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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 22 November 2016 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:005pm | Confirmation of minutes of meeting of 18 October 2016 |
| 12:30pm | New applications (see over for details) |
|  | i 16/STH/188  ii 16/STH/177  iii 16/STH/181  iv 16/STH/182  v 16/STH/184  vi 16/STH/185  vii 16/STH/186  viii 16/STH/187  ix 16/STH/183 |
| 4:15pm | Substantial amendments (see over for details) |
|  | i 16/STH/104/AM01  ii 14/STH/115/AM05  iii 14/STH/115/AM06  iv 14/STH/115/AM07 |
| 5:15pm | General business:   * Noting section of agenda |
| 5:45pm | 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 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 | Apologies |
| Dr Devonie Eglinton | 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 Sarah Gunningham | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |

## Welcome

The Chair opened the meeting at 12pmand welcomed Committee members, noting that apologies had been received from Dr Mathew Zacharias.

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 22 November 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/STH/188** |
|  | Title: | The Christchurch Health and Development Study - 40 Year Follow-up |
|  | Principal Investigator: | A/Prof John Horwood |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 November 2016 |

Dr John Horwood 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 is the 40 year follow up assessment for participants enrolled in the Christchurch Health and Development Study.
2. The study is a longitudinal study of 1265 participants who were born in Christchurch in 1977.
3. Extensive information will be collected about study participants. This includes life history, health status, and psychosocial functioning.

Summary of ethical issues (resolved)

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

1. The Committee queried how many of the original cohort are still participating in the study. The researcher stated that around 80% of the cohort are still participating.
2. The Committee noted that previous consent has been acquired for research participation
3. The Committee stated that the participant information sheet was well designed and presents the information in a very accessible way.
4. The Committee noted that the study has informed policy development in the health and social sectors and has the potential to contribute to knowledge.
5. The Committee noted that 5 participants would be unable to provide informed consent for their continued participation in the study. However, the researcher provided adequate justification for their continued inclusion in this longitudinal trial with consent being obtained from NOK as has been done previously.
6. The Committee noted that as the study continues more participants may become unable to provide informed consent for continued participation in the study, as a result of medical events or trauma. The Committee suggested that this may be mitigated by including an optional check box in the next consent form, allowing participants to select whether they would like to continue to be included in the study even if they lost the ability to provide informed consent at some point in the future.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **16/STH/177** |
|  | Title: | (duplicate) CTLA4-Ig (Abatacept) Prevention Trial |
|  | Principal Investigator: | Professor Russell Scott |
|  | Sponsor: | Walter and Eliza Hall Institute of Medical Research |
|  | Clock Start Date: | 10 November 2016 |

Dr Jinny Willis 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 the potential of the drug abatacept to delay the onset of type one diabetes.
2. The study population is comprised of individuals who are in the at risk group of type 1 diabetes.
3. The researcher explained that the study population will have around an 80% chance of developing type 1 diabetes over 15 years.
4. Participants will receive regular infusions of abatacept, with a period of observation after each dose.

Summary of ethical issues (resolved)

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

1. The Committee queried if the study drug is approved for use in children. The researcher stated that the drug is and referred to the investigator’s brochure which contains examples of studies using the drug that have been conducted with children.
2. The Committee queried what the expected outcomes of the study are. The researcher explained that the only successful trial of the drug has shown that there can be a delay in diagnosis of up to four and a half years.
3. The Committee asked if the researchers will continue to provide the drug after the trial ends. The researcher explained that barring any compassionate reasons they will not. This is due to the drug being donated and the study not being sponsored.
4. The Committee requested that information and consent for future unspecified research be provided in a separate form.
5. The Committee enquired as to what kinds of birth control are recommended for study participants. The researcher explained that they do not have a definitively recommended method of contraception. The committee requests that the participant information sheet include a section informing partners about contraception and specifying the type(s) of contraception that is best recommended

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

1. Please include a section in the participant information sheet that explains what types of contraception are recommended.
2. Please include a section in participant information sheet that informs the partners of study participants about what type of contraception to use.
3. Please amend the title of the 12-15 year old assent form to reflect the age group it is targeted at.
4. Please add a parental signature block to the assent forms for future use.
5. Please amend the study documents so that information and consent for future unspecified research is given in a single, separate form.

Decision

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

The non-standard conditions are as follows:

* 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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| **3** | **Ethics ref:** | **16/STH/181** |
|  | Title: | A Study Comparing the safety and effectiveness of 3 different doses of study medication to placebo in people with early Alzheimer's Disease |
|  | Principal Investigator: | Dr Nigel Gilchrist |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 10 November 2016 |

Dr Nigel Gilchrist 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 the effectiveness of the study drug ABBV-8E12, which is an immunotherapy medication, against a placebo.
2. Three of the four arms of the study will provide a different dose of the study drug.
3. Participants in this study will have minimal symptoms, most will have minor memory impairments.
4. There will be 6 participants recruited in New Zealand with 400 recruited worldwide.
5. Participants will be aged between 55 and 85.

Summary of ethical issues (resolved)

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

1. The Committee queried the use of a lumbar puncture procedure to collect a cerebrospinal fluid sample. The researcher explained that this procedure is the fastest way for researchers to detect the presence and levels of the protein that the drug combats.
2. The researcher explained that lumbar punctures would be performed under radiological guidance. The researcher explained that participants will also receive a full neurological workup and imaging. This will also provide more certainty of diagnosis and the progression of their disease.
3. The Committee asked if study participation will require participants to stop other medications. The researcher explained that participants will be able to continue any other medications where participants are receiving a stable dose.
4. The Committee asked about the payment for medicines statement in the participant information sheet. The researcher explained that this was there in error and would be removed.
5. The Committee queried the blinding process. The researcher explained that there will be two pharmacists, one blinded and the other unblinded. This helps ensure individuals receive the correct doses.
6. The Committee asked what would happen if a participant’s partner is unwilling or unable to continue. The researcher explained that unless a participant has a family member, partner, or other person who sees them on a regular basis then they will not be able to continue in the study. The Committee requested that the participant information sheet be amended to reflect this.
7. The Committee noted that the protocol wording implies that consent by proxy would be sought in this study. The Committee stated that proxy consent is only legally acceptable in cases where the medical experiment would save the person’s life or prevent serious damage to the person’s health. Therefore the documents should only be used to gauge views of relatives/ friends/ EPOA of potential participants involved that are unable to consent for themselves. This means that the forms should not involve language whereby the relative/friend/EPOA consent on behalf of someone else. As an alternative, the language should reflect that the document seeks the friend/relative/EPOA’s view that the non-consenting person would be agreeable in participating. This is in line with Right 7(4)cii: If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.
8. The Committee noted that the participant information sheet was of high quality.
9. The Committee noted that the study has received approval from the Standing Committee on Therapeutic Trials.

Summary of ethical issues (outstanding)

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

1. Please make sure that the text of the information sheet and consent form is broken up into a sufficient number of paragraphs. The Committee felt that this will make the information more accessible to participants.
2. Please include information about the number of individuals who have received the drug to date, the number of doses they have been exposed to, and the range of doses used in humans to date. Please state how this relates to the doses used in the current study.
3. Please clarify the information about retention of samples and their storage duration.
4. Please make sure that all information about future unspecified research is removed from the main information sheet and is confined to the future unspecified research information sheet and consent forms.

Decision

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

The non-standard conditions are as follows:

* 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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| **4** | **Ethics ref:** | **16/STH/182** **(CLOSED)** |
|  | Title: | A study comparing how fast the trial drug GS-9876 is cleared from the body, in healthy adults and in adults with mild, moderate and severely reduced kidney function. |
|  | Principal Investigator: | Dr Richard Robson |
|  | Sponsor: | Gilead Sciences, Australia and New Zealand |
|  | Clock Start Date: | 10 November 2016 |

Dr Richard Robson was present in person for discussion of this application.

Potential conflicts of interest

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

Dr Devonie Eglinton declared a conflict of interest on this application. The Chair resolved that she would not be able to participate in the discussion

Decision

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

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| **5** | **Ethics ref:** | **16/STH/184** |
|  | Title: | Evaluation of the Nurse Maude/St John's staysafe@home service trial |
|  | Principal Investigator: | Mr Tom Love |
|  | Sponsor: | St John |
|  | Clock Start Date: | 10 November 2016 |

Dr Tom Love was present via teleconference for discussion of this application.

Ms Gill Coe and Ms Mary-Anne Stone were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the models and technologies involved in home care. They will be analysing the personal alarms, heat detectors, and smoke detectors and how they notify St John’s and Nurse Maude.
2. Anyone elderly person who lives alone or who spends long periods of time alone will be eligible for study participation.

Summary of ethical issues (resolved)

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

1. The Committee queried why this study would be considered health research. The researchers explained that while aspects of the study can be considered an audit, as defined under the Standard Operating Procedures, their project also has an intervention like design and outcomes.
2. The Committee asked if the study data had already been used and linked with DHB data. The researchers explained that data had already been linked. The researchers stated that it had and that the data had already been provided to the Principal Investigator. The Committee stated that they are unable to provide approval for studies that have already commenced. The Committee requested that the data be destroyed and the researchers reapply. The researchers stated that they are committed to good process and would duly destroy the data.
3. The Committee asked if the coordinating investigator is independent or contracted to St John’s. The researchers explained that the investigator is contracted to St John’s Ambulance but is otherwise independent.
4. The Committee noted that the researcher would be covered by the same privacy rules and laws as St. John’s Ambulance as a result of this contract.
5. The Committee noted that under the Health Act the sharing of data between two providers is permitted for the purposes of clinical care of individuals receiving treatment from those two providers. The Committee stated that this exception does not apply to research.
6. The Committee stated that all research participants need to have the capacity to be able to provide consent for participation. The researchers stated that they are not intending to recruit anyone who is not able to provide informed consent for themselves. The Committee stated that participants will need to be certified as able to consent by a qualified professional who can provide a clinical judgement.
7. The Committee suggested that the researchers approach an independent advice body to help them with their research design and application.
8. The Committee requested that the researchers contact InterRAI to ensure that all data disclosure for research purposes is compliant with InterRAI requirements.
9. The Committee enquired if the study is simply an evaluation of care. The researchers explained that the Nurse Maude will be providing additional care as part of the study.
10. The Committee queried if the items used in the study are commercially available from the sponsor. The researchers stated that these devices are available online but are not available from St. John’s.

Summary of ethical issues (outstanding)

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

1. The Committee requested that the researchers use suitable information sheets and consent forms. The Committee suggested that the researchers use the templates provided by the Health and Disability Ethics Committees website as a guide. These templates can be found here: <http://ethics.health.govt.nz/>
2. The Committee requested that the researchers confirm that the study is legal. Please provide evidence that the disclosure of health information is being done lawfully.
3. The Committee requested that a participant information sheet and consent form for the control group be developed unless the researchers can provide justification for why seeking their consent is not necessary.
4. Please check to see if the Nurse Maude’s enrolment form includes specific consent for research.
5. The Committee stated that the protocol and application must be clearer about what is being done in the study.

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

1. Please removal emotional statements from the participant information sheet.
2. Please remove all promotional statements form the participant information sheet and consent form.
3. Please remove any leading statements from the participant information sheet.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* This study, as presented in this application, involves accessing health information from patients, and speaking to their clinicians, without consent. The Committee was very concerned that health information had been accessed for research purposes, without consent, and prior to approval by an HDEC. The Committee noted that participants have a right to know that their health information is being used in research. Right 6(1)(d) of the HDC Code of Rights states:
  1. *Every consumer has the right to information that a reasonable consumer, in that consumer’s circumstances, would expect to receive, including … notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval.*

The Committee noted that they can approve access to identifiable health information without consent for research in certain circumstances. The Ethical Guidelines for Observational Studies states at Paragraph 6.43:

* 1. *Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:*
     1. *the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and*
     2. *there would be no disadvantage to the participants or their relatives or to any collectives involved; and*
     3. *the public interest in the study outweighs the public interest in privacy.*

To approve a study involving access to health information without consent the Committee must be satisfied that these requirements are met by the study concerned.

* Please ensure the trial is registered with a WHO-approved clinical trials registry before the study commences. *Standard Operating Procedures for Health and Disability Ethics Commitees para 126.3)*

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| **6** | **Ethics ref:** | **16/STH/185** |
|  | Title: | Things that matter to children in hospital |
|  | Principal Investigator: | Mr Shayne Rasmussen |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 10 November 2016 |

Mr Shayne Rasmussen and Ms Annette Dickinson 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. The study builds on previous research about children’s experiences of hospitalisation. The researchers explained that there needs to be more in depth research done on family member’s understanding and experience of this process.
2. The study will interview children about their experiences and supplant this with staff interviews to build a better understanding.

Summary of ethical issues (resolved)

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

1. The Committee stated that the data in this study is partially de-identified, not de-identified.
2. The Committee noted that Māori consultation box was not correctly filled out and reiterated the importance of consultation with Māori.
3. The Committee noted that given participants a made-up name was a good and suitable method of de-identification for the study population.
4. The Committee queried the age of the children in the study. The researchers explained that the younger group of children will be aged between five and eight. The Committee suggested that the researchers consider using pictorial consent.

Summary of ethical issues (outstanding)

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

1. Please provide suitable information sheets and assent forms. This includes an information sheet and consent form for parents of participants unable to provide informed consent, an information sheet and consent form for participants able to provide their own informed consent (this includes all participants aged 16 years or older and may include some younger participants if they are deemed competent), an information sheet and assent form for children, and a very simple information sheet and assent form for young children that should very simply explain their participation in the study. Guidance on assent can be found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>.
2. The Committee requested that the language in the information sheets, assent, and consent forms be checked for suitability to their audience.
3. The Committee stated that health information from the study must be retained until participants turn 16.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please provide suitable information sheets and assent forms. This includes an information sheet and consent form for parents of participants unable to provide informed consent, an information sheet and consent form for participants able to provide their own informed consent (this includes all participants aged 16 years or older and may include some younger participants if they are deemed competent), an information sheet and assent form for children, and a very simple information sheet and assent form for young children that should very simply explain their participation in the study.

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

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| **7** | **Ethics ref:** | **16/STH/186** |
|  | Title: | Parenting From the Start |
|  | Principal Investigator: | Ms Leith Pugmire |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 November 2016 |

Ms Leith Pugmire and Dr Natasha Tassell-Matamua 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. The study investigates the effect of an antenatal evidence-based parenting workshop and a sling on the health outcomes and development of newborn infants.
2. Participants will be randomised to a waiting list control or the intervention group. Intervention group participants will participate in a parenting workshop and be given a sling. After one year control participants will participate in a workshop and receive a sling.

Summary of ethical issues (resolved)

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

1. The Committee queried if the researchers will provide the Ministry of Health guidance on bed sharing. The researchers explained that they will.
2. The Committee queried why other methods will be presented if the Ministry of Health guidelines have been presented. The researcher explained that international research shows that not talking about methods of bed sharing and the issues arising from these is correlated with negative outcomes.
3. The committee stated that due stress should be placed on NZ guidelines for both sleeping and feeding and that no sense of blame for birthing interventions be presented.
4. The Committee queried the Quaker grant that was received by the researcher and if the Quakers would have any interaction with the study. The researchers explained that they received a Quakers scholarship but otherwise they have no impact, control, or access to the study.
5. The Committee queried the blinding of the study. The researcher explained that to not blind participants could contaminate the results and would make the control group no longer a control.
6. The Committee queried the age range of mothers. The researcher explained that there is no age range and mothers will be randomised.
7. The Committee queried if low study recruitment would have an effect on the powering of the study. The researchers explained that previous studies with low numbers have been powered and that they are prepared to extend the recruitment phase of the study as required.

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

1. Please make sure the information sheet explain that participants may be allocated to the control arm of the study.
2. Please check the language of the information sheet for complexity. The Committee felt that the language was too scientific and not layperson friendly.
3. Please remove all promotional wording and tools from the information sheet and advertisement. In particular, remove the statement “not available elsewhere” and remove any bolding, underlining, capitalisation or italicising of the word “free” from both documents.

Decision

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

The non-standard conditions are as follows:

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

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| **8** | **Ethics ref:** | **16/STH/187** |
|  | Title: | Micronutrient RCT for depression and anxiety during pregnancy |
|  | Principal Investigator: | Dr Julia Rucklidge |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 November 2016 |

Dr Julia Rucklidge and Ms Hayley Bradbury were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is a double blind, randomised control trial of a micronutrient formula versus a placebo in third trimester pregnant women who have depression.
2. The first phase of the study lasts for twelve weeks where participants will receive a placebo or micronutrients.
3. In the second phase of the study all participants will receive micronutrients until birth.
4. The researchers will follow up with mothers at one, three, and 6 month intervals.

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 study drug can cross the placenta and thus the foetus will be exposed to the drug.
2. The Committee noted that only women in their third trimester of pregnancy will be recruited. This will help offset any congenital anomalies.
3. The Committee stated that they had serious concern about the intervention standards for depression and anxiety and requested these be added to the participant information sheet.
4. The committee asked what is being done to diagnose anxiety and depression and if this would involve the diagnosis of clinically significant disorders. The researchers explained that this would involve diagnoses. The Committee stated that the researchers must inform participants of the current best intervention standard upon them receiving a diagnosis.
5. The Committee asked if consent for future unspecified research is being sought as part of this study. The researchers explained that at this time there is not. The Committee stated that if the researchers wish to seek consent for future unspecified research then this must be sought using a separate participant information sheet and consent form.

Summary of ethical issues (outstanding)

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

1. The Committee asked about the use of painkillers and their use alongside the study drug and which painkillers are safe to use alongside the study drug. The Committee requested that the information sheet be amended to clearly explain which medicines are listed as safe in pregnancy and for use with the study drug.
2. The Committee requested that information sheets and consent forms be provided to participants undergoing the paternal survey part of the study.
3. The Committee requests what procedures will be put in place to manage diagnosis of clinical symptoms of the fathers participating in the survey. Please amend the study protocol to explain this.
4. The committee expressed concerns that diagnosing of psychiatric disorders be done by suitably qualified interviewers.
5. The Committee asked about the qualifications of the research advisor to make these diagnoses. The researchers explained that Dr Rucklidge is qualified to make such diagnoses and that they will be made under her supervision. Please clarify the process of how diagnoses will be made.

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

1. Please add information on the current best standard of care for significant depression and anxiety to the first page on the information sheet, in bold.
2. Please amend the title of the information sheet to be lay-friendly
3. Please add a footer with the study title to each page.
4. Please change the language around the frequency of the term ‘daily essential nutrients.’
5. Please remove the name Hardy’s from the information sheet and consent forms.
6. Please only state adverse effects and not positive effects in the side effects section.
7. Please explain that samples will be sent overseas and where they will be sent.
8. Pleas state that participants may see an increase in their symptoms.
9. Please include advice and information about when and how to contact psych emergency services.
10. Please state that if participants see an increase of symptoms then they should contact their GP.
11. Please make sure that the information sheet clearly states the current best intervention standard and alternatives to study participation.
12. 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.”*
13. Please remove unnecessary tickboxes from the consent form.
14. Please provide a separate information sheet and consent form if data from this study will be made available for future research.
15. Please clearly state which painkillers are safe to be used alongside the study drug.
16. Please amend the consent form to have participants agree to the disclosure of study participation and any diagnoses to their GP and lead maternity carer.

Decision

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

* Please provide evidence of the outcome of SCOTT review. (*Ethical Guidelines for Intervention Studies* Appendix 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*).
* Please provide the participant information sheet, consent forms, and questionnaires for the paternal survey.
* Please provide a new study protocol that includes how diagnoses of clinically significant symptoms of participants taking part in the paternal survey will be managed. (*Ethical Guidelines for Intervention Studies paras 7 to 7.14)*

This following information will be reviewed, and a final decision made on the application, by Ms Angelika Frank Alexander and Dr Mira Harrison-Woolrych.

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| **9** | **Ethics ref:** | **16/STH/183** |
|  | Title: | INTEGRATE II |
|  | Principal Investigator: | Professor Michael Findlay |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 November 2016 |

Professor Michael Findlay and Ms Kathryn Johntstone 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 is a randomised phase three, double-blind placebo controlled study of the drug regorafenib in patients with advances oesophageal cancer.
2. The study aims to determine if the study drug improves the survivability of patients.
3. Three participants will be recruited in New Zealand. Six participants had been recruited in Australia at the time of 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 stated that participant information sheet was of very high quality.
2. The Committee stated that participants should not need to fill out a form to withdraw from the study.

Decision

This application was *approved* by consensus.

## Substantial amendments

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| **1** | **Ethics ref:** | **16/STH/104/AM01** |
|  | Title: | Ketamine therapy among patients with treatment-res |
|  | Principal Investigator: | Professor Paul Glue |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 November 2016 |

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

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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The main application was approved with the condition that the name of the active control was stated in the participant information sheet. Following discussion with the Co-ordinating Investigator, the researcher now wishes to remove the name of the active control.
2. The Committee queried the argument put forward that participants would be unblinded in the event that the active control was named, as they would recognise the symptoms of midazolam. However, elsewhere in the submitted documentation it is stated that the doses used in the study are low and are unlikely to be associated with symptoms. This was confirmed by the researcher. The Committee reasoned that if the effects of the two drugs are significantly different at the doses administered, blinding will be difficult to maintain whether the active control is named or not. If no significant difference in effects is anticipated the justification provided for with-holding the name of the active control appears flawed.
3. The Committee noted that participants will be asked if they have allergies to medicines relating to the study drug or active control and thus will be able to make reasoned inferences about the nature of the drug they are on. Therefore the blinding would not be sufficient.
4. The Committee stated that there needs to be better scientific justification for not informing participants about the active control and that they had not received sufficient explanation.

Decision

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

The Committee felt that they had not received sufficient scientific justification for the removal of the name of the study drug from the information sheet. *(Ethical Guidelines for Intervention Studies Appendix 1).*

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| **2** | **Ethics ref:** | **14/STH/115/AM07** |
|  | Title: | The Anorexia Nervosa Genetics Initiative (New Zeal |
|  | Principal Investigator: | Professor Martin Kennedy |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 November 2016 |

Professor Martin Kennedy was present in person for discussion of this amendment.

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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee stated that they were unable to check the consistency of study materials with the Broad institute document as presented.
2. The Committee stated that they would require evidence being provided by the researchers for how the new documents are consistent.
3. The Committee requested that the researchers resubmit the amendment with more information about how the consent form and use of tissue is consistent with the Broad Institute data use limitation document.
4. The Committee suggested that the researchers check the document against the HDEC guidance for future unspecified use of tissue.

Decision

Following discussion with the researcher it was agreed that the researcher would withdraw the amendment and resubmit it at a later date.

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| **3** | **Ethics ref:** | **14/STH/115/AM06** |
|  | Title: | The Anorexia Nervosa Genetics Initiative (New Zeal |
|  | Principal Investigator: | Professor Martin Kennedy |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 November 2016 |

Professor Martin Kennedy was present in person for discussion of this amendment.

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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee stated that participants have the right to withdraw from trials at any time and that following up with individuals who had specifically opted not to consent to the use of samples for other research would be considered coercion.

Decision

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

The Committee stated that participants are free to decide about their participation in research and that the chasing up of individuals who have declined to consent could be considered coercion. (*Ethical Guidelines for Intervention Studies paras 6.7 -6.8)*.

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| **4** | **Ethics ref:** | **14/STH/115/AM05** |
|  | Title: | The Anorexia Nervosa Genetics Initiative (New Zeal |
|  | Principal Investigator: | Professor Martin Kennedy |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 November 2016 |

Professor Martin Kennedy was present in person for discussion of this amendment.

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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee noted that they can approve access to identifiable health information without consent for research in certain circumstances. The Ethical Guidelines for Observational Studies states at Paragraph 6.43:
2. *Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:*
3. *the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and*
4. *there would be no disadvantage to the participants or their relatives or to any collectives involved; and*
5. *the public interest in the study outweighs the public interest in privacy.*

To approve a study involving access to health information without consent the Committee must be satisfied that these requirements are met by the study concerned.

Decision

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

The Committee stated that there had not been sufficient justification provided for the disclosure of data without consent (*Ethical Guidelines for Observational Studies paras 6.43)*.

## 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:** | 13 December 2016, 12:00 PM |
| **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 5:45pm.