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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 11 December 2018 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 11:00am | Welcome |
| 11:05am | Review of approved studies (see over for details)  Review of response to provisional approval of 18/STH/177 **(CLOSED)**  Confirmation of minutes of meeting of 13 November 2018  Noting section of agenda |
| 11:45am | New applications (see over for details) |
|  | i 18/STH/222  ii 18/STH/231  iii 18/STH/240  iv 18/STH/232  v 18/STH/233  vi 18/STH/235  vii 18/STH/238  vii 18/STH/239  ix 18/STH/241  x 18/STH/242  xi 18/STH/243  xii 18/STH/245 |
| 5:10? | 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 |
| Ms Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Dr Paul Chin | Non-lay (intervention studies) | 27/10/2018 | 27/10/2021 | Present |

**Also in attendance:**

|  |  |
| --- | --- |
| *Name* | *Position (or reason for attending)* |
| Professor Jean Hay-Smith | New Member of Southern HDEC |

## Welcome

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

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Cordelia Thomas and Mrs Sandy Gill confirmed their eligibility, and were co-opted by the Chair as members 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.

The Chair welcomed the new member Professor Jean Hay Smith.

## Confirmation of previous minutes

The minutes of the meeting of 13 November 2018 were confirmed.

## Review of Responses to Provisional Approval

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| **1** | **Ethics ref:** | **18/STH/177** |  |
|  | Title: | BEDROC Study |  |
|  | Principal Investigator: | Prof Paul Glue |  |
|  | Sponsor: | Douglas Pharmaceuticals |  |
|  | Clock Start Date: | 30 August 2018 |  |

Decision

This application was *approved* by consensus.

**Closed Minutes**

## New applications

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| **1** | **Ethics ref:** | **18/STH/222** |  |
|  | Title: | The effects of oral health and family function on quality of life in young children. |  |
|  | Principal Investigator: | Dr Arun Natarajan |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 29 November 2018 |  |

Professor Murray Thompson 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 investigates how the treatment of tooth decay affects children’s day-to-day lives and family functioning more generally. Specifically, whether treatment improves quality of life for both the child and their family.

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 the researcher what they intended to do with the collected data. The researcher responded that it was to be used in multi-variant modelling, to assess whether or not scores were significant when modelling change and improvement.
2. The Committee questioned how geo-coding information was relevant to the study. The researcher responded that this enabled participants to be assigned a deprivation score.
3. The Committee asked how collecting information on prior extractions and repairs was relevant to the study. The researcher responded that when characterising the effects of dental treatment on children they need to report on what was done to them. The Committee agreed with this.
4. The Committee inquired whether the health information other than dental records would be accessed in the course of the study. The researcher confirmed that it would not be.
5. The Committee requested the phrase “putting to sleep” be changed. The researcher responded that this is a generally accepted term which people understand. The Committee accepted this explanation.

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 no plan to deal with adverse events was included in the protocol. The researcher responded that questionnaires will be answered by parents, and that the parent report is being used so that there is a single scale throughout the study. The Committee replied that there still needs to be safety provision for the parents. (*Ethical Guidelines for Observational Studies para. 4.12).*
2. The Committee queried whether different levels of treatment will be looked at. The researcher answered that two types of intervention will be analysed: quick extraction and…(missed this). The Committee stated that it was unclear in the protocol how this information will be used. (*Ethical Guidelines for Observational Studies para. 5.11).*
3. The Committee noted that no peer review had been sought for this study. (*Guidelines for Observational Studies para. 5.8*).
4. The Committee questioned why children were to receive a koha when it was the views of parents being collected. (*Ethical Guidelines for Observational Studies para. 6.25*).
5. The Committee asked for justification of why the children’s views were being excluded. (*Ethical Guidelines for Observational Research para. 4.8*).

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

1. Include a plan to deal with problems arising for parents during this study.
2. Please add a section on whanau.
3. Please fix spelling and grammatical errors.
4. Please structure the document according to the online HDEC template.
5. Please make clear that geo-coding information will be collected.
6. Remove the child consent form from the study’s documentation.

Decision

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

* Patient information sheets and consent forms that adequately secure informed consent. (*Ethical Guidelines for Observational Studies para. 6.10)*.
* Provision for the protection of participants. (*Ethical Guidelines for Observational Studies para. 4.12*).
* A protocol that clearly states the conduct and aims of the study. (*Ethical Guidelines for Observation Studies para. 5.11*).
* Adequate peer review of scientific validity. (*Ethical Guideline for Observational Studies para. 5.8*).
* Justification of exclusion conditions. (*Ethical Guidelines for Observational Studies para. 4.8*)

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| **2** | **Ethics ref:** | **18/STH/231** |  |
|  | Title: | STOP-MSU |  |
|  | Principal Investigator: | Dr Teddy Yuan-Hao WU |  |
|  | Sponsor: | The Florey Institute of Neuroscience and Mental He |  |
|  | Clock Start Date: | 29 November 2018 |  |

Dr Teddy Yuan-Hao Wu was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates whether providing intravenous tranexamic acid within 2 hours of stroke onset lowers rates of haematoma growth.

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 that haemorrhagic strokes are difficult to treat and the need for more research in this area.
2. The Committee asked how the study could be considered in a participant’s best interests. The Researcher explained that all participants, including those in the control arm, will receive additional scans on top of what they would normally receive.
3. The Committee asked how many of the patients would be incompetent to give informed consent at the time of enrolment. The Researchers stated that about half will be unable to provide informed 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. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

1. Please amend the study documents to remove any references to participant’s families, whānau, or legal guardians consenting for their participation as proxy consent is not permitted for “medical experiments” on incompetent adults in New Zealand (apart from the exceptions in s18 Protection of Personal Property and Rights Act 1988). All signatures from family members etc. should be sought on the grounds that they feel that they have been informed/consulted about their relative’s participation in accordance with Right7(4) of the Code. Right 7(4) provides that the provider can make the decision to enrol the incompetent adult if:

* Participation is in the best interests of the patient; and
* The patient’s views about the research are known and enrolment is consistent with those views; or
* The provider takes into account the views of other suitable persons interested in the welfare of the patient who are available to advise the provider (note these people do not give consent to the patient’s participation)

1. Please explain what an ECG is at first use.
2. Please use the current HDEC ACC compensation for studies with eligible patients from the HDEC website.
3. Please explain that all blood samples in the study will be collected as part of standard care.
4. Please make sure header and footer text does not merge with body text.
5. Please use a lay-friendly title as STOP-MSU is not lay friendly.
6. Please remove all references to ‘persons responsible.’
7. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by Dr Cordelia Thomas and Dr Nicola Swain

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| **3** | **Ethics ref:** | **18/STH/240** |  |
|  | Title: | TARGET Protein Feasibility Study |  |
|  | Principal Investigator: | Dr Paul Young |  |
|  | Sponsor: | Medical Research Institute of New Zealand |  |
|  | Clock Start Date: | 15 November 2018 |  |

Dr Paul Young 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

1. The study investigates protein requirements for critically ill patients on life support who are being fed by a nasal tube. It will compare the effectiveness of two guideline-recommended treatments. This is a feasibility study to check that the protocol is acceptable for a phase 3 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 queried whether patients who refuse to participate could still have their data included in the study, as indicated in the study cover sheet. The researcher clarified that in practice people participate in various degrees, such as allowing the use of already-collected data but declining follow-ups. The cover sheet allows people to agree to certain degrees.
2. The Committee asked why the research team will auto-enrol patients into the study, and why they do not foresee problems in gaining consent. The researcher responded that the study compares standard treatments, so the risks to patients outside the study are the same as those within.
3. The Committee queried how participation was in the best interest of each participant. The researcher stated that a previous large nutrition trial had found that high calorie nutrition did not increase mortality and reduced side effects. Additionally, ICU staff are more vigilant when aware a patient is involved in a study, and the patients will receive collateral benefits from participation including increased monitoring. Those involved in the trial will also benefit from long-term follow-ups.
4. The Committee observed that whanau and friends were said to be able to withdraw a person from this study, and informed the researcher that this was not the case. The researcher clarified that the study would only use friends and family as indicators of the patient’s wishes, and staff would then make a decision as to whether participation is in the person’s best interests having taken into account the views of friends/family.The committee noted that the participants wishes are not likely to be known in which case Right 7(4) of the Code requires the provider to take into account the views of suitable persons who are available to advise the provider.
5. The Committee noted that scientific review had been received from the director of the chief investigator’s institute and asked the researcher to comment on whether this was independent evaluation. The researcher stated that the study had been developed with colleagues in Australia and that the reviewer had no involvement in it.

Decision

This application was *approved* by consensus.

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| **4** | **Ethics ref:** | **18/STH/232** |  |
|  | Title: | Understanding Skin Conditions and Developing New Treatments |  |
|  | Principal Investigator: | Dr Hilary Sheppard |  |
|  | Sponsor: | The University of Auckland |  |
|  | Clock Start Date: | 13 November 2018 |  |

Dr Hilary Shepherd was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates techniques for growing sheets of skin in the laboratory using a patient’s own cells to treat skin conditions.

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 Researchers had imported cell lines for the study purposes and so did not need to transform participant’s tissue.

Summary of outstanding ethical issues

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
2. The Committee queried why the researchers were performing the study with children as participants. The Researcher explained that there are low numbers of patients with this condition in New Zealand and it is a life-limiting disease. The Committee asked the Researchers to consider amending their protocol so as to only include those over 16, and to submit an amendment to include children at a later date. (*Ethical Guidelines for Intervention Studies* *para 5.41)*
3. The Committee asked that the researcher amend the information sheets and consent forms to explain that the researchers are looking at, or limit the protocol and information sheets to focus on EB only. The researchers would then be able to submit an amendment at a later date with the required documents to include children & patients with other conditions. (*Ethical Guidelines for Intervention Studies* *para 5.41 & Ethical Guidelines for Observational Studies para 6.10)*
4. Please provide evidence of favourable independent peer review of the study protocol. The current documents read as though they are declining the study. (*Ethical Guidelines for Intervention Studies* Appendix 1)
5. The Committee noted that Māori would be excluded from the study and noted that to do so would be in contravention of the Human Rights Act 1993 and against the Treaty of Waitangi, and the recommendations of research best practice documents such as Te Mata Ira. The Committee requested that the researchers amend their study protocol to include Māori. *(Ethical Guidelines for Observational Studies para 2.5 & Ethical Guidelines for Intervention Studies* *para 5.41)*

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

1. Please explain that the project will involve the grafting of skin onto mice.
2. Please make sure all assent documents refer to assent only, not consent.
3. Please provide information sheets and assent forms aimed at ‘younger children’ and ‘older children’. This way the researchers can gauge a child’s competence and provide them with the appropriate document. Rather than going by age alone.
4. Please consistently explain the size of the skin biopsies in a lay friendly manner. i.e. 1.6cm2 should just be referred to as 14mm in diameter.

Decision

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

* The Study protocol needs significant amendment and there are issues to be addressed around the involvement of children and the scope of conditions being researched. (*Ethical Guidelines for Intervention Studies* *para 5.41 & Ethical Guidelines for Observational Studies para 6.10)*
* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* The Committee was not satisfied with the scientific validity of the study. (*Ethical Guidelines for Intervention Studies* Appendix 1)
* The Committee had strong concerns about the exclusion of Māori and asked that this exclusion criterion be removed. *(Ethical Guidelines for Observational Studies para 2.5 & Ethical Guidelines for Intervention Studies* *para 5.41)*

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| **5** | **Ethics ref:** | **18/STH/233** |  |
|  | Title: | Comparison of two brincidofovir formulations, in healthy adults. |  |
|  | Principal Investigator: | Dr Chris Wynne |  |
|  | Sponsor: | Chimerix, Inc. |  |
|  | Clock Start Date: | 29 November 2018 |  |

Dr Chris Wynne was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a phase 1 study to test the bioavailability of brincidofovir, used to treat viruses such as cytomegalovirus and adenovirus, in healthy Japanese and non-Japanese participants. Specifically, it will compare brincidofovir in both its oral and IV formulations.

Summary of outstanding ethical issues

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

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

1. Please fix pages 2 and 9, which currently tell participants to use two forms of hormonal contraception and cause confusion as to whether having had a vasectomy is a prerequisite for participation.
2. Please add that compensation will be considered for participants making extra clinic visits.
3. Please change the title on page 1 so that it is suitable for lay-people.
4. Please change the label on page 1 from consent form to information sheet.

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* *para 6.22*).

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| **6** | **Ethics ref:** | **18/STH/235** |  |
|  | Title: | IDI Health Research Study |  |
|  | Principal Investigator: | Dr Hiran Thabrew |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 29 November 2018 |  |

Dr Hiran Thabrew was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates patient views on the use of the Statistics New Zealand Integrated Data Infrastructure database’s health data for research purposes.

Summary of outstanding ethical issues

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
2. The Committee noted that the protocol and information sheet need to include study processes. For example, how participants will be informed about the IDI and how confidentiality will be managed. The Committee had concerns how bias would be managed in the informing of participants about the IDI, as the researchers would be informing participants. *(Ethical Guidelines for Observational Studies paras 6.10, 5.7, and 5.11)*
3. Please detail the data analysis plan in the protocol. *(Ethical Guidelines for Observational Studies paras 5.11)*
4. The Ethical Guidelines for Observational Studies states that researchers should justify why the inclusion of children in the study is necessary, or exclude them from the study. *(Ethical Guidelines for Observational Studies para 6.19)*
5. Please provide the Committee with the finalised list of questions that will be posed to participants. The Committee recommended open questions to help reduce risk of bias. *(Ethical Guidelines for Observational Studies paras 5.11)*
6. The Committee requested that the presentations for participants be provided. (*Ethical Guidelines for Observational Studies para 6.10)*
7. The Committee were not satisfied that this studies’ protocol had not undergone sufficient independent peer review and requested that this be provided using the HDEC template. (*Ethical Guidelines for Intervention Studies* Appendix 1)

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

1. Please simplify the information sheet for children as the information included is very technical.
2. Please make sure to explain that the IDI contains a range of data and not just health data, e.g. justice or social services.
3. Explain if study data will be sent overseas for analysis.
4. Please ensure that the title is consistent throughout all documents.

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 study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Observational Studies* *para 5.11*)
* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* The Committee were not satisfied that the scientific validity of the study and requested further review using the peer review template. (*Ethical Guidelines for Intervention Studies* Appendix 1)
* The Committee requested that the researchers justify the inclusion of children or exclude them from the study. *(Ethical Guidelines for Observational Studies paras 6.19)*
* Please provide the finalised questionnaires and IDI information presentation. (*Ethical Guidelines for Observational Studies para 6.10)*

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| **7** | **Ethics ref:** | **18/STH/238** |  |
|  | Title: | Epidermolysis Bullosa in New Zealand |  |
|  | Principal Investigator: | Doctor Russell Gear |  |
|  | Sponsor: | DEBRA International |  |
|  | Clock Start Date: | 19 November 2018 |  |

Dr Russell Gear 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

1. This is a descriptive study which seeks to collate the epidemiological, clinical, pathological, and genetic characteristics of epidermolysis bullosa in New Zealand.

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 study involved the establishment of a registry. The researcher responded no, that this was merely a one-off descriptive analysis of epidermolysis bullosa in New Zealand at present. The Committee asked why it was chosen not to establish a registry. The researcher responded that they were not in a position to proceed with that process.
2. The Committee asked how long information in this study was intended to be kept. The researcher replied that it would be retained for 10 years.

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 why this project had not consulted with Maori. The researcher answered that they saw no specific cultural issues arising in this research so didn’t think it was necessary. The Committee clarified that Maori consultation is required if they are to be included in the study. (*Ethical Guidelines for Observational Research para. 4.4*).

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

1. Please remove sections in the assent forms which address children, so that the document addresses parents only.
2. Remove request for age and NHI of parents in the assent forms.
3. Please make the name of disease clear before using acronyms.
4. Please replace terms such as ‘collate’ and ‘demographic’ with simpler language.
5. Amend mention of “verbal consent” as simply “consent.”

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 Observational Studies para. 6.10*).
* Please provide evidence of Maori consultation (*Ethical Guidelines for Observational Studies para. 4.4*).

This following information will be reviewed, and a final decision made on the application, by Mrs Sandy Gill and Dr Nicola Swain.

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| **8** | **Ethics ref:** | **18/STH/239** |  |
|  | Title: | Toward understanding how contraction stimulates glucose uptake in skeletal muscle |  |
|  | Principal Investigator: | Dr Jessica Dent |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 29 November 2018 |  |

Dr Jessica Dent was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates how contraction stimulates glucose uptake in skeletal muscle.

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

1. Please explain what is being asked of participants in lay terms. i.e. they are being asked to provide small blood and muscle samples whilst under their general anaesthetic.
2. Please explain that participant’s records have been checked prior to the invitation approach to make sure they have not got a diagnosis or history of diabetes.
3. In the “what will my participation in the study involve” section please explain it will increase the surgery duration by about five minutes.
4. The “my rights” & “what happens if I change my mind” sections duplicate that participants can withdraw until their surgery.
5. Please explain that no further participation is required after tissue is collected on the day of surgery.

Decision

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

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

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| **9** | **Ethics ref:** | **18/STH/241** |  |
|  | Title: | IM011047: A Study to Measure How Safe and Effective BMS-986165 is for the Treatment of Moderate-to-Severe Plaque Psoriasis. |  |
|  | Principal Investigator: | Prof Marius Rademaker |  |
|  | Sponsor: | Bristol-Myers Squibb (NZ) Limited |  |
|  | Clock Start Date: | 29 November 2018 |  |

Prof Marius Rademaker was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is a multi-centre, randomised, double-blind, placebo-and active comparator-controlled study to evaluate the efficacy and safety of BMS-986165 in people with moderate-to-severe plaque psoriasis.

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

1. Please amend ‘required’ to complete closeout with ‘asked’.
2. Please seek parental consent for babies’ participation once they are born alive. Parents cannot consent for this prior to birth.
3. Please remove any statements about cancer from the information sheet.
4. Please clearly state if the drug will no longer be available at the end of the study, or if there will be compassionate extension.

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* *para 6.22*).
* Please amend the study protocol to explain how patients who disclose mental health issues, such as suicidal ideation, will be cared for. (*Ethical Guidelines for Intervention Studies* *para 5.41*)

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| **11** | **Ethics ref:** | **18/STH/242** |  |
|  | Title: | WORTH study |  |
|  | Principal Investigator: | Assoc Prof Rinki Murphy |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 29 November 2018 |  |

Associate Professor Rinki Murphy was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates how two additional medications for type 2 diabetes effect patients’ glucose levels.

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 if there is any Future Unspecified Research occurring as part of the study. The Researcher confirmed that there is not.

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 how the recruitment process would work. The Researchers explained that they will be accessing patient records in order to identify who is eligible for participation. The Committee asked that clinical staff who are not involved with the study perform this task to protect patient privacy; as the Researchers should not be involved until the participants have consented to participate. *(Ethical Guidelines for Observational Studies para 6.46 & 5.10)*
2. 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)*
3. Please provide protocol-specific peer review as the grant award letter for this study does not show that this study’s protocol has been reviewed, only the programme. (*Ethical Guidelines for Intervention Studies* Appendix 1)

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

1. Please remove tickboxes except where the item is truly optional, e.g. to receive a summary of results of the study.
2. Please remove the ‘please add site-specific logo’ text.
3. On page three of the document please explain the randomisation process in more simple terms. Participants should be able to understand they will be randomly assigned to one, and then will receive the other after four weeks. I.e. that there is a crossover.
4. Please use a lay title that is not a potentially leading acronym. The non-lay title can remain ‘the WORTH’ study but this should not be on any patient-facing documents until after their consent.
5. Please explain that the differences in responses between Māori and Pākehā is one of the features that the researchers are investigating. To not disclose this would be a deception of participants.
6. Please explain the risks of adverse drug reactions and interactions including: what they are, their severity, and how frequently they occur.
7. 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.”*
8. Please explain that the samples will be held for up to 15 years, due to potential delays in testing, but will then be destroyed. Please also give the option for disposal with karakaia if possible.

Decision

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

* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 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)*
* Please change the process for screening of potential participants, taking into account the suggestions made by the committee*. (Ethical Guidelines for Observational Studies para 6.46 & 5.10)*

This following information will be reviewed, and a final decision made on the application, by Mrs Sandy Gill and Associate Professor Mira Harrison-Woolrych

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| **12** | **Ethics ref:** | **18/STH/243** |  |
|  | Title: | 298 Youth Health Centre ACE Survey |  |
|  | Principal Investigator: | Dr Ronan Whyte |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 29 November 2018 |  |

Dr Ronan Whyte was not 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

1. The study investigates the extent to which adverse childhood experiences (ACE) affect recovery from mental illness and functional outcomes in young people with mental health diagnoses.

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 they did not believe the risks of using the ACE-Q model questionnaire had been adequately mitigated. The Committee had concerns that this way of using the questionnaire could cause distress for people completing it. The Committee raised delayed shock response as a significant risk that had been omitted. The Committee noted that a twelve months follow up timeframe would not be safe and that there should be a more recent follow up *(Ethical Guidelines for Observational Studies paras 4.2.b & 4.9 – 4.12)*
2. The Committee noted that they would like to see further evidence for the efficacy of the modified version of the questionnaires. *(Ethical Guidelines for Observational Studies para 5.8)*
3. The Committee noted that the application notes that wraparound care would be available in the event of stress but what this would entail is missing from the protocol. *(Ethical Guidelines for Observational Studies para 5.11)*
4. The Committee stated that there was a conflict of interest by having youth workers identify potential participants for approach. Staff involved in a potential participant’s care should not make the initial research approach due to the power imbalance and risks of coercion in an already vulnerable group. *(Ethical Guidelines for Observational Studies para 6.11)*
5. The Committee noted that it is unusual to involve untrained youth workers in research and were not reassured that these individuals would have the skills to conduct the study. The Committee noted that the youth workers would be administering questionnaires, randomising participants, and making research approaches. The Committee stated that they would need to be assured that all study staff have the appropriate expertise to conduct study processes. *(Ethical Guidelines for Observational Studies para 5.9)*
6. The Committee noted that studies should only be conducted by those with the relevant skills and experience. The Committee were not assured that the lead investigator and youth workers has the relevant skills to lead a study in a vulnerable population with Māori being overrepresented. The Committee noted that skills to provide routine services and skills to conduct research are different and the risks involved with research are higher. *(Ethical Guidelines for Observational Studies para 5.9)*
7. The Committee noted that the application stated that there would be no issues for Māori. The Committee noted that whakamā would be a potential issue for Māori participants and asked that a process for managing this be developed. *(Ethical Guidelines for Observational Studies para 4.4 & 4.8)*
8. The Committee noted that peer review had been provided but requested further peer review from a psychiatrist or psychologist. *(Ethical Guidelines for Observational Studies para 5.8)*
9. The Committee noted that points 14, 16, 17, and 18 from the previous decline letter did not appear to have been addressed. *(Standard Operating Procedures for Health and Disability Ethics Committees paras 128 – 129)*
10. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

1. The Committee asked that the language be checked for appropriateness. For example, ‘incarcerated’ is not an appropriate term for young people and may be too complex.
2. The Committee asked that the HDEC template wording for ACC-covered studies be inserted into the information sheet.
3. Please change “impact of negative childhood experiences” to more appropriate language, e.g. refer to stressful life events.
4. Please explain that only those over 16 will be invited to participate, not all young people.
5. Please explain what information will be provided to youth workers.
6. Please explain what the 12 months follow up will involve and how long it will take.
7. Please explain the confidentiality process for data. Where will it be stored, and for how long? The Committee noted that all health information in the study must be retained for ten years, as per the law.
8. Please add an independent Māori cultural support contact person’s details to the end of the information sheet. This person must be informed about the study but be independent from the study team.

Decision

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

* The information sheet needs revisions, including those made as part of the previous decline decision. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* The Committee stated that risks associated with the study remained high in light of the potential benefits from participation. The Committee stated that these risks must be mitigated. *(Ethical Guidelines for Observational Studies paras 4.2.b & 4.9 - 4.12)*
* The Committee had concerns over the involvement of potentially untrained or inexperienced staff in research that appears to carry significant risk to participants. The Committee stated that they must be assured that all persons involved in the study have the necessary skills to conduct the study. Otherwise it would be unethical to expose participants to risks that cannot be suitably managed and risks the scientific validity of the study. *(Ethical Guidelines for Observational Studies para 5.9)*
* The Committee noted that points of the previous decline letter remain outstanding and must be addressed. *(Standard Operating Procedures for Health and Disability Ethics Committees paras 128 – 129)*
* The Committee stated that scientific issues with the study and use of the questionnaire must be addressed. This includes the need for scientific review by a psychologist or psychiatrist. *(Ethical Guidelines for Observational Studies para 5.8)*
* Please amend the study protocol taking into account the suggestions made by the Committee. *(Ethical Guidelines for Observational Studies para 5.11)*

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| **12** | **Ethics ref:** | **18/STH/245** |  |
|  | Title: | MK3475 799 |  |
|  | Principal Investigator: | Dr Gareth Rivalland |  |
|  | Sponsor: | MSD |  |
|  | Clock Start Date: | 30 November 2018 |  |

Dr Gareth Rivalland was not 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

1. The study inv the effectiveness of pembrolizumab in combination with platinum doublet chemotherapy and radiotherapy for patients with unresectable, locally advanced Stage III Non-Small Cell 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 noted that the quality of the application was very high.

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

1. Add Māori cultural support contact details to the information sheet. Please note that this cannot be the Health and Disability Commissioner’s Advocacy Service as they do not provide Māori cultural support.
2. Please refer to the HDEC contraception wording template which defines what forms of birth control are acceptable and available in a New Zealand context.
3. Please use yes/no tickboxes for the final two bulleted options on the consent form.
4. Please add information about what questions the study doctors will ask as part of enrolment and then seek consent for this in the consent form.
5. Please remove references to legally authorised representatives as a proxy cannot consent tor an incompetent adult’s participation in research in New Zealand (apart from the exceptions in s18 Protection of Personal Property and Rights Act 1988).

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* *para 6.22*).

## Substantial amendments

## Review of approved studies

## 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:** | 29 January 2019, 11:45 AM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

The following members tendered apologies for this meeting.

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.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 4:15pm