and animal faecal samples for lab testing. The control group do not provide samples. Instead they will give oral consent to be involved in a questionnaire. The researcher explained that the final question asks if the control participant would then want to be involved in the tissue component of the study. If they are interested they send back their contact information. Following this a PIS/CF can be sent through to them. This PIS/CF outlines the study and includes collection packs for the tissue samples.
* There is also the option for family and friends to participate.

Summary of ethical issues (resolved)

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

* What process will be followed regarding incidental findings? Researcher noted that the GP would be identified. The Committee suggested having a specialist involved to interpret findings. The researchers explained that they will have several microbiologists who will be able to assist, as well as explaining that they will only cultures very specific bacteria.
* The Committee and researchers discussed the informed consent process. Researcher stated for case participants the PIS/CF is sent directly and they decide if they want to participate. However controls initially take part in the verbal questionnaire. At the end of that they are given the choice of participating further. PIS/CF will then be sent out and will be offered the chance to give the PIS/CF to other people in the household.
* What occurs if the other people in the household don’t return the forms? The researchers explained they will not follow up any non-responses from other family members.

Summary of ethical issues (outstanding)

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

* The Committee noted that a tissue bank is a collection of human tissue samples stored for potential use in research beyond the life of a specific research project. All tissue banks require registration with HDEC. Please view chapter 13 of the Standard Operating Procedures for more information on establishing a tissue bank at <http://ethics.health.govt.nz/home>
* If you have questions please contact HDEC secretariat.
* The committee noted that they cannot approve storage of tissue beyond the length of the study unless it is being stored in an established tissue bank. Please explain which tissue bank is being used.
* The committee asked if children will be participants. Researchers explained that they were planning of having children involved in the questionnaire component of the study.
* The Committee noted that there must be an information sheet for children. The Committee noted there is guidance on assent forms found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>
* Please explain how the consent process will work for children in a cover letter response to HDEC.
* The Committee discussed the vet being informed about incidental results. The researchers noted that it was important to inform as best as possible and share information to try and give people the option of discussing results with the vet. The Committee suggested adding information in the PIS on veterinarian being contacted in these cases.
* (P.1.1) the committee confirmed that consent will occur prior to collection of tissue samples (or any study related procedure). Please make it clear to participants that consent will occur prior to collecting samples.
* Please clarify how assent will work in cases of control groups.
* The Committee noted that the future unspecified research patient information sheet needed more information, information included below.

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

* Please explain for participants what an NHI number is and what kind of information will be collected as a result of this.
* Please make it explicit that people will consent for themselves and not that anyone will be consenting for anyone else.
* Please emphasise where the samples are for optional future use and where the samples are not mandatory for study participation. A side heading which states ‘the following is optional’.
* Please add some basic lay language inclusion and exclusion criteria at the beginning of the PIS. Primarily exclusion criteria.
* Please amend ACC statement to:

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.  
  
If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

* Committee notes identifiable health information requires stored by minimum of 10 years.
* Please add Maori contact details for cultural consultation and support.
* Amend yes/no tickboxes. Only have the options if these are truly optional. Committee suggests bullet pointing the first section of tickboxes. Leave options for final 6.
* For the separate future unspecified research document please include more information – the HDEC template. Below are the requirements that must be included in FUR PIS/CF:

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| **Future Unspecified Research (FUR) and Biobanking \*note these are requirements for FUR** |
| * an indication of the type and nature of the research to be carried out and its implications for the donor, where possible, and an explanation of why the potential donor is being approached for their tissue and specifically what tissue is being sought. |
| * known possible researchers or institutions that might use the tissue sample, if possible. |
| * whether the donor’s sample is going to be, or is likely to be sent overseas, and where possible, to what country or countries. |
| * acknowledgement that all future unspecified research in New Zealand will be subject to ethical review. However, when a tissue sample is sent overseas, unless it is sent in conjunction with a New Zealand research project, future research is likely to be considered by an overseas ethics committee without New Zealand representation. |
| * whether the donor’s identity and details will remain linked with the sample or whether the sample will be de-linked. |
| * a statement that if a donor consents to a tissue sample being unidentified or de-linked, they relinquish their right to withdraw consent in the future. |
| * whether the donor may be contacted in the future regarding their tissue sample. Whether or not, and under what circumstances, information about the future unspecified research will be made available to the donor and/or (where relevant) their clinician. |
| * acknowledgement that the donor will not own any intellectual * property that may arise from any future research. |
| * whether there is provision to withdraw consent for the use of human tissue samples in the future. Where there is provision to withdraw consent, only tissue samples remaining at the time of a request to withdraw and any information held for future unspecified research may practically be withdrawn. Tissue samples or information used in research before the request to withdraw is received is unlikely to be able to be returned or * destroyed. |
| * acknowledgement that the donor’s decision regarding the consent for use of their tissue sample for unspecified future research will in no way affect the quality of a donor’s current or future clinical care. |
| * where and for how long a tissue sample will be stored, how it will be disposed of and whether there is a cultural protocol for its disposal. For example, information about the institution holding the tissue sample: its aims, research procedures and research governance. |
| * whether or not tissue samples could be provided to other researchers and institutions, and whether or not such provision could include sending samples to other countries |
| * whether or not collected samples will be provided to commercial biomedical companies or will be used in commercial research collaborations, if known. |
| * what provisions will be made to ensure patient confidentiality. |
| * that different cultural views may inform choice about donation of tissue; for example, for some Maori, human tissue contains genetic material that is considered to be collectively owned by whanau, hapu and iwi. |
| * that cultural concerns may arise when tissue samples are sent overseas, including how tissue samples are stored and disposed of. Processes for monitoring and tracking what happens to samples may not be acceptable to donors. |
| * that donors may want to discuss the issue of donation with those close to them, for example; family, whanau, hapu and iwi. |
| **Note:** FUR must be listed as OPTIONAL and must be **distinct** from the main study – this can either be a separate PIS (if there is substantial information that warrants it) or it can be a separate consent area on the consent form (if the additional tests are optional but not that different from the primary study).   * HDEC has a preference for separate PIS/CF for optional sub studies, FUR or bio banking as the information required is often different to the main study. * For more information see the Guidelines for Future Unspecified Research <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> |

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Clarify whether a tissue bank would be established to store tissue beyond length of the study. *(Standard Operating Procedures, Chapter 13).*
* Please provide an assent form for non-consenting participants to sign (*Ethical Guidelines for Observation Studies 6.21)*

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

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| **5** | **Ethics ref:** | **15/CEN/48** |
|  | Title: | Modafinil 100 mg bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Southern Cross Pharma Pty Ltd |
|  | Clock Start Date: | 16 April 2015 |

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

Potential conflicts of interest

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

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

Summary of Study

* The study investigates bioequivalence of study drug under fasting conditions.

Summary of ethical issues (resolved)

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

* The Committee queried whether it was essential to declare all medical illnesses that participants have had. The Committee noted this should be more specific. The researchers explained that the process is that participants do go through their medical history with the consenting researcher and make sure it is safe for participants to take part.
* Researchers confirmed a mouth test to confirm study drug has been taken is international standard practice.
* Confidentiality of records – is there information on informing the GP about trial participation? The researcher confirmed there is.
* Please explain the role of the reserves? The researchers explained that these participants go through the screening but will not necessarily be involved in the full study and are used to fill in for any participants who drop out.
* P.4.1 - Committee queried if there is any information or data about Maori and prevalence of the disease in Maori. If there are no statistics you can state that.
* P.4.2 is answered well.

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

* Pg.10 – sentence drops off – please amend. Add ‘an HIV test’.
* The committee queried ‘and/or HIV’. Please amend to only state ‘and’.
* The committee queried what relevance was of what the definition of a standard drink (of alcohol) was. Researchers explained that this is to identify dependency on alcohol. The Committee requested that information on why these questions were being asked was included in the PIS.
* Amend ‘you are a woman and you are not pregnant’ to ‘if you are a woman’.
* ‘Confinement period’ – please note that there is no right to detain people – please amend to ‘treatment period’.
* Please change ‘you are required not to leave’ from ‘you are not allowed to leave’.
* Pg.9 – ‘any misbehaviour’. Please amend to non-compliance with study rules.
* Pg.4 ‘if there are no alternative forms of treatment’ – please remove or add ‘future treatment’ as these are healthy volunteers.

Decision

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

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

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

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| **6** | **Ethics ref:** | **15/CEN/50** |
|  | Title: | Maxigesic® Oral Suspension PK-PD Study |
|  | Principal Investigator: | Prof Brian J Anderson |
|  | Sponsor: | AFT Pharmaceuticals Ltd |
|  | Clock Start Date: | 16 April 2015 |

Dr Hartley Aitkinson 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

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

* Study will recruit 200 children from 2 – 12 years old.

Summary of ethical issues (resolved)

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

* The Committee requested justification of the age range with respect to younger populations.
* Dr Aitkinson explained that the drug which is being developed would be used in children as young as 2, once shown to be safe and effective. The study therefore needs to be tested in this age group. While efficacy can be transferred from adult to children the regulator will not accept information on tolerability and pharmacokinetic differences without testing in the age group, so it must be studied in the specified age range.
* (R.3.9) researcher confirmed there is no future unspecified research.
* The Committee asked if there has been research with the study drug in children. Dr Aitkinson explained there have been prior studies that generated efficacy and safety data. The age range was 2-12 year olds. Earlier study information is not included in the information brochure.
* Dr Aitkinson noted that assent forms were provided for those that were competent to provide assent.
* The Committee asked if there were any significant differences in pharmacokinetics across the age groups. Dr Aitkinson explained there was a lack of data which meant it did not show any difference, but acknowledged data was quite limited.
* Dr Aitkinson confirmed that PIS/CF is given at an early consultation – the participants will have plenty of time to consider study participation.
* (P.2.1) states ‘informed consent will be taken on or before day of surgery’. Dr Aitkinson explained that it will not be on day of surgery.
* Dr Aitkinson noted the possibility that participants may have the PIS for some time prior to the day of surgery though may bring the signed consent form back on day of surgery. Committee noted that generally the PIS should be signed in front of CI.
* (R.4.1) The Committee asked if there was any risk of study producing incidental results? Committee noted one sample will test for hep c, and HIV. Please explain reason for testing this in children? Dr Aitkinson noted that the testing group (lab) would not test the samples without having a tested guarantee that the samples did not have HIV. This was a safety precaution.
* Dr Aitkinson confirmed that there are no additional blood draws.

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

* Assent form: between ages 7-12. Researcher confirmed. The committee requested changing ‘why do we need your help’ to ‘why are we doing the study’. Amend ‘special medicine’ – please delete the word “special”.
* Please include some basic, lay language exclusion criteria for participants.
* The Committee requested information in the patient information sheet, regarding tissue samples going overseas. Where it is going etc.
* Please remove yes no options from the consent form if the statement is not truly optional.
* The heading should be ‘assent’ rather than ‘consent’ for the child form.
* The Committee noted that child could consent in some cases.
* Make it clear that a 7 year old, in most cases, cannot give legal consent.
* Inconsistent use of ‘your child’ – please review for consistency.
* Pg.4 queried use of ‘proper’ treatment – please remove and add ‘appropriate’.
* Please move confidentiality info on page 1 rather than 4.
* The Committee noted that the diary completion should be clarified in the PIS. Currently suggested that diary completion is required every 2 hours for longer than just the first day.
* Would the children have the IV line in for 6 hours in normal standard of care? Dr Aitkinson explained that it was up to 6 hours. Committee noted that for study it is a minimum of 6 hours, so please add this in the information sheet, as this potentially differs from standard care.
* Dr Aitkinson added it was a normal peripheral IV access line. Please amend this in the information sheet as currently it is misleading referring to an “internal venous line”
* The Committee noted there was a small chance of identifying HIV, or hepatitis. Please include what happens if it were to be identified for participants in the PIS.

Decision

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

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

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

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| **7** | **Ethics ref:** | **15/CEN/51** |
|  | Title: | Can one month of Blis K12 lessen Group A Streptococcal carriage and infection? |
|  | Principal Investigator: | Dr John Malcolm |
|  | Sponsor: | Eastern Bay Primary Health Alliance |
|  | Clock Start Date: | 16 April 2015 |

Dr John Malcom was present in person and by Dr Pareake O’Brien, Sandra Ball, Maud Takarua

And Michelle 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 Study

* The study will involve offering a probiotic (BLIS K12) over a 1 month course of treatment to primary school children in Whakatane. Three schools will be involved.
* The goal of the study is to reduce levels of strep throat which in turn may reduce instances of rheumatic fever.
* Two schools start at same time with one school starts a month later.
* We will compare between the staggered control group and the two groups that start together.
* Study will involve taking tissue samples which may identify strep throat. The researchers will then provide 10 days of antibiotics in these events.

Summary of ethical issues (resolved)

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

* The researchers confirmed there was information on withdrawing from the study (pg.2).
* The Committee queried who pays for the BLIS? The researchers responded - Eastern bays innovation fund.
* (R.1.2.1.1) can you link swab results? Researchers confirmed swabs will be linked to NHI.
* Committee noted the application should be proof read prior to submission.

Summary of ethical issues (outstanding)

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

* Please provide assent forms, and younger person consent forms and patient information sheets. The Committee noted that there must be an information sheet for children. The Committee noted there is guidance on assent forms found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>

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

* The researchers explained that 5-10 year olds who will have written consent provided by the parents. The Committee noted that a child’s grandfather, grandmother or caregiver can’t give consent for research. The committee requires legal guardianship, not just to live with them. Amend patient information form to state legal guardian.
* The Committee noted that the current PIS was lacking important information. Please view <http://ethics.health.govt.nz/home> and view the patient information sheet template on the right hand side of the screen, under quick links.
* Please add some basic exclusion criteria in the patient information form.
* Please add ACC statement to:

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

* Please add version, date, footer etc.

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Please provide an assent form for non-consenting participants to sign (*Ethical Guidelines for Observation Studies 6.21)*

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

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **15/CEN/52** |
|  | Title: | Paediatric Perianaesthesia Questionnaire validation in New Zealand |
|  | Principal Investigator: | Dr Victor Birioukov |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 April 2015 |

Ellen Weymouth and Elsa X 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

* The study aims to validate the Paediatric Perianaesthesia Questionnaire (PPQ) by repeating the German study protocol to see whether it can be transferred for use in New Zealand.
* 1000 participants.

Summary of ethical issues (resolved)

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

* The researchers noted possible harm from bringing back memories or stress from questionnaires, adding that the participants are children.
* Researchers explained that for each child and or adult only one questionnaire will be filled out.
* The Committee questioned whether it was appropriate to have a separate questionnaire for child, one for adult parent. The researchers explained that they were going to use the German protocol to test the acceptability in New Zealand populations, so only one questionnaire was to be used.
* Please explain how the questionnaire will be validated. The researchers explained that researchers who develop questionnaires have been consulted on how the questionnaire can be validated. They advised that they should start with the German template, apply it to NZ patient population and then review and compare these results against the German results. If there are large discrepancies we will need to start from the beginning, including focus groups and development of a new questionnaire.

Summary of ethical issues (outstanding)

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

* The Committee asked for more information on the consent process, noting some of the younger participants may be able to provide informed consent. Furthermore there should be assent forms that are age appropriate.
* Please provide assent forms, and younger person consent forms and patient information sheets. The Committee noted that there must be an information sheet for children. The Committee noted there is guidance on assent forms found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>
* Please explain who the participant is – the child or the adult? Researchers explained that would ideally have perspective of the child however parent involvement is generally required in all cases. The committee noted that this suggested that the parent would be a participant as well; please provide a consent form / information sheet for them too. Researchers were agreeable.
* The Committee noted that parents and legal guardians can legally give consent on behalf of a person under 16 who is not competent to consent for themselves. The child must provide assent too. The parents should give consent for their own involvement too. In some cases the child may be competent to provide informed consent themselves.

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

* (F.2.1) main exclusion criteria. Please include the first two in the PIS/CF.
* Add confidentiality statement. See HDEC template PIS/CF for examples at <http://ethics.health.govt.nz/home>
* Please add ACC statement to:

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

* Amend child to young people.
* (R.2.2) what patient information will the researchers be accessing? The researchers responded that it was whether any missing health information could not be recalled, such as prior surgeries. Also health information screening it will be used to ensure participants meet the inclusion exclusion criteria. Please include what kind of information will be disclosed in the PIS.

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Please provide an assent form for non-consenting participants to sign (*Ethical Guidelines for Observation Studies 6.21)*

This following information will be reviewed, and a final decision made on the application, by Mrs Gael Donoghue 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:** | 26 May 2015, 08:00 AM |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington , 6011 |

The following members tendered apologies for this meeting.

Dr Patries Herst.

1. **Problem with Last Minutes**

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

The meeting closed at 4.30pm