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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 08 May 2018 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 11:30am | Welcome |
| 11:35am | Confirmation of minutes of meeting of 10 April 2018 |
| 11:45am | New applications (see over for details) |
|  | i 18/STH/98  ii 18/STH/94  iii 18/STH/95  iv 18/STH/96  v 18/STH/97  vi 18/STH/92  vii 18/STH/99 |
| 3:00pm | General business:   * Noting section of agenda |
| 3:15pm | 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 10 April 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/STH/98** |
|  | Title: | CX-839-008: A Phase 2 study of CB-839 in Advanced Renal Cell Carcinoma |
|  | Principal Investigator: | Dr Carmel Jacobs |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 April 2018 |

Dr Carmel Jacobs was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study comparing CB-839 in combination with cabozantinib with cabozantinib alone involves advanced kidney cancer patients who have failed first or second line treatment.

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 in future applications the name of the CRO representative should be provided, in this application it is listed as “Mr Novotech Regulatory”.
2. The Committee noted that any data provided for use in other studies must be de-identified.
3. The Committee accepted the proposed process for potential participants to be initially approached by a member of their clinical care team.
4. The Committee considered whether only tumour material will be analysed in this study, and whether the genetic markers being studied are directly related to cancer. The Committee confirmed the proposed plan is acceptable.
5. The Committee noted that the cultural questions in the application form have been answered poorly, with generic answers that do not appear to relate to this study. In future applications please use the guidance available on the HDEC website (ethics.health.govt.nz) to assist with answering these questions. The Committee noted that the use of tissue is a primary ethical concern for Māori in this study.
6. The Committee questioned whether Māori are over represented with this condition. The Researcher explained that to the best of their knowledge this Māori are similarly represented with this condition.
7. The Committee noted that cultural consultation is required for this study and must be undertaken before the study begins.

Summary of outstanding ethical issues

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

1. Please clarify in the Consent Form that tissue collected in this study will be sent overseas.
2. Please do not make statements in participant facing documents about ‘the country where you live’, please revise these documents to be New Zealand specific.
3. Please add a short lay title to the Participant Information Sheet, this title should still describe the study and not be an acronym.
4. Please revise the Participant Information Sheet to explain that if participants withdraw from the study they will only be followed up with their consent.

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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| **2** | **Ethics ref:** | **18/STH/94** |
|  | Title: | SOLOIST-WHF Trial |
|  | Principal Investigator: | Professor Richard Troughton |
|  | Sponsor: | Sanofi Aventis Australia Pty Ltd |
|  | Clock Start Date: | 26 April 2018 |

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

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that some of the questions in the application form have been answered incorrectly, such as question H, please ensure the application form is completed more carefully in future.
2. The Committee noted that the physical exam must be conducted by a qualified medical professional. The study documentation currently indicates that it will be ‘someone from the research team’ without any detail of their relevant qualifications or experience. This is a condition of approval, any variation of this must be submitted as an amendment and approved before the study begins.
3. The Committee noted that despite the answer in the application form indicating it is not required, Māori cultural consultation is necessary for this study and must be undertaken before the study begins.
4. The Committee noted that updated urgent safety information may need to be provided to participants during the study before an updated Participant Information Sheet is approved by the HDEC. Please ensure that as necessary urgent updates are provided to the participants quickly.
5. The Committee noted that the application form indicates that participants will be initially approached by a member of the research team. The Committee requested that instead the initial approach is made by a member of the potential participant’s clinical team, who can then refer any interested patients to the researchers for the consent process to be continued. This is a condition of approval, any variation of this must be submitted as an amendment and approved before the study begins.

Summary of outstanding ethical issues

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

1. The Committee requested that a lay friendly title is added to the Participant Information Sheet, this title should clearly explain what the study is about instead of just providing an acronym.
2. The Committee raised concerns about the phrasing of the sentence ‘… in New Zealand drugs and devices must be approved by the government to be used.’ The Committee suggested that the sentence may be clearer if the words ‘to be used’ are removed.
3. Please revise the Participant Information Sheet to remove statements about destroying study results, this seems to be incorrect.
4. The Participant Information Sheet is currently split in to two parts, with separate headings. Please remove these headings to keep the Participant Information Sheet as one part.
5. The Committee noted that the contraception section in the Participant Information Sheet contains incorrect information for New Zealand participants. Please update this section with the relevant information from the HDEC template, available at ethics.health.govt.nz.
6. The Committee noted that the Participant Information Sheet appears to indicate that the participant will give consent for information to be collected about their partner and baby, in the event their partner becomes pregnant. The Committee noted that the participant cannot give this consent and it must be obtained from the pregnant person themselves, and consent must be obtained from the parent or legal guardian after birth to collect information about the child. Please provide a suitable pregnant partner Participant Information Sheet and Consent Form that includes a provision to obtain consent after birth if it is intended to collect information on the baby.
7. Please do not make statements in participant facing documents about ‘your country’, please revise these documents to be New Zealand specific.

Decision

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

* Make the changes listed in resolved ethical issues.
* 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:** | **18/STH/95** |
|  | Title: | BGB-A317-303 |
|  | Principal Investigator: | Dr. Gareth Rivalland |
|  | Sponsor: | BeiGene, Ltd. |
|  | Clock Start Date: | 26 April 2018 |

Dr. Gareth Rivalland, Lisa Wong, and a co-investigator were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study investigates a potential new immunotherapy treatment for lung cancer.

Summary of resolved ethical issues

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

1. The Committee questioned whether IV line infections are a risk in this study. The Researcher explained that this would be very uncommon and they do not believe it poses enough risk to warn participants about it.
2. The Committee noted that in the application form, the responses to questions that asked for brief and plain English answers were not satisfactory and appeared to have been copied from the study protocol. Please ensure that better responses are provided in future.
3. The Committee noted that only a study code should be included on information sent to the study sponsor, and any other identifiers (such as initials or date of birth) should be removed.
4. The Committee raised concerns about participants needing to pay for medication to manage side effects from study treatment. The Committee noted that this medication should be paid for as part of the study, and if participants needed to pay it should only be for a standard prescription fee.
5. The Committee questioned how the conflict between the researcher’s role as a doctor and role as a researcher will be managed in this study, to help prevent participants being unduly pressured in to study participation. The Researcher explained that potential participants will be clearly informed that study participation is optional and able to go away and think about the study away from the recruiting clinician.
6. The Committee questioned whether the study meets the equipoise standard. The Researcher explained that they do not know if the study drug will provide any benefit above standard care, or if it may have additional side effects. Because of this the Researcher believe that the equipoise standard is met as it is not known whether the placebo or active arm is more likely to be beneficial.
7. The Committee requested that in future applications documents are not submitted with tracked changes. Although tracked changes are useful when responding to concerns raised by the Committee, they are confusing when included in the initial application.

Summary of outstanding ethical issues

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

1. The Committee noted that the Participant Information Sheet is difficult to understand for lay people and must be revised. The Committee explained that currently excessive information and jargon clouds the information that participants actually want to know.
2. Please revise the statement in the Participant Information Sheet about the performance assessment to assess their ability to look after themselves. The Committee noted that the current wording may concern participants by implying they won’t be able to care for themselves anymore and their performance is being assessed.
3. Please clarify in the Participant Information Sheet how long participants will be in the study. The Committee acknowledged that an exact length of time may not be suitable to state, but some indication of the length of participation needs to be included.
4. Please add a short lay title to the Participant Information Sheet, this title should still describe the study and not be an acronym.
5. If it is intended to collect information after a baby is born from any participants, or their partners, who become pregnant during the study, this consent must be obtained after the baby is born. Please revise the relevant Consent Forms to reflect this.

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*).

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/96** |
|  | Title: | (duplicate) Mental health and wellbeing of high risk Pasifika youth |
|  | Principal Investigator: | Dr Julia Ioane |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 April 2018 |

Dr Julia Ioane 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 resolved ethical issues

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

1. The Committee noted that it is unclear from the application what the primary purpose and outcome measures for this study are. The Committee discussed that although it is stated that the study is investigating the rates of mental health and substance use disorders in Pasifika youth offenders, the study takes measures at baseline and at 3 time points following this and appears to be investigating changes in the disorder rates following a targeted approach, which would imply this is a pilot intervention study. The Researcher confirmed that their primary purpose is to investigate the rates, not to trial a programme.
2. The Committee questioned whether the young person can participate in the study without their caregiver also participating, or if participation requires a matched pair of youth and caregiver. The Researcher confirmed that both will need to agree to participate in the study.
3. The Committee questioned whether young women could be in the study. The Researcher confirmed they could be.

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 although it is acceptable to explain the study to the youth and caregiver together, that consent must be obtained from each of them separately to reduce coercion on the young person and to allow them to ask any questions they may be unwilling to ask in front of their caregiver. The Committee further noted that the interviews must be conducted separately to protect the participant’s privacy. The Researcher confirmed that they already planned to conduct the interviews separately, although they had planned on obtaining consent from the youth and caregiver at the same time. The Committee requested details are provided on how obtaining consent will be managed to ensure both participants in each pair are able to ask questions and decline participation without pressure. Informed consent must be voluntary and free from undue influence such as manipulation or coercion (Ethical Guidelines for Observational Studies paragraph 6.11).
2. The Committee questioned if rates of mental health and substance abuse disorders will be compared between the study groups and any other groups, or between the two study ethnicities. The Committee requested details of this planned analysis is provided. Please also provide information regarding any existing data on other populations, e.g. Māori or Pakeha youth or adults in the justice system. Scientific validity is an important component of good ethical practice in research (Ethical Guidelines for Observational Studies paragraph 5.8).
3. Please justify why specifically Samoan and Tongan youth have been selected for this study and why young people from other ethnicities/backgrounds are excluded. An investigator must not discriminate in the selection and recruitment of participants by including or excluding them on the grounds of ethnicity, age, sex, disability or religious or spiritual beliefs, except when such exclusion or inclusion is essential to the purpose of the study (Ethical Guidelines for Observational Studies paragraph 4.8).
4. The Committee raised serious concerns about how the potential disclosure of concerning information will be handled. The Committee stated that a range of issues could be raised in the study and these would all need a protocol for handling them in a suitable way. This includes if it is discovered that a participant has clinically significant mental health or substance use disorders; if participants disclose information about suicidality; the possibility of participants disclosing additional criminal activity, or planned criminal activity; and any other concerning information that could be disclosed. Please provide a detailed protocol explaining how the interviewers will be trained to identify and handle these eventualities, and the protocol for dealing with these. If it is reasonably foreseeable that health problems previously unknown to an individual will be identified during the study process, then arrangements for referral, with the individual’s consent, should be made (Ethical Guidelines for Observational Studies paragraph 9.1).
5. The Committee noted that a more detailed plan for protecting participants must be provided. This must include when participants will be referred to other services, when information could be disclosed without their consent, and what services will be available to those who make concerning disclosures.
6. The Committee requested that a detailed plan is provided regarding how disclosures of previously unknown drug use or criminal activity will be handled and what the confidentiality arrangements and limitations for these are. Individuals’ privacy and confidentiality of information need to be ensured unless there is an overriding ethical concern (for example, health or safety) justifying the release of such information or if such release is required by law (Ethical Guidelines for Intervention Studies paragraph 9.2).
7. The Committee questioned the expertise of the interviewers. The Researcher explained that they hope to recruit researchers who have research experience, but that clinical experience or training is not a requirement. The Committee explained that if the interviewers are not suitably experienced and qualified, that details of the training they will be provided with (and a protocol for them to follow with conducting the interviews) must be provided. Studies must be conducted or supervised only by investigators with the necessary skills and resources to conduct the study and deal with any contingencies that may affect participants (Ethical Guidelines for Observational Studies paragraph 5.9).
8. Please provide a researcher protocol that details the plans for the interviews, how these will be conducted, and what the interviewers should do if concerning information is disclosed.

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

1. The Committee noted that the Participant Information Sheet is not well written and does not make study participation clear, the Committee suggested it is revised to present the information in a similar way to how the researcher plans to explain the study in person. The fundamental problem with the Participant Information Sheet is that it does not accurately describe the aims, design and methods of the study as detailed in the protocol.
2. The Participant Information Sheet indicates that participants are being asked to provide their views of being involved in the youth justice system, however this is inaccurate. Please revise this to clearly state the purpose of the study. Information about the purpose of the study should be as specific as possible without compromising the validity of the study (Ethical Guidelines for Observational Studies paragraph 6.12).
3. Please remove the large box from the beginning of the Participant Information Sheet, although it must be clear that participation is optional this can be presented in a friendlier way.
4. Please state in the Participant Information Sheet what kind of information would require the researchers to break confidentiality, for example if the participant discloses information that makes the interviewer believe they are a risk to themselves or others.
5. Please state in the Participant Information Sheet that the interviews will be audio recorded, who will transcribe these (including if they have signed a confidentiality agreement), and how long these recordings will be stored for.
6. Please state in the Participant Information Sheet that study information will be retained for 10 years following the end of the study.
7. The Committee requested the compensation wording is added for completeness, 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.”*

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* paragraph *6.10)*
* Please respond to the outstanding ethical concerns detailed above.

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

Assc Prof Mira Harrison-Woolrych and Dr Nicola Swain.

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| **5** | **Ethics ref:** | **18/STH/97** |
|  | Title: | A Phase 2a, 24-Week, Multi-Center, Open-Label Study Evaluating the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of SM04646 Inhalation Solution in Subjects with Idiopathic Pulmonary Fibrosis |
|  | Principal Investigator: | Prof Lutz Beckert |
|  | Sponsor: | Quintiles Pty Limited (IQVIA) on behalf of Samumed |
|  | Clock Start Date: | 26 April 2018 |

Prof Lutz Beckert 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 outstanding ethical issues

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

1. The Committee questioned the plans for data safety monitoring, noting that the study protocol should include details of proposed times to review safety data at key time points. The Researcher explained that they do not know the current plans. Provide details of the Data Safety Monitoring plans (*Ethical Guidelines for Intervention Studies* paragraph 6.50).
2. The Committee discussed the study risks for participants.
3. The Committee noted that genetic testing is currently listed as mandatory in this application, however, in New Zealand the only aspects of study participation that should be mandatory are those required for the study to achieve its aims. The purpose of this is to reduce the burden on participants and to allow those with diverse views to access the potential benefits of study participation. Please adjust the study documents to make genetic testing optional for study participants. Studies must have a fair distribution of burdens and benefits (Ethical Guidelines for Intervention Studies paragraph 4.5).

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

1. Please remove genetic testing from the main Participant Information Sheet and Consent Form and provide a separate Participant Information Sheet and Consent Form for this optional aspect of study participation.
2. Please add information on the potential risks of study participation to the Participant Information Sheet, specifically about potential adverse effects of the study drug. Any information available on the rates of these should also be included, if this information is not available please state this in the Participant Information Sheet.
3. In the Participant Information Sheet the risks are currently detailed in a paragraph, please revise this to be a bullet-pointed list as this will make it easier to understand.
4. Please update the reproductive risks section of the Participant Information Sheet, a template is available on the HDEC website (ethics.health.govt.nz) to assist with this.

Decision

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

* Provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies* paragraph 6.50).
* Please respond to the outstanding ethical concerns detailed above.
* 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*).

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

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| **6** | **Ethics ref:** | **18/STH/92** |
|  | Title: | CCX140-B in Subjects with Focal Segmental Glomerulosclerosis (FSGS) |
|  | Principal Investigator: | Dr Janak de Zoysa |
|  | Sponsor: | ChemoCentryx, Inc. |
|  | Clock Start Date: | 26 April 2018 |

Dr Janak de Zoysa 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 resolved ethical issues

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

1. The Committee questioned if the study will be approved by SCOTT. The Researcher confirmed it would be and not indicating this was a mistake in the application form.
2. The Committee questioned whether the safety margins are acceptable in this study, given that dosing in previous studies was much lower. The Researcher explained that the margins are acceptable.
3. The application indicates that data made available for future use will be identifiable, however, identifiers should be removed. Please ensure no data made available for future research contains identifiers.
4. The Committee questioned if the study meets equipoise, noting that the availability of standard care as an alternative to study participation does not mean the study meets this requirement. The Researcher explained that they do not know if the study drug is going to be beneficial or have increased side effects compared to the control arm. The Committee accepted that the study arms are in equipoise.
5. The Committee questioned whether all New Zealand study sites are adequately resourced to conduct the study as the protocol requirements are quite intensive and demanding on the site. The Researcher confirmed that all sites are comfortable they are suitably resourced to conduct the study. The Secretariat noted that this will also be considered as part of locality approval for each site.

Summary of outstanding ethical issues

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

1. Please remove the yes/no tick boxes from the consent form for all statements that aren’t truly optional, that is a participant could select ‘no’ and still participate in the study.
2. Please make note in the Participant Information Sheet that HIV, HepB and HepC are notifiable diseases.
3. In New Zealand, withdrawal of consent can be verbal. It is not necessary for this to be made in writing, please change the section of study documents that states this.
4. On the optional genetic consent, it states that participants can withdraw from the study at any time. The Committee questioned if this is possible due to the level of blinding of study data, please ensure this is accurate. The Committee noted that Future Unspecified Use of Tissue must be included in a separate Participant Information Sheet and Consent Form, not in the main forms. Please provide a suitable separate Participant Information Sheet and Consent Form for Future Unspecified Use of Tissue.
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 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 update the information in the Participant Information Sheet about reporting requirements for notifiable diseases.

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*).

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/99** |
|  | Title: | Biomarkers and Intestinal Flora in Children with Coeliac Disease |
|  | Principal Investigator: | Professor Andrew Day |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 April 2018 |

Professor Andrew Day and a co-investigator 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 resolved ethical issues

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

1. The Committee questioned the reasons for including children in the study, specifically whether they expected the results for children to be different to those of adults. The Researcher explained that if they conducted the study in adults that the results would not be translatable to children. The Committee accepted this justification for the inclusion of children.
2. The Committee questioned whether study participation included more scopes or blood tests than standard care. The Researcher explained that more blood will be taken from an existing line than in standard care, but most of the rest of the tests are being conducted for standard care. In addition to standard care saliva and stool samples will also be collected, however, these are not invasive collections.
3. The Committee questioned whether control participants could have coeliac disease. The Researcher explained that part of the inclusion criteria for the controls is that it is confirmed they do not have coeliac disease.
4. The Committee queried why control participants do not receive a petrol voucher. The Researcher explained that this is because they have to attend less study visits.

Summary of outstanding ethical issues

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

1. Please clarify in the Participant Information Sheet what tests and sample collections are additional to standard care, and that blood will be taken from an existing line.
2. Please revise the Participant Information Sheet to clarify that not all participants have coeliac disease, as some participants are controls.
3. Please clarify in the Participant Information Sheet that control participants will be followed up as per standard care, whereas the coeliac patients will have additional study follow up.
4. Please clarify in the Participant Information Sheet what is being done with study biopsies.
5. The flow chart in the Participant Information Sheet is confusing and should be revised for the adult Participant Information Sheet and removed from the child Participant Information Sheets.
6. The younger children Participant Information Sheet should be simplified and revised.
7. Please remove the eligibility criteria from the Participant Information Sheets.
8. The Committee noted that the age groups for the Participant Information Sheets and Assent Forms should be used simply as guides, and the titles of these forms should be revised to indicate that they are for younger and older children, the researchers can use their judgement when selecting the form to give to child participants.
9. Please revise the Participant Information Sheets and Consent Forms to have consistent language throughout, for example the tests and procedures should be referred to by the same name throughout the documents.
10. 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 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.”*
11. The left hand bullet points in the Consent Form should be revised or removed as the current formatting makes them appear as tick boxes.

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*).

This following information will be reviewed, and a final decision made on the application, by Dr Nicola Swain and Ms Raewyn Idoine.

## 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 June 2018, 11:30 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 3:15pm