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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 29 January 2019 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 11:00am | Welcome |
| 11:05 | General business:   * Confirmation of minutes of meeting of 11 December 2018 * Noting section |
| 11:30 | New applications (see over for details) |
|  | i 19/STH/4  ii 19/STH/1  iii 19/STH/5  iv 19/STH/3  v 19/STH/6 **(Closed)**  vi 19/STH/8  vii 19/STH/10  viii 19/STH/11  ix 19/STH/12  x 19/STH/18  xi 19/STH/22  xii 19/STH/23 |
|  | Substantial amendments (see over for details) |
|  | OTA/95/10/113/AM14 |
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| 4:30pm | 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 |  |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |  |
| Dr Paul Chin | Non-lay (intervention studies) | 27/10/2018 | 27/10/2021 | Apologies |  |
| Professor Jean Hay-Smith | Non-lay (health/disability service provision) | 31/10/2018 | 31/10/2021 | Present |  |

## Welcome

The Chair opened the meeting at 11:00am and welcomed Committee members, noting that apologies had been received from Dr Paul Chin.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mrs Helen Walker confirmed her eligibility, and was co-opted by the Chair as a member of the Committee for the duration of the meeting.

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 11 December 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **19/STH/4** |  |
|  | Title: | KCAD Psych Study |  |
|  | Principal Investigator: | Dr Chanel Prestidge |  |
|  | Sponsor: | The Children's Hospital at Westmead |  |
|  | Clock Start Date: | 14 December 2018 |  |

No researcher 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 Study

This is a longitudinal study looking at educational, behavioural, and cognitive outcomes in children and adolescents with chronic kidney disease.

Summary of resolved ethical issues

1. The Committee commended the provision of multiple patient information sheets of differing levels of complexity, and parents being given the capacity to select the form best suited to their child.

Summary of outstanding ethical issues

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

1. The Committee noted inconsistencies across the application, protocol, and PIS, relating to the age of study participants (*Ethical Guidelines for Observational Research* paragraph 5.11) at enrolment, and the duration of follow-up.
2. The Committee noted that the protocol cites the age of consent as 18, whereas the age of consent in New Zealand is 16. It was also noted that participants under the age of 16 years can provide their own informed consent, if it is considered that they are competent to do so.
3. The Committee noted that participants unable to provide informed consent must be assented for each year that they will be involved in the study. (*Ethical Guidelines for Observational Studies* section 6).
4. The Committee noted an inconsistency between the application (n = 200) and protocol (sample size justification n = 170)l about the population size of the study (*Ethical Guidelines for Observational Studies* paragraph 5.11).
5. The Committee observed that the application indicated that no interviews or questionnaires would be involved in this study, and that no such documents had been submitted for review. However, the PIS makes repeated mention of participants’ requirement to answer questionnaires (*Standard Operating Procedures* paragraph 42.4.6).
6. The Committee observed that R.4.1.1 of the application form states that unexpected clinically significant findings may arise during the study, but does not outline how the findings will be communicated / managed.

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

1. Please use the HDEC template for the adult PIS/CF, as the current version uses an Australian template with references to Australian localities; this will include an ACC statement which is missing from the submitted PIS.
2. Please remove reference to the ‘Wealth and Health’ study.
3. .Please amend the adult PIS/CF so that it uses lay-language (for example, the researcher should replace the term ‘cognitive’ with a lay-friendly term or explain the term clearly).
4. Please make clear whose participation is being referred to in the adult PIS/CF; the parent and/or the child.
5. Please communicate in the assent forms that this study will interview children’s parents / caregivers as well.
6. Please fix spelling and grammatical errors in the assent forms.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (*Ethical Guidelines for Observational Studies* paragraph 6.10).
* Please address inconsistencies relating to both the age of study participants and the size of the participant population in the study’s documentation (*Ethical Guidelines for Observational Studies* paragraph 5.11).
* Please amend the protocol to reflect the age of consent in New Zealand, which is 16 (*Ethical Guidelines for Observational Studies* section 6).
* If your study will involve interviews or questionnaires, please provide these to the Committee for review (*Ethical Guidelines for Observational Studies* paragraph5.11).
* Please clarify how unexpected clinically significant findings that arise during the study will be communicated to participants and appropriately managed.

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| **2** | **Ethics ref:** | **19/STH/1** |  |
|  | Title: | Assessment of two insulin pump insulin delivery systems in type 1 diabetes. |  |
|  | Principal Investigator: | Dr Martin de Bock |  |
|  | Sponsor: | N/A |  |
|  | Clock Start Date: | 17 January 2019 |  |

Dr Martin de Bock 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.

Dr Devonie Waaka declared a conflict of interest with the Christchurch Clinical Studies Trust. The Committee allowed Dr Waaka to remain present for discussion of the application in a researcher capacity only.

Summary of Study

This study aims to see how well a new algorithm controls blood glucose levels in Type 1 Diabetes. Two different algorithms will be compared as applied to the MiniMed 670G 4.0 insulin pump.

Summary of resolved ethical issues

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

1. The Committee queried whether the 80 year-old participants would be based at home during the course of the study. The researcher confirmed that this would be a home-based study for this participant group.
2. The Committee queried why no PIS/CF had been submitted for participants at the Dunedin locality. The researcher responded that only the CCST (lead site) PIS/CF was submitted as per the HDEC Standard Operating Procedures, and that an appropriately localised version of the approved document would be used for Dunedin participants.
3. The Committee noted that the Investigator will work in partnership with Medtronic but that the Investigator designed the study and will retain the right to independently publish study results. The Investigator therefore does not believe the study meets criteria for being labelled a commercial study. The Committee will seek advice on the definition of ‘investigator-led’ research for these types of studies going forward.
4. The Committee asked for justification of the inclusion of children in this study. The researcher answered that the mean of age of people diagnosed with type 1 diabetes is 8, and that by excluding children in data this creates unequal access to this technology. The Committee queried whether this was a suitable stage in the research for children to be included, and the researcher responded that children have been included in close-loop studies for the past ten years.
5. The Committee asked how participants would be recruited into this study. The researcher answered that interest would be registered by the treating clinician who would then pass this on to the independent research team.
6. The Committee noted that conflicts of interest had been raised with researchers not listed as investigators in this study. The researcher responded that these researchers were not lead-investigators at any study site and were therefore not named in the application form.

Summary of outstanding ethical issues

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

1. Please ensure that participants are aware that they cannot keep the devices beyond the conclusion of this study.
2. Please add that the sleep study is optional for participants.
3. Please correct spelling and grammatical errors on page 3.
4. Please replace jargon with lay-language in the adult PIS, for example: “Subcutaneously”.
5. Please ensure this is written in British, not American English.

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Decision

This application was approved by consensus, subject to the following non-standard conditions:

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

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| **3** | **Ethics ref:** | **19/STH/5** |  |
|  | Title: | Comparison study of methylprednisolone aceponate fatty ointment applied to the skin in healthy male and female volunteers. |  |
|  | Principal Investigator: | Dr Noelyn Hung |  |
|  | Sponsor: | Aspen Australia |  |
|  | Clock Start Date: | 17 January 2019 |  |

Dr Noelyn Hung and Linda Folland were present via 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.

Summary of Study

This study aims to determine the *in vivo* bioequivalence of Methylprednisolone Aceponate fatty ointment in comparison to Advantan fatty ointment.

Summary of resolved ethical issues

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

1. The Committee queried what the expected drop-out rate for participants was projected to be at the screening phase. The researchers estimated that 40 to 60 participants would continue to the study phase from the 90 that are screened.
2. The Committee queried whether previous studies conducted by Zenith with creams, ointment, and lotions had not resulted in any adverse effects, as stated in the PIS. The researchers confirmed that 15 prior studies produced no adverse effects. The Committee commented that this was extremely unusual in the setting of any clinical trials, particularly as adverse events should be recorded regardless of relationship to the product under study.
3. The Committee asked whether pregnancy is a contraindication in this study. The researchers responded that this is the case. The Committee then queried whether participants who become pregnant in the study will be asked to provide information on the pregnancy and its outcome. The researcher confirmed that this would be done.

Summary of outstanding ethical issues

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

1. The Committee stated that the results of this study will be of interest to participants, and that all participants should be given the option of receiving a lay-summary of results (*Ethical Guidelines for Intervention Studies* paragraph 6.22)

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

1. Please rewrite the inclusion and exclusion criteria in lay-language; for example, "…topical dermatological drug therapy on the ventral forearms", and “'Topical or systemic corticosteroids…". Explain terms and give examples of brand names.
2. Please expand and change the ordering of the risk section, listing all side effects from most common to rare and giving an indication of frequency.
3. If the low-risk nature of the study does not require participants to use contraception, as indicated by the researchers, please remove the reproductive risk section from the PIS/CF and update the protocol accordingly. If contraception is required, please amend this so that it is line with the HDEC template, including male contraceptive advice if appropriate.

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* paragraph 6.22).
* Please ensure that participants will be provided with a lay-summary of results at the conclusion of the study (*Ethical Guidelines for Intervention Studies* paragraph 6.22)

This following information will be reviewed, and a final decision made on the application, by Mrs Raewyn Iodine and Dr Devonie Waaka.

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| **4** | **Ethics ref:** | **19/STH/3** |  |
|  | Title: | BEDROC-1 Study |  |
|  | Principal Investigator: | Professor Paul Glue |  |
|  | Sponsor: | Douglas Pharmaceuticals |  |
|  | Clock Start Date: | 17 January 2019 |  |

Professor Paul Glue was present via 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

This is a multi-centre phase 2a open-labelled extension study of R-107 in Major Depressive Disorder treatment resistant subjects who responded to treatment in the R107-C205 study.

Summary of resolved ethical issues

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

1. The Committee expressed that it was disappointed with the poor quality of the application. For example, the Committee noted that section r.1.1 of the application, in relation to the possible adverse reactions to ketamine, was inadequately filled in.
2. The Committee queried how many other countries the trial would have sites located in. The researchers confirmed that there would be two other countries involved in this trial, Australia and Singapore.
3. The Committee queried what publication restrictions were in place, as the application form referenced the CTA but did not provide any detail. The researchers responded that the sponsor will not place restrictions on publication, but will review any planned publication and provide feedback within a 6 month timeframe.
4. The Committee queried where results from previous studies, included in the PIS, came from. The researchers explained that these results came from the study with HDEC ethics reference 16/STH/121.

Summary of outstanding ethical issues

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

1. The Committee noted that the application incorrectly indicated that human tissue will not be used or collected in the course of this study, and therefore necessary sections of the application were not filled in (*Standard Operating Procedures* paragraph 42.3)

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

1. Please include all possible adverse reactions to ketamine, including those which are rare. Frequencies should be provided where available.
2. Please expand the advice concerning driving after a ketamine dose. This should indicate the possible risk of disassociation for participants after each subsequent dose, and its impact on driving and the operation of machinery.
3. Please be consistent in descriptions of ketamine. Please also remove the reference to ketamine as a new drug, and remove statements about ketamine’s prior use in the treatment of depression.
4. Please amend the adverse risks section to cover risks of dependency, abuse, and overdose with ketamine and R-107, as well as the risks involved with their use in conjunction with other medications / recreational drugs. Please also provide guidance on possible interactions with alcohol and alcohol consumption during the study.
5. Please make clear that distributing or sharing study medication with other people is strictly prohibited

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1. Please remove abstinence as a “highly effective” method of birth control.
2. Please explain the term ‘disassociation’ for a lay-readership.

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* paragraph6.22).
* Please provide a cover letter answering the ‘r’ section questions relating to the use and/or collection of human tissue (*Standard Operating Procedures* paragraph 42.3):
* **r.3.2.** What types of human tissue will be collected and/or used in your study?
* **r.3.3.** Will your study involve human tissue collected from participants and / or existing stored human tissue samples?
* **r.3.7.** Please briefly explain how human tissue samples will be stored during your study, and how the privacy of donors and participants will be protected.
* **r.3.8.** Will human tissue collected in New Zealand be sent overseas as part of your study?
* **r.3.9.** Will the use of all human tissue in your study be in accordance with the informed consent (including consent to future unspecified research) that has been or will be obtained from participants, donors of existing stored human tissue, or other persons entitled to give informed consent under the Human Tissue Act 2008?
* **r.3.10.** What types of tests or analyses will be carried out on human tissue as part of your study?
* **r.3.11**. What will happen to human tissue at the end of your study, or if participants withdraw consent for its use in this study?

The following information will be reviewed, and a final decision made on the application, by Mrs Helen Walker and Assc. Prof. Mira Harrison-Woolrych.

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| **5** | **Ethics ref:** | **19/STH/6** |  |
|  | Title: | NHFO2: Algorithm 2 |  |
|  | Principal Investigator: | Dr James Harper |  |
|  | Sponsor: | Fisher & Paykel Healthcare Limited |  |
|  | Clock Start Date: | 17 January 2019 |  |

The Committee approved this application.

**Closed minutes.**

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| **6** | **Ethics ref:** | **19/STH/8** |  |
|  | Title: | Synbiotics and liver transplantation |  |
|  | Principal Investigator: | Associate Professor Lindsay Plank |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 17 January 2019 |  |

Assc. Prof. Lindsay Plank was present via 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

This study will compare the use of synbiotics post-liver transplantation to current the standard of care, in relation to the levels of infection following this operation.

Summary of resolved ethical issues

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

1. The Committee asked what the ratio of randomisation will be. The researcher answered that the ratio will be 1:1.
2. The Committee queried whether patients would be able to participate without providing a blood or faecal sample. The researcher responded that this is correct as some people may object to this, and it is desirable to maximise the size of the participant group. The Committee questioned how these patients would be assessed for infection. The researcher responded that they would be assessed clinically.
3. The Committee asked, as this is a double-blind study, how the research team will be organising the randomisation. The researcher responded that the randomisation will be prepared by a researcher in the department of surgery who is independent to the study. Further, the samples will be provided by a company in Sweden, labelled A and B, and the research team will not know the contents of either. The Committee asked if there would be a problem unblinding if there is a complication in the study. The researchers indicated that a Data Monitoring Committee will be involved, and a statistician employed who will provide reports to the DMC and have access to the unblinded samples. Unblinding would happen if there is a serious adverse event.
4. The Committee suggested that, as health claims may be made using the results of this study, it would be worthwhile for the researcher to contact SCOTT to determine if Medsafe approval is indicated.

Summary of outstanding ethical issues

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

1. The Committee noted that the protocol lacks a clear outline which predetermines the DMC and states how it will monitor and manage adverse events. The protocol should also outline the stopping rules for this study, for example, a significant difference in the infection rates to those in the prior study (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
2. The Committee noted that the PIS mentions pregnancy as an exclusion criterion, but this is not listed as an exclusion in the protocol (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
3. The Committee requested that evidence of recently acquired international peer review be provided (*Ethical Guidelines for Intervention studies* Appendix 1).
4. The Committee requested a formulation sheet for the Synbiotic used in the study (*Standard Operating Procedures* paragraph 42.4).
5. The Committee noted that detail on the collection of samples for future use of tissue needs to be added to the protocol if there is the intention of future unspecified research (*Ethical Guidelines for Intervention Studies* paragraph 5.41).

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

1. Please amend the confidentiality section, stating how participants will be identified, how blood samples will be identified, and who will have access to study information. Please also make clear whether there will be future use of data, and what measures will be put in place to protect the privacy of participants; for example, whether the data will be de-identified.
2. Please include information on the payment and reimbursement of participants, for example for travel and parking for outpatient visits.
3. Please provide a separate PIS/CF addendum for the use of tissue for future unspecified research, and provide information on where samples are to be stored. Please also reword the statement that participants can retain control over samples which they donate to make it clear that this applies only to withdrawal of samples. The Secretariat will provide a future unspecified research PIS/CF template.
4. Please amend language so that it is less promotional; for example, remove statements which advocate the taking of synbiotics.
5. Please state that there may be no benefit to participants in this study.
6. Please add a section on risks, including the potential of side effects such as nausea and vomiting, and incorporating the statement on increased mortality in a previous trial.
7. Please add that patients are able to withdraw from the study, and include information on what will happen to their data and samples, or what options are available with regards to these, upon withdrawal.
8. Please add a footer to the document with version number and date.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
* Please add to the protocol an outline of the DMC, including how it will monitor and manage adverse events. Please also add stopping rules for the study, the pregnancy exclusion criterion, and the parameters of any future research on human tissue (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
* Please provide evidence of peer review (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Please provide a formulation sheet for the synbiotics to be used in this study (*Standing Operating Procedures* paragraph 42.4).

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| **7** | **Ethics ref:** | **19/STH/10** |  |
|  | Title: | Closed vs open abdomen in severe secondary peritonitis |  |
|  | Principal Investigator: | Dr Li Hsee |  |
|  | Sponsor: | N/A |  |
|  | Clock Start Date: | 17 January 2019 |  |

Dr Teresa Holm was present via 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

This study aims to determine whether open or closed abdominal management is best treatment for surgical patients with life-threatening abdominal infections. It will compare in-hospital survival and the blood level of bacterial toxins of patients managed with both open and closed abdominal management, and measure the level of immune cells in the blood and abdominal fluid of these patients.

Summary of resolved ethical issues

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

1. The Committee explained that New Zealand law does not allow patients to be consented for participation in an intervention study retrospectively, through “regained capacity consent”.

Summary of outstanding ethical issues

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

1. The Committee requested that the study design be revised to secure the informed consent of patients prior to them entering theatre, and to remove reference to “regained capacity consent” (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
2. The Committee noted that all participants must have the opportunity to receive a lay-summary of the study results when they become available (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
3. The Committee noted that formal Māori consultation is required for this study, and requested confirmation that the discussion with Helen Wihongi was formal (*Ethical Guidelines for Intervention Studies* paragraph 1.7).

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

1. Please add a lay-language title.
2. Please remove the international contact information from the title page.
3. Please add an ACC and Māori tissue statement, using the HDEC PIS template

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1. Please correct issues of tense.
2. Please remove use of the term ‘survival’. For example, “in-hospital survival”.
3. Please clarify what will happen to patients’ data and samples if they withdraw from this study.
4. Please reduce the complexity of the document. For example, the list of tests on page 3 and the benefits section on page 4.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies* paragraph6.22*)*.
* Please revise the study design so that the informed consent of patients is secured prior to them entering theatre, and that reference to “regained capacity consent” is removed (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
* Please ensure that all participants have the opportunity to receive a lay-summary of the study results when they become available (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
* Please confirm that formal that the discussion with Helen Wihongi constituted formal Māori consultation (*Ethical Guidelines for Intervention Studies* paragraph 1.7).
* Please provide more information on data safety monitoring, as section r.1.4 of the application form was too vague on this subject. This should reflect the Canadian trial data safety monitoring.

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| **8** | **Ethics ref:** | **19/STH/11** |  |
|  | Title: | Asahi Outrider Study |  |
|  | Principal Investigator: | Dr Scott Harding |  |
|  | Sponsor: | BIO-EXCEL(Australia) PTY LTD |  |
|  | Clock Start Date: | 17 January 2019 |  |

Dr Scott Harding was present via 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

This study investigates a new device, the Asahi Outride Support Catheter, and its ability to assist in retrieving guidewires during coronary angioplasties.

Summary of resolved ethical issues

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

1. The Committee queried why several Investigators would potentially be performing the study procedure, when only 5 participants will be enrolled. The researcher clarified that this has changed since the submission of the application, and that the CI will be performing all procedures.
2. The Committee commented that the researchers should consider using the HDEC template for their PIS/CF.
3. The Committee noted that the researcher’s previous application was reviewed by the Central HDEC, not the multi-region HDEC.

Summary of outstanding ethical issues

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

1. The Committee queried whether health information is being accessed for screening purposes, and this was confirmed by the researcher.
2. The Committee requested that the initial approach to potential participants should be made by a member of the individual’s clinical care team. (*Ethical Guidelines for Intervention Studies* paragraph 6.2).

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

1. Please state that representatives from the sponsor will be present during the operation.
2. Please include a bold box statement on page 1, stating that this is a first-in-human study

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1. Please state that there may be no benefit to participants from taking part in the study.
2. Please add that, as this is a first-in-human study, there may be risks which the researchers are unaware of. Add that participants will be informed of any information which emerges which might affect their decision to take part in the study.
3. Please update the compensation section to conform to the new HDEC template.
4. Please add information on patients’ confidentiality and how their information will be used / stored.
5. Please add information on participants’ right to withdraw from the study, including information on alternative treatments and standard of care. Please also state whether data collected prior to a participant’s withdrawal will continue to be used.
6. Please add to the risks section that, as this is a new device, there is a possibility that the length of the procedure will be take longer than usual; this in turn increases likelihood of other risks.
7. Please rewrite the explanation of the device and procedure in lay-language, including a picture of the device.

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* paragraph 6.22).
* Please ensure that a person external to the research team will recruit participants for this study (*Ethical Guidelines for Intervention Studies* paragraph 6.2).

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



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| **9** | **Ethics ref:** | **19/STH/12** |  |
|  | Title: | AROAPOC31001: Study of ARO-APOC3 in Adult Healthy Volunteers as well as in Severely Hypertriglyceridemic Patients and Patients with Familial Chylomicronemia Syndrome |  |
|  | Principal Investigator: | Doctor Christian Schwabe |  |
|  | Sponsor: | Novotech (New Zealand) Limited |  |
|  | Clock Start Date: | 17 January 2019 |  |

Dr Christian Schwabe was present via 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

This study is to test the safety and tolerability of ARO-APOC3 in healthy volunteers with raised triglyceride levels, hypertriglyceridemic patients, and patients with Familial Chylomicronemia Syndrome (FCS).

Summary of resolved ethical issues

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

1. The Committee noted that the lay-summary provided in the application form was a technical explanation extracted from the protocol. The Committee requested that future applications use lay language in the application form where indicated.
2. The Committee requested that the answer to p.2.7 in the application form be updated in future applications, as this appears to be a templated response and does not address the requirement to inform participants of important new safety information prior to the approval of updated informed consent documents.

Summary of outstanding ethical issues

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

1. Please simplify information about the escalating dose, as it currently allows for misinterpretation by participants who may believe that *their* dose is escalating, as opposed to escalating doses across cohorts.
2. Please clarify that day 1 safety bloods will be fasted.
3. Please rewrite the statement in the clinic visits table, “In the event that the concentration of your APOC-III level has not returned to above 50% of your baseline value…”, in lay-language, and explaining whether this result would be of any risk to participants.
4. Please make clear that participants on other standard treatments may be required to cease this treatment to be included in the study.
5. Please correct formatting issjues to improve readability (margin sizes too wide, text merges into the footers, headings not on same page as content, no gaps between paragraphs).

1. Please rewrite the active/placebo ratio for each cohort as “X people will get active drug and X people will get placebo”, rather than “1.5 more likely chance”.
2. Please clarify whether patients will be required to stay overnight as part of the screening process, and if so, what the compensation will be for this.
3. Please remove references to the health of the child from the pregnant partner PIS/CF, as this must be consented for after the child’s birth. Please also put paragraphs 5 and 6 with paragraph 3.
4. Please amend the study instructions to state that participants must comply with meal requirements, removing the statement that participants ‘acknowledge they will be removed’ for non-compliance.
5. Please sure macrons are used (e.g. Māori).

Decision

This application was *approved* by consensus, subject to the following non-standard conditions:

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

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| **10** | **Ethics ref:** | **19/STH/18** |  |
|  | Title: | A study comparing the trial drug AVT02 and Humira®, in healthy adults. |  |
|  | Principal Investigator: | Dr Chris Wynne |  |
|  | Sponsor: | IQVIA RDS |  |
|  | Clock Start Date: | 17 January 2019 |  |

No researcher was present 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.

Dr Devonie Waaka declared a conflict of interest with the Christchurch Clinical Studies Trust. The Committee allowed Dr Waaka to remain present for discussion of the application in a researcher capacity only.

Summary of Study

The study will compare single doses of AVT02 with Humira from the USA and Europe, used in the treatment of inflammatory diseases.

Decision

This application was *approved* by consensus.

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| **11** | **Ethics ref:** | **19/STH/22** |  |
|  | Title: | Mobility skills programme for children with cerebral palsy |  |
|  | Principal Investigator: | Mrs Gaela Kilgour |  |
|  | Sponsor: | Australian Catholic University |  |
|  | Clock Start Date: | 17 January 2019 |  |

Mrs Gaela Kilgour 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 aims to determine the effect of a high-level mobility skills training programme on sustained participation in community-based physical activity of ambulant children with cerebral palsy.

Summary of resolved ethical issues

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

1. The Committee queried what kind of physical activities children be involved in. The researcher answered that this could be organised, such as a football match, or informal, such as simple running. The researcher explained that children will set their own physical and participation goals.
2. The Committee asked whether children need to set a goal which they may not achieve. The researcher answered that the study will take place over a long period of time; goals will be challenging yet attainable, and there is a possibility some children will not achieve their goals. The Committee queried whether the child will determine their own goals. The researcher answered yes, that children from 7 years of age and older will do so, with the expectation that families can meet this goal.
3. The Committee questioned whether the activity groups will involve children other than those diagnosed with cerebral palsy. The researcher clarified that the program is designed for children with physical disabilities, and there will be children involved who do not hav cerebral palsy.
4. The Committee queried whether people will be recruited to take part in the activity groups who are not part of the study. The researcher confirmed this.
5. The Committee confirmed that pictures can be added to the PIS documents.
6. The Committee noted that the age of consent in New Zealand is 16, not 18 years-old.
7. The Committee asked if an attempt will be made to recruit patients of the same age group. The researcher responded that participants will recruit along the lines of physical ability, not age. The Committee queried whether a population size of 8 was too small. The researcher responded that this is appropriate for a study of this size.
8. The Committee asked whether data from this study will be stored in Australia or New Zealand. The researcher answered that data will be stored in Australia.

Summary of outstanding ethical issues

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

1. The Committee noted that all participants must have the opportunity to receive a lay-summary of the study results when they become available (*Ethical Guidelines for Intervention Studies* paragraph 6.22).

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

1. Please make clear in the PIS the difference between group activities and the individual sessions, for example goal-setting and testing.
2. Please add the time commitments involved with testing.
3. Please rewrite the informed consent / assent documents in lay-language. The 7-11 assent form is age-appropiate, however the 11-16 year assent form and adult PIS/CF forms are use overly technical language.
4. Please remove health insurance information can be removed from the 11-16 assent form.
5. Please only use tick boxes for optional yes/no questions.
6. Please add information on withdrawing from the study to the adult PIS, and whether information collected prior to withdrawal will continue to be used.
7. Please state how participant information will be used in the study, and how this will be identified.

Decision

This application was *approved* by consensus, subject to the following non-standard conditions:

* Please ensure that participants will receive a lay-summary of study results when they become available (*Ethical Guidelines for Intervention Studies* paragraph 6.22).
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph6.22).

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| **12** | **Ethics ref:** | **19/STH/23** |  |
|  | Title: | Emerging Sources and Pathways for Leptospirosis - a paradigm shift |  |
|  | Principal Investigator: | Dr Shahista Nisa |  |
|  | Sponsor: | Massey University |  |
|  | Clock Start Date: | 17 January 2019 |  |

Dr Shahista Nisa was present via 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

This project aims to appraise risk factors associated with leptospirosis, identify pathogenic strains of leptospira, identify sources and pathways of infection, assess drivers of acceptance for ACC cover, and assess attitudes towards animal vaccination and personal protective equipment.

Sum

Summary of outstanding ethical issues

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

1. The Committee noted that documents relating to participants in the study, specifically the PIS/CF and questionnaires for the control group, have not been submitted for review (*Standard Operating Procedures* paragraph 42.4).
2. The Committee noted that information on the informed consent process, including planned verbal consent, needs to be included in the protocol. It was stated that all attempts should be made to secure consent in writing, and that records should be kept of how consent is attained. (*Ethical Guidelines for Observation Studies* paragraphs 5.11 and 6.27).
3. The Committee noted that data in the study needs to be retained for a minimum of 10 years, and that the protocol currently states retention is for 2 years (*Ethical Guidelines for Observational Studies* paragraph1.9).
4. The Committee observed that if human tissue samples are to be stored for future research, the researchers must either submit an application to form a tissue bank, or contact a registered tissue bank and store samples there. Alternatively, samples must be destroyed at the conclusion of the study. (*Ethical Guidelines for Observational Studies* paragraph 1.9 and the *Human Tissue Act 2008*).
5. The Committee noted that support persons would be interviewed as part of the study. The researcher was advised either to make clear that support persons would participate in this study, or else remove interview questions which address them (*Ethical Guidelines for Observational Studies* paragraph 5.11).
6. The Committee requested that the protocol be amended to label data disseminated in this study as ‘de-identified’, not anonymous (*Ethical Guidelines for Observational Studies* paragraph 5.11).
7. The Committee requested information on how control participants will be recruited into the study (*Ethical Guidelines for Observational Studies* section 5).
8. The Committee stated that the risks associated with answering questions about anxiety and depression in the questionnaire were not adequately addressed, and that the “thank you” conclusion was too abrupt (*Ethical Guidelines for Observational Studies* paragraph 5.5).

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

1. If tissue samples are to be stored for future research, please provide a PIS/CF for future unspecified research using the HDEC template. This should make clear the parameters for its use, such as where it will be stored, who will have access to them, and how participants can request their samples be returned.
2. Please make clear to participants how identifiable their data will be, and how it will be used. The Committee noted that interview data will likely be at most de-identified, not anonymous.
3. Please add that participants’ health care provider and the MOH will be notified if a diagnosed of leptospirosis is made, as it is a notifiable disease and requires active treatment.
4. Please rework the description of what participation involves, so that it is clear to participants what they will be doing. Include what questions will be asked, how responses will be recorded, who is conducting the interviews and writing up transcripts, and how data will be de-identified or anonymised. This must outlined for each step of the study (mandatory and optional sections).
5. Please address risks associated with answering sensitive questions around anxiety and depression in the interview.
6. Please include a Māori tissue statement.
7. Please make clear how samples and data will be identified.
8. Please add information on how participants can withdraw from this study, and whether data and samples can be withdrawn by participants.
9. Please amend the consent forms and ensure they are consistent with the HDEC template.
10. Please reword the blood sample PIS, making sure participants understand that they are only consenting for the sample, and will give consent to take part in the remainder of the study at a later time.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observational Studies* paragraph 6.10).
* Please outline the risk management plan associated with sensitive questions around anxiety and depression in the interview, should any red flags or alerts arise in response to these questions. *(Ethical Guidelines for Observational Studies paragraph 5.5).*
* Please outline the experience / training interviewers will have in taking these interviews, given the potential for red-flag responses to the mental health related questions.(*Ethical Guidelines for Observational Studies* paragraph 5.5).
* Please submit the PIS/CF and questionnaires for the control group for review (*Standard Operating Procedures* paragraph 42.4).
* Please provide information on how control participants will be recruited into the study (*Ethical Guidelines for Observational Studies* section 5).
* Please provide information on participants’ consent process, justify why all consent will not be secured in writing, and ensure that records are kept of how consent is attained. (*Ethical Guidelines for Observation Studies* paragraphs 5.11 and 6.27).
* Please ensure that data in this study will be retained for a minimum of 10 years (*Ethical Guidelines for Observational Studies* paragraph1.9).
* If human tissue samples are to be stored for future research, please either submit an application to form a tissue bank, or contact a registered tissue bank to store samples there. (*Ethical Guidelines for Observational Studies* paragraph 1.9 and the *Human Tissue Act 2008*).
* Please make clear that support persons will participate in this study, or else remove interview questions which address them. Please also amend the protocol to state that data disseminated in this study will be ‘de-identified’, not anonymous (*Ethical Guidelines for Observational Studies* paragraph 5.11).

## Substantial amendments

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|  | **Ethics ref:** | **OTA/95/10/113/AM14** |  |
|  | Title: | Rare Disease Surveillance |  |
|  | Principal Investigator: | Dr Ben Wheeler |  |
|  | Sponsor: | Mr Grant Storey |  |
|  | Clock Start Date: | 10 October 2018 |  |

Dr Mavis Duncanson was present via 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.

Assc. Prof. Mira Harrison-Woolrych declared a conflict of interest as she is a colleague of the CI. The Committee allowed Assc. Prof. Harrison-Woolrych to remain for the discussion the application.

Summary of Study

This is an active surveillance system with the aim of finding children with symptoms which resemble polio, and checking that no polio virus is present. This amendment is seeking approval to collect NHI numbers as part of this surveillance.

Summary of resolved ethical issues

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

1. The Committee queried whether this health information was being requested for the purposes of research. The researcher confirmed that the intention was to publish results, and it therefore constituted research.
2. The Committee queried whether this application met any of the justifications for collecting health information without consent, as set out in the *Ethical Guidelines for Observational Studies* paragraph 6.43. The researcher responded that this collection would be both in the public interest and would significantly impact on the scientific validity of the study should informed consent be required. The Committee was satisfied with this, provided that NHI number are not included on the dataset.
3. The Committee asked how many people would have access to the collected health information with NHI numbers initially attached. The researcher answered that in practice only one person would have access.

Decision

This application was *approved* by consensus.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 12 February 2019 |
| **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 4:30pm.