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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 16 February 2016 |
| **Meeting venue:** | Teleconference |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 08 December 2015 |
| 12:10pm | New applications (see over for details) |
|  | i 16/STH/13  ii 16/STH/3  iii 16/STH/14 |
| 1:10pm | General business:   * Noting section of agenda |
| 1:15pm | 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 |
| Mrs Angelika Frank-Alexander | 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 Mathew Zacharias | Non-lay (health/disability service provision) | 27/10/2015 | 27/10/2018 | Present |
| Dr Devonie Eglinton | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | 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 |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 08 December 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/STH/13** |
|  | Title: | Time course of airways inflammation with FF/VI in adult asthma. |
|  | Principal Investigator: | Dr James Fingleton |
|  | Sponsor: | GlaxoSmithKline |
|  | Clock Start Date: | 04 February 2016 |

Dr George Bardsley 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 Committee commended the high quality of the application. They stated that all questions in the application form had been answered appropriately.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether the study treatment would be available to participants after the study ends. It was noted that some participants in this study may experience a significant benefit from the study treatment and may wish to continue the treatment after the end of the study. The Committee also noted that the study may attract participants who would not otherwise have the financial means to access the study treatment, and, consequently, would not be able to afford to continue accessing this treatment after the conclusion of the study. The Committee stated that this may be further exacerbated by the high level of reimbursement offered for participation in this study as this may attract participants with less financial means. The Researcher explained that the study treatment could be prescribed by a GP after completion of the study, but was unsure as to what the cost of the prescribed medication would be.
2. The Committee agreed that this was a straightforward study and that the level of reimbursement seemed appropriate given the requirement for participants to remain at the study sight for 5 days. The Committee also appreciated the explanation in the Participant Information Sheet that reimbursement was calculated based on a living wage and that a further reimbursement of $50 per study visit would be provided to cover the cost of travel.
3. The Committee questioned the statement in the application form that tissue samples may be transferred to another company, they questioned whether this meant that tissue samples may be sold by the sponsor to another company. The Researcher explained to the Committee that they believed that this related to the fact that it is currently unknown where samples provided for Future Unspecified Research will be stored and tested. The Researcher stated that they did not believe that the study sponsor would receive a financial gain from the transfer of tissue samples.
4. The Committee noted that the peer reviewer questioned whether E-cigarette use came under the definition of smoking and would be an exclusion criteria for this study. The Researcher explained that they intended to collect information on the rates of E-cigarette use but that it is not an exclusion criteria for this study.

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

1. The Committee noted that the Participant Information Sheet is overall good, however they requested that the statement ‘some of the information in this form is required by law’ is removed to ensure that the Participant Information Sheet is aimed at New Zealand participants.
2. Please add some examples of acceptable contraceptive methods to the Participant Information Sheet.
3. 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.”*
4. The Committee noted that the Participant Information Sheet for Future Unspecified Use of Tissue states that research on DNA and genetic material will not occur, however, the Consent Form allows for “research of any type”. Please ensure the information provided in these forms is consistent by adjusting the consent form statement to exclude genetic and DNA research.

Decision

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

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

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| **2** | **Ethics ref:** | **16/STH/3** |
|  | Title: | (duplicate) Genetic variation and human disease |
|  | Principal Investigator: | Dr Louise Bicknell |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 January 2016 |

Dr Louise Bicknell 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 Committee noted that this is a resubmission of a study that was previously declined by the Committee. The Committee was pleased with the higher quality of the Participant Information Sheets, stating that the form for older children was particularly well laid out and readable.
2. The Committee noted that positive peer review had been obtained from Prof. Stephen Roberts, Curekids, Paediatric Genetics, as well as a letter of support from Joanne Dixon, Clinical Geneticist & National Director of Genetic Health Service NZ.
3. The Committee noted that the study aims are much clearer in the new application.

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 application indicated that individual participants could be identified from the published study results and questioned why this was the case. The Researcher explained that the study results may include photos of the participants and due to the small number of participants it may be possible to identify individuals.
2. The Committee questioned where skin biopsies would be performed. The Researcher explained that this would vary depending on the participant’s location and that it was most likely to be at a hospital as an out-patient appointment.
3. The Committee questioned whether participants’ GPs should be informed of their participation in case of unexpected findings. The Researcher explained that the referring geneticist would be informed of any unexpected findings and also agreed to encourage participants to tell their GP about their involvement in the study.
4. The Committee noted that all participants 16 years and older will provide consent to their participation in the study, and that most children under 16 years old will assent to participate in the study and their parents will provide informed consent.
5. The Committee reminded the Researchers that although this was the most common way to obtain consent, it is also acceptable for suitably competent individuals under the age of 16 years to consent for themselves. Consequently, although the HDEC suggests providing a range of consent and assent forms based on participants’ age (assent forms for participants 7-11 years and 12-15 years, as well as parent consent forms for children unable to consent for themselves, and consent forms for participants 16 and older) this age based split of consent v. assent may not apply in all cases and it would be possible for a suitably competent participant under 16 years old to consent for themselves.
6. The Committee questioned whether the Participant Information Sheet for participants with a known diagnosis should name their diagnosis. The Researcher explained that there is a large range of possible diagnoses and that participants are expected to be well informed of their diagnosis. The Committee agreed that it was appropriate for the form to not specify the diagnosis of each individual participant

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

1. Please add the name of the study to the footer of the Participant Information Sheet and Consent Forms.
2. Please provide an assent form for younger children (7-11 years old). The Committee noted that this should be a relatively simple and short form and could benefit from pictures to help with the explanation.
3. Please provide a copy of the information sheet and consent form used to obtain consent to take and use photographs of participants.
4. The Participant Information Sheet talks about coded DNA samples but does not explain how they will be de-identified until later in the document. Please add information about this earlier in the document where coded DNA samples are first mentioned.
5. Please explain in the Participant Information Sheet that DNA is shared between extended family.
6. Please add a statement to the Participant Information Sheet regarding where samples will be sent overseas, and why they need to be sent overseas.
7. Please consider reformatting the adult Participant Information Sheet to improve readability. The Committee suggested that it may benefit from the addition of some more white space and that it is acceptable for the form to take up more pages if the readability was improved in the process.
8. The Committee noted that the Participant Information Sheet states that health information will be retained for 30 years or until the termination of the study, whichever is sooner. The Committee stated that health information must be retained for a minimum period of 10 years (Health (Retention of Health Information) Regulations 1996). Please ensure this is reflected in the Participant Information Sheet.
9. The Committee noted that the Participant Information Sheet states that all participants will give informed consent, however, most participants who are children will give assent rather than consent. Please ensure this statement is amended to improve accuracy.

Decision

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

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)*

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

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| **3** | **Ethics ref:** | **16/STH/14** |
|  | Title: | CEDOR Tissue Bank |
|  | Principal Investigator: | Dr Jeremy Krebs |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 January 2016 |

Dr Amber Parry-Strong 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 Committee appreciated the high quality of this application.

Summary of ethical issues (resolved)

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

1. The Committee questioned the governance arrangements for this study, they stated that they understand that there is a governance committee and wondered if one person had overall responsibility for the tissue bank. The Researcher explained that the clinical director, Dr Jeremy Krebs, has overall responsibility for the tissue bank.
2. The Researcher explained that the tissue bank has an annual auditing process.
3. The Committee questioned whether all applications to use tissue would be considered at the annual governance meeting. The Researcher explained that they would hold meetings as required to consider applications to use tissue from the bank.
4. The Committee noted that the Participant Information Sheet only referred to blood samples, however, the application talks about a range of tissue types. The Researcher explained that at this stage they only collect blood samples but hope to expand in future to include further kinds of tissues. The Researcher confirmed that if they change to include other kinds of tissue they will amend the Participant Information Sheet and submit this to HDEC for review.
5. The Committee questioned how long signed consent forms would be stored for as the hospital records are only stored for 15 years and tissue samples are stored for 30 years. The Researcher explained that they will store signed consent forms as long as they keep the tissue as they have their own filing system.
6. The Committee noted that the application referenced a legal review that stated no issues with the tissue bank beyond those being progressed. The Committee questioned what issues were being progressed. The Researcher explained that this referred to the lab being taken over by Southern Clinical laboratories and that this raised some possible uncertainty of the ongoing working arrangements. The Researcher stated that they expect that no changes to the working arrangements will occur with this this change, but that it also involved the development of a new MOU regarding the use of tissue from the tissue bank.
7. The Committee noted that their approval of this application is based on the working arrangements provided in this application and any substantial amendments would need to be submitted for review, minor administrative changes such as changes to the MOU that are consistent with the approved guidelines can be included in the annual reports submitted to HDEC.

Decision

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

1. Please provide a letter from your lawyer stating that this tissue bank has had legal review.

## 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:** | 15 March 2016 |
| **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 1:10pm