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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 01 February 2018 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 11:30 | Welcome |
| 11:35 | Confirmation of minutes of meeting of 5 December 2017. |
| 11:45 | New applications (see over for details) |
|  | i 17/STH/249  ii 17/STH/252  iii 18/STH/1  iv 18/STH/3  v 18/STH/4  vi 18/STH/8  vii 18/STH/9  viii 18/STH/10  ix 18/STH/11  x 18/STH/13  xi 18/STH/14  xii 18/STH/15 |
| 4:45pm | General business:   * Noting section of agenda |
| 5pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 27/10/2015 | 27/10/2018 | Present |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Nicola Swain | Non-lay (observational studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Fiona McCrimmon | Lay (the law) | 27/10/2015 | 27/10/2018 | Present |
| Dr Anna Paris | Lay (other) | 24/08/2017 | 24/08/2020 | Present |

## Welcome

The Chair opened the meeting at 11:30am 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 5 December 2017 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **17/STH/249** |
|  | Title: | The Appraisal of Sense of Self in People Experiencing Psychological Difficulties |
|  | Principal Investigator: | Prof. Martin J Dorahy |
|  | Sponsor: |  |
|  | Clock Start Date: | 18 January 2018 |

Prof. Martin J Dorahy and Ms Brooke Johnson were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study will observe memory and self-concept in people on the psychotic spectrum, specifically the study involves looking for disruption in these areas.

Summary of ethical issues (resolved)

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

1. The Committee noted that the researchers had responded to the outstanding issues in the decline letter for their previous application.
2. The Committee queried if the control group information sheet and consent had already been used to recruit participants. The researchers confirmed that it had and that the form had been approved by a different ethics committee.

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

1. Please check the information sheet and consent form for consistent use of first or second person.

Decision

This application was *approved* *with a non-standard condition* by consensus. The non-standard condition for this study is:

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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| **2** | **Ethics ref:** | **17/STH/252** |
|  | Title: | Continuous Glucose Monitoring improves glycaemic control and quality of life in children with Type 1 Diabetes Mellitus |
|  | Principal Investigator: | Dr Karen Mackenzie |
|  | Sponsor: |  |
|  | Clock Start Date: | 18 January 2018 |

Dr Elizabeth Anderson was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates whether continuous glucose monitoring improves glycaemic control and quality of life in children with type 1 diabetes.

Summary of ethical issues (resolved)

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

1. The Committee queried how and where data would be stored. The researcher explained that data would be securely stored in their department at CDHB as per department protocols.
2. The Committee queried who would complete the survey or questionnaires for the study. The researcher explained that this would be parents unless the children were judged as able to complete the surveys themselves.

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

1. Explain that all information will be securely held in the unit according to the unit’s security and privacy protocols.
2. Explain that the ‘you’ in the information sheet refers either to adolescents able to provide their own informed consent or the parent or legal guardian of the child.
3. Add a space for parents to sign the consent form.
4. .Remove the sentence ‘Tick to indicate your consent’ from the consent form.
5. Please check the titles of all information, consent, and assent forms.
6. Explain that all data will be held for 10 years after participants turn 16 as required by NZ law.
7. Please amend the title to be less leading as the current one implies an expected finding.

Decision

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

* 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*).
* All health information created or recorded in this study must be retained for ten years after participants reach the age of 16. Please amend the protocol data storage section to reflect this. *Health (Retention of Health Information) Regulations 1996*

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| **3** | **Ethics ref:** | **18/STH/1** |
|  | Title: | Identification and intervention in patients at high risk of re-admission with a diagnosis of asthma using Smartinhaler technology |
|  | Principal Investigator: | Dr Jeffrey Garrett |
|  | Sponsor: | Counties Maukau Health Research |
|  | Clock Start Date: | 18 January 2018 |

Dr Jeffrey Garrett was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates whether there is evidence of improved adherence and earlier intervention using smartinhaler technology with patients who are at high risk of re-admission with a diagnosis of asthma.

Summary of ethical issues (resolved)

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

1. The Committee queried who designed and initiated the study. The Researcher explained that they did and that the producer of the smartinhaler, Adherium, did not play a role in this.
2. The Committee queried if Adherium were providing funding or remuneration to the researchers or if the company would control the results and publication of the study. The Researcher stated that they were not receiving any benefits from the manufacturer and that the manufacturer would not control any element of the publication or data analysis.
3. The Committee noted that there would be Adherium technical advisors available during study procedures but these advisors would be there only when called to provide technical assistance with the smartinhaler device if necessary.
4. The Committee resolved that the study is not a commercially sponsored intervention study that is conducted primarily for the benefit of the manufacturer and participants would therefore be eligible to apply for ACC compensation.
5. The Committee noted that data from smartinhaler use would be stored in Adherium’s cloud storage. The researcher explained that this is part of the agreement that smartinhaler user agree to when using the device as part of care and is not to do with the study.
6. The Committee asked if the Researcher would be linking any study data with information stored with the device manufacturer. The researcher stated that they would not.
7. The Committee noted that there was a large sample size for a feasibility study. The researcher explained that this is the number required to show that compliance was improved and that the feasibility aspect relates to determining the sample size needed for a larger trial.

Summary of ethical issues (outstanding)

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

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

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

1. Please bold the section that begins “If your asthma worsens…”
2. Please add a footer with the version number, date, ethics approval number, and page numbers.
3. Please explain that data collected in this project will not be shared and provide any terms of use for the data in lay-friendly terms.
4. Please remove tickboxes from the consent form for all items that are not 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 following information will be reviewed, and a final decision made on the application, by Dr Nicola Swain and Dr Anna Paris.

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| **4** | **Ethics ref:** | **18/STH/3** |
|  | Title: | KidCOM study |
|  | Principal Investigator: | Dr William Wong |
|  | Sponsor: | Hospital for Sick Children |
|  | Clock Start Date: | 15 January 2018 |

Dr William Wong was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This project involves the contribution of a patient’s data to an overseas international registry for their condition.
2. By contributing data and blood samples to the registry then more extensive testing will be possible.

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 if the registry was already established and running. The researcher confirmed that this was the case.
2. The Committee noted that the project was relatively low risk.

Summary of ethical issues (outstanding)

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

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

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

1. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*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 Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
2. Remove reference to printed witness as this is not applicable under New Zealand law.
3. Please check that New Zealand researchers and other required contact details are on the information sheets. The other required details can be found at the end of the HDEC PIS template. All contact details should be at the end of the form.
4. Add New Zealand to the list of countries where the trial is being run.
5. Please add a lay-friendly title.
6. Please check that the language in the ICF is localised to New Zealand English.

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by Associate Professor Mira Harrison-Woolrych and Dr Fiona McCrimmon.

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| **5** | **Ethics ref:** | **18/STH/14** |
|  | Title: | Lithium and Fampridine EEG |
|  | Principal Investigator: | Professor Paul Glue |
|  | Sponsor: |  |
|  | Clock Start Date: | 18 January 2018 |

Professor Paul Glue was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the effects of Lithium and Fampridine on Electroencephalography Profiles in Healthy Volunteers.

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 stated that there was significant information missing from the study protocol. This includes:
   * the justification for the doses selected (for example, 20 mg qd fampridine when dosing recommendation for patients are 10mg bid) and evidence of safety of repeat dosing at the intended dose levels
   * the justification for administering lithium in the fasted state, where datasheets recommend dosing in the fed state to reduce nausea
   * the detail regarding intended dosage (tablet size, number and blinding procedures)
   * the justification for the observation period post dose, noting that the observation period ends prior to anticipated tmax/cmax of one of the medications under study
   * adequate screening assessments (renal function, ful blood count, electrocardiograms, urinalysis or justification for why this is not required…)
   * adequate safety monitoring (as per previous point)
   * exclusion criteria to explicitly exclude conditions in which lithium or fampridine administration is contra-indicated
   * exclusion criteria to explicitly exclude concomitant administration of medications with which lithium or fampridine is contra-indicated.

The Committee stated that the above will need to addressed on resubmission. (*Ethical Guidelines for Intervention Studies* *Appendix 1,* *para 3.10, 3.11, & 5.41*)

1. Please provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*
2. Please provide evidence of favourable independent peer review of the study protocol *(Ethical Guidelines for Intervention Studies Appendix 1)*
3. 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*).
4. The Committee stated that they were not convinced that the researcher had justified exposing healthy volunteers to lithium, a drug with the potential for severe side effects, for the duration of the study. (*Ethical Guidelines for Intervention Studies* *paras 3.10 & 3.11*).

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

1. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *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.”*
2. Please explain what lifestyle restrictions participants will have to make.
3. Please explain what safety procedures are in place for the study.
4. Please explain in lay terms the risks of each medication, including rare but potentially serious risks.
5. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*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 Māori 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.”*
6. Please include reproductive risks and what methods of contraception are appropriate for participants.

Decision

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

* Please clarify and amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please provide evidence of favourable independent peer review of the study protocol (Ethical Guidelines for Intervention Studies Appendix 1)
* Please justify the study design in terms of risk to participants versus the lack of potential benefits. (*Ethical Guidelines for Intervention Studies* *paras 3.10 & 3.11*).

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| **6** | **Ethics ref:** | **18/STH/15** |
|  | Title: | POLARIX |
|  | Principal Investigator: | Dr Peter Ganly |
|  | Sponsor: | Covance New Zealand |
|  | Clock Start Date: | 18 January 2018 |

Ms Helen McDermott was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is a Phase lll, multicenter, randomized, double-blind,placebo-controlled trial comparing the efficacy and safety of Polatuzumab Vedotin in combination with Rituximab and CHP (R-CHP) versus Rituximab and CHOP (R-CHOP) in previously untreated patients with diffuse large b-cell lymphoma.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. Please ensure that whole genome sequencing is optional for participants. The study protocol notes that this may be made optional at the request of the reviewing body. The Committee were concerned that there was a risk of coercion for participants in this area as the project is therapeutic. (*Ethical Guidelines for Intervention Studies* *para 6.7*).
3. Please clarify if participants would have to pursue any compensation claims against the study sponsor in New Zealand or overseas. HDECs do not support the requirement that these claims be pursued overseas. (*Ethical Guidelines for Intervention Studies* *para 4.5*).

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

1. Please add more detailed information on contraception. A template for this can be obtained from the HDEC secretariat.
2. Please check the formatting of footers as they currently match that of body text and run into each other.
3. Please add a consent section for parents consenting for access of their infant’s information.
4. Amend the information sheet to explain that whole genome sequencing is optional and the associated risks or benefits to this.
5. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*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 Māori 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.”*

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please ensure that whole genome sequencing is optional for participants. (*Ethical Guidelines for Intervention Studies* *para 6.7*).
* Please clarify if participants would have to pursue any compensation claims against the study sponsor in New Zealand or overseas. (*Ethical Guidelines for Intervention Studies* *para 4.5*)

This following information will be reviewed, and a final decision made on the application, by Dr Sarah Gunningham and Dr Anna Paris.

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| **7** | **Ethics ref:** | **18/STH/9** |
|  | Title: | Listening Effort in Children with CI |
|  | Principal Investigator: | Prof Suzanne Purdy |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 18 January 2018 |

Professor Suzanne Purdy was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the feasibility of using a listening effort assessment protocol designed for adults with cochlear implants in a population of children.

Summary of ethical issues (resolved)

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

1. The Committee noted that data associated with this study should be stored for 10 years after the youngest participant has turned 16, as per New Zealand law, not 6 years as stated in the protocol. The Researchers agreed to amend this.
2. The Committee noted the high quality of the information sheet and consent form.

Decision

This application was *approved* by consensus.

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| **8** | **Ethics ref:** | **18/STH/10** |
|  | Title: | A Comparative Outcome Study Using Tranexamic Acid in Arthroscopic Medial Meniscectomy |
|  | Principal Investigator: | Professor Gary Hooper |
|  | Sponsor: |  |
|  | Clock Start Date: | 18 January 2018 |

Dr Michael Douglas was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates if Tranexamic Acid improves short term results and patient satisfaction after arthroscopic knee meniscectomies.

Summary of ethical issues (resolved)

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

1. The Committee noted that the population would likely be elderly and that those with a history of thrombosis would be excluded.

Summary of ethical issues (outstanding)

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

1. Please add women who are on the oral contraceptive pill as an exclusion criteria in order to ensure their safety. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
2. The Committee stated that participants should have the opportunity to take the information sheets home to discuss with their family. (*Ethical Guidelines for Intervention Studies* *para 6.8*)
3. The Committee stated that researchers should not be making the initial research approach as this could be considered coercive. Please have independent staff make the initial approach asking if patients want to discuss participating. (*Ethical Guidelines for Intervention Studies* *para 6.8*)
4. 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*).

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

1. Explain the exclusion criteria (including a history of thrombosis) in lay terms.
2. Add a header and footer with relevant information.
3. Add page numbers
4. Remove yes/no tickboxes except for those items where indicating no would not exclude someone from participation.
5. Add the details of the approving HDEC and HDEC reference number
6. Check the information sheet and consent form for typographical errors and grammar.
7. Please explain thrombotic risk in lay terms e.g. signs and symptoms of deep vein thrombosis or pulmonary embolism.
8. Please remove the word ‘welcome’
9. Please explain that TXA is safe.
10. Check for use of medical jargon and replace with lay-friendly terms. E.g. debride is not lay friendly.
11. Please use a lay-friendly title
12. Please state that the project is a pilot study and what this means.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *paras 5.41 and 6.8*)

This following information will be reviewed, and a final decision made on the application, by Associate Professor Mira Harrison-Woolrych and Dr Fiona McCrimmon.

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| **9** | **Ethics ref:** | **18/STH/11** |
|  | Title: | Symptom Burden when going through a Stem Cell Transplant and perception of Specialist Paediatric Palliative Care by children and families. |
|  | Principal Investigator: | Dr Amanda Evans |
|  | Sponsor: |  |
|  | Clock Start Date: | 18 January 2018 |

Dr Amanda Evans was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study will explore the experience of symptoms (physical - eg nausea, pain, loss of appetite, psychosocial eg anxiety, depression and spiritual) in all children who received a Stem Cell Transplant at the National Allogenic Transplant Centre at Starship Children's Hospital between January 2013 and August 2018.

Summary of ethical issues (resolved)

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

1. The Committee stated that participants who are under 16 but have the capacity to provide informed consent must be given the opportunity to do so. The Researcher agreed to this.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

1. Substitute a more lay-friendly term than palliative. The Committee stated that this term is liable to be misinterpreted and could cause distress.
2. Remove the statement “can anything bad come from this study…” and simpy state that there will be no blood tests.

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 Devonie Waaka and Dr Anna Paris.

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| **10** | **Ethics ref:** | **18/STH/13** |
|  | Title: | Families at Risk: Mechanisms for Change |
|  | Principal Investigator: | Ms Sarah Whitcombe-Dobbs |
|  | Sponsor: | University of Canterbury |
|  | Clock Start Date: | 18 January 2018 |

Ms Sarah Whitcombe-Dobbs was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates some psychological characteristics of parents that are associated with change over a six month period.
2. Participants are parents of children who have ongoing involvement with the child protection agency, who retain custody of their children.

Summary of ethical issues (resolved)

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

1. The Committee noted that the project had already commenced and that any approval will only apply to study procedures and documents submitted with the application and conducted after the date of final approval.
2. The Committee noted that there is a safety plan in place for the coordinating investigator.
3. The Committee asked how the potential for whakamā would be managed. The Researcher stated that they will be using culturally responsive practice and have sought Māori consultation for their project.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

1. The Committee suggested the researcher use the HDEC information sheet and consent form templates from the HDEC website.
2. Please provide a better explanation of why participants are being approached and the aim of the study.
3. Substitute references to Child Youth and Family Services (CYFS) to Oranga Tamariki (MVCOT)
4. Add the HDEC reference number and sate the approving HDEC.
5. Remove the statement that a thesis is a public document or explain what this means in lay-friendly terms.
6. The Committee suggested that headings be used to break up the body text of the information sheet.
7. Please provide a better explanation of study procedures that states when, what, and how long study processes go on for.
8. Please resolve contradictory information around data confidentiality.
9. Explain what type of information will be released from MVCOT
10. Explain that participants can have a support person if necessary.
11. Explain what form data will be stored in, how it will be stored, and how long. For example that all health information must be stored for ten years per New Zealand law.

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 Observational Studies para 6.10)*

This following information will be reviewed, and a final decision made on the application, by Associate Professor Mira Harrison-Woolrych and Ms Raewyn Idoine.

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| **11** | **Ethics ref:** | **18/STH/4** |
|  | Title: | AROHBV1001: A study of ARO-HBV in healthy volunteers and HBV Patients |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Arrowhead Pharmaceuticals Inc |
|  | Clock Start Date: | 18 January 2018 |

Prof Edward Gane was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is a phase 1/2a Single Dose-Escalating Study to Evaluate the Safety, Tolerability and Pharmacokinetic Effects of ARO-HBV in Normal Adult Volunteers and Multiple Escalating Doses Evaluating Safety, Tolerability and Pharmacodynamic Effects in HBV Patients

Summary of ethical issues (resolved)

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

1. The Committee queried if part B of the study is therapeutic. The researcher explained that while the second part of the study may produce some benefit this will not be curative and will not last after the end of the study.
2. The Committee asked if participation in this study would limit participants enrolling in other HBV therapeutic trials. The researcher stated that it would not.

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

1. Add an explanation that part B of the project is not curative but may provide benefit for the duration of the study.
2. Please consider adding the HDEC standard contraception wording.
3. Please add the option for parents to consent for the use of their child’s health information after delivery.

Decision

This application was *approved* *with non-standard conditions* by consensus. The non-standard condition for this study is:

* 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*).

|  |  |  |
| --- | --- | --- |
| **12** | **Ethics ref:** | **18/STH/8** |
|  | Title: | A first in human study of single and multiple doses of JNJ-440 |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 18 January 2018 |

Prof Edward Gane was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is a Multi-part Phase 1, Double-Blind, Randomized, Placebo-Controlled, First in Human, Study of Orally Administered JNJ440 to Evaluate the Safety, Tolerability, and Pharmacokinetics after Single Ascending Doses Including Food Effect Evaluation (Part 1); after Multi Day Dosing (Part 2) in Healthy Subjects; and after Multiple (Ascending) Doses in Subjects with Chronic Hepatitis B (Part 3).

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

1. Please space out items in the information sheet to help readability.
2. Please increase the font size in the consent form
3. Please amend the statement on page 13 of the ICF to explain that Hep B patients should not donate blood.
4. Please consider adding the HDEC standard contraception wording.

Decision

This application was *approved with non-standard conditions* by consensus. The non-standard for this study is:

* 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*).

## 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:** | 13 February 2018, 08:00 AM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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 5pm.