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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 16 August 2016 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:15pm | Training – Use of Health Information Without Consent |
|  | Confirmation of minutes of meeting of 19 July 2016 |
| 12:30pm | New applications (see over for details) |
|  | i 16/STH/123  ii 16/STH/122  iii 16/STH/112  iv 16/STH/113  v 16/STH/114  vi 16/STH/119  vii 16/STH/121  viii 16/STH/104  ix 16/STH/111 |
| 4:15pm | General business:  Noting section |
| 4:30pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 27/10/2015 | 27/10/2018 | Present |
| Mrs Angelika Frank-Alexander | Lay (consumer/community perspectives) | 27/10/2015 | 27/10/2018 | Present |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Nicola Swain | Non-lay (observational studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Mathew Zacharias | Non-lay (health/disability service provision) | 27/10/2015 | 27/10/2018 | Present |
| Dr Devonie Eglinton | Non-lay (intervention studies) | 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 |

## Welcome

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

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 21 June 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/STH/123** |
|  | Title: | (duplicate) Effect of probiotic BLIS M18 on the post-radiotherapy oral microbiome. |
|  | Principal Investigator: | Associate Professor Richard Douglas |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 05 August 2016 |

Dr Kim Gear and Miss Anna Vesty 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 Committee noted that this is a resubmission of a previously declined application.
2. The Committee felt that the concerns raised in their initial declined has been well addressed by the resubmission of this application, including the protocol being much more specific and higher quality peer review.
3. The Committee congratulated the researchers on their new application and stated that the concerns were well addressed and the application much improved.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether the study involved any Future Unspecified Use of Tissue. The Researcher confirmed that there would be no storage or use of tissue beyond the end of this research project.
2. The Committee questioned whether any placebo would be used by the control group, such as a lozenge without the study component. The Researcher explained that there was no lozenge for the control group, they would just get standard of care.
3. The Committee noted that the peer review questioned the lack of a placebo lozenge. The Researcher stated that they have considered this but are unable to have a placebo lozenge because there is no similar looking lozenge available for the control group.
4. The Committee noted that the number of participants in the study had been increased in response to comments by the peer reviewer.

Summary of ethical issues (outstanding)

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

1. Please revise the Participant Information Sheet to ensure clarity regarding whether participants can have their tissue returned or withdrawn from the study at any time.
2. The Participant Information Sheet includes statements regarding the tissue being used or stored for future research, but as this no longer applies to this study, these statements must be removed.
3. Please ensure the name of the approving ethics committee is correct in the Participant Information Sheet, this should be the ‘Southern Health and Disability Ethics Committee’ or the ‘Southern HDEC’.
4. The Committee were pleased that the statements regarding possible benefits from the study lozenge were removed, however, please add a statement to the potential benefits section that participants may receive no benefit from their participation.

Decision

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

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*).

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| **2** | **Ethics ref:** | **16/STH/112** |
|  | Title: | EPOC |
|  | Principal Investigator: | Dr Ravinder Ogra |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 August 2016 |

Dr Gary Lim 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 study investigates whether antiplatelet therapy needs to be stopped prior to elective colonoscopy.
2. This study aims to determine whether the rate of use of intraprocedural endoscopic rescue clips or clinically significant post-polypectomy bleeding differs in patients continuing on clopidogrel, prasugrel or ticagrelor compared with those who temporarily cease them. Patients potentially benefit from continuing their antiplatelet medication with ongoing cardiovascular protective effects whilst also having removal of small polyps at colonoscopy.
3. Participants will be randomised to continue their antiplatelet medication or not. Some patients who are at increased risk will continue with their usual medication. All participant’s cardiologists will be consulted, as is standard of care, to determine if their medication can be stopped safely.
4. The Committee stated that this is an interesting study with practical implications.

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 questions regarding potential cultural issues in the application form were not well addressed. Please be more careful about answering these questions in future.
2. The Committee noted that due to some questions in the application form being incorrectly answered, some later questions regarding participant access to ACC do not appear. The Committee stated that although they can determine that participants will have access to ACC these questions must be answered correctly in future.
3. The Committee raised concerns about participants being asked to conceal their group allocation from the doctor performing their colonoscopy. The Researcher explained that the risks will be managed by having all doctors being fully aware of the study and treating all patients like they are at increased risk of bleeding, and the doctors are able to find out a patients group allocation if necessary.
4. The Committee questioned whether the risk of perforation needs to be mentioned in the Participant Information Sheet. The Researcher stated that the risk is so minimal they do not feel it needs to be mentioned. The Committee accepted this.

Summary of ethical issues (outstanding)

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

1. The Committee noted that the potential side effects are well explained in the Participant Information Sheet.
2. Please state in the Participant Information Sheet that if large polyps are discovered during the colonoscopy that participant may need to come back for another procedure.
3. Please remove all Australian references, statements, and wordings from the Participant Information Sheet. The Participant Information Sheet must be New Zealand specific.
4. Please revise the Participant Information Sheet to ensure that the references to Group 1 and Group 2 are consistent throughout. Currently at some points it states that Group 1 continue to take their medication and other sections state that Group 2 continue to take their medication.
5. The Committee noted that currently the Participant Information Sheet states that it is desirable for participants to inform their GP of their participation, however they would prefer that all participants’ GPs are informed and that this is done by the research team. Please revise the Participant Information Sheet to be clear that all participants’ GPs will be informed of their study participation and it should be noted on the consent form.
6. Please revise the Consent Form taking in to account the statements included in the HDEC template.
7. Please clarify in the Participant Information Sheet what participants must do if they experience any bleeding.
8. The Committee noted that the Consent Form currently offers the option for participants to receive a copy of the published results. Please replace this with the option to receive a lay summary of the results that will be presented in a way accessible to participants.
9. The Committee noted that currently a withdrawal of consent form is included. Please revise this form to ensure it is very clear that participants do not need to complete this form, they can withdraw their consent verbally or by email and that this form is optional.
10. Please state that patients will continue on their current dose of aspirin (delete the 75 or 100mg.
11. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
12. Please remove the reference to catholic institutions from the Participant Information Sheet as it this does not apply in New Zealand.
13. Please clarify in the Participant Information Sheet the reasons for participants to not tell the doctor performing their colonoscopy their group allocation and include statements about how this risk is managed, including that doctors will assume all participants are at increased risk and can find out their group allocation if necessary.
14. The Committee noted that some statements in the Participant Information Sheet are unclear, such as ‘the risk is potentially very small’, please revise the Participant Information Sheet to ensure clarity of all statements.
15. Please remove assumptive language from the Participant Information Sheet, this includes statements like ‘you will be participating in a study’ and ‘once we have received your consent’ as these assume patients will consent to being in the study. The Committee suggests the use of statements like ‘if you agree to be in the study…’.

Decision

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

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*).

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

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| **3** | **Ethics ref:** | **16/STH/113** |
|  | Title: | (duplicate) vTv Therapeutics-TTP488-301/ STEADFAST |
|  | Principal Investigator: | Dr Nigel.L Gilchrist |
|  | Sponsor: | inVentiv Health Clinical |
|  | Clock Start Date: | 03 August 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 Committee noted that this is a resubmission of a previously declined application.

Summary of ethical issues (resolved)

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

1. The Committee questioned how participants would be prevented from taking the study drug incorrectly (by accident/due to memory issues). The Researcher explained that the involvement of participants’ caregivers was intended to mitigate this risk, and that the number of pills remaining will be checked at each study visit. The Researcher also confirmed that the pills could be provided in blister packs to reduce the risk of confusion. The Committee agreed that this would help.
2. The Committee questioned whether participants whose mental capacity deteriorated during the study would be withdrawn from the study. The Researcher explained that as participants provided fully informed consent at the point of recruitment they would remain in the study unless they (or their caregiver) indicated that they would no longer like to participate. If the participant’s caregiver decides at any point that they do not wish to be in the study for any reason they can withdraw, and as participation for patients requires a participating caregiver the patient participant will no longer be eligible to participate if their caregiver decides to withdraw from the study.
3. The Committee questioned how it is determined whether a participant needs to be withdrawn from the study. The Researcher explained that this is covered in the study protocol and can be for a number of reasons.
4. The Committee questioned whether this study involves any Future Unspecified Use of Tissue. The Researcher confirmed that it does not and samples will only be used for this study, not stored or tested after the study ends.

Summary of ethical issues (outstanding)

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

1. The Committee stated that although the Participant Information Sheet is much improved from the initial application they feel that it is still too long and complex for the participant group. Please revise the Participant Information Sheet to shorten and simplify it.
2. The Committee noted that the information sheets and consent forms suggest that consent to participation will be obtained from caregivers on behalf of the patients if the patient loses the ability to provide informed consent. However, at no point does this study involve proxy consent. Please revise the Participant Information Sheet and Consent Form to ensure it is clear that patients and their caregivers give their own informed consent to participate and if one of a pair withdraws, this automatically withdraws the other (as an inclusion criteria is for a participating patient to be linked with a participating caregiver).
3. The Participant Information Sheet refers to previous studies of this drug in animals, however it has also been tested in humans, so please also include this information in the Participant Information Sheet.
4. Please revise the Participant Information Sheet to be clear what happens to a participant’s tissue samples during and after the study, including whether they can withdraw them later. The Committee noted that participants should retain the right to withdraw their data and/or samples if it is possible to do so. It also needs to be made clear that data from samples which have already been analysed, and other information that has already been collected, will continue to be used, even if the participant withdraws from the study.
5. Please give the Participant Information Sheet a lay study title.
6. The Committee suggests that the Participant Information Sheet should begin with a simple 1 page summary of the study and what is required.
7. The Committee requested that the sponsor’s company name is shortened throughout the Participant Information Sheet, as each time it is stated in full and this reduces the readability of the Participant Information Sheet.
8. Please revise the Participant Information Sheet to remove or explain any technical/medical terms.
9. Please consider adding tables and diagrams to the Participant Information Sheet if possible, to help clearly explain the study to those with reduced cognitive function.

Decision

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

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*).

This information will be reviewed, and a final decision made on the application, by Dr Mathew Zacharias and Mrs Angelika Frank-Alexander.

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| **4** | **Ethics ref:** | **16/STH/114** |
|  | Title: | VerICiguaT glObal study in subjects with heart failure with Reduced ejectIon frAction (VICTORIA) |
|  | Principal Investigator: | Professor Richard Troughton |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited |
|  | Clock Start Date: | 03 August 2016 |

Professor Richard Troughton and Ms Renee Malcolm 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 main objective of this study is to evaluate the efficacy of vericiguat in comparison to placebo on a background of standard of care in increasing the time to first occurrence of the composite of cardiovascular death or Heart failure (HF) hospitalization in subjects with Heart Failure with reduced ejection fraction.

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 questions regarding data safety monitoring for this study were well answered in the application form.
2. The Committee questioned who would make the initial approach to potential participants. The Researchers explained their plan is for a member of the research team to make the initial approach to prevent participants getting the impression that the study is endorsed by their clinicians or part of their care plan, this is to reduce the risk of any conflicts of interest. The Committee stated that it is their preference that potential participants are asked by their treating clinician whether they are interested in being approached about a research project before a member of the research team is able to contact them. The Committee explained that this is to prevent the details of unwilling patients being given to researchers without their consent, and to ensure that the approach by the research team is not a shock to participants, but they do appreciate the value of having the consent process completed by someone independent from the participant’s treating team. The Researcher agreed that this would be a suitable recruitment method and they would adopt this.
3. The Committee noted that the question in the application form regarding the potential for reducing health inequalities was poorly answered. The Researcher apologised for this and offered more information on the potential results to reduce inequalities as Māori are disproportionately affected by cardiac issues. Because Māori are disproportionately represented in patients with the condition being studied, they are also expected to make up a higher proportion of the participants in the study.

Summary of ethical issues (outstanding)

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

1. The Committee queried the lack of a Māori tissue statement in the sub-study 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.”*
2. The Committee noted that the sub-study uses leftover blood from the main study and does not involve the collection of new blood. Because of this, the risks of pain from blood draws should not be included in the Participant Information Sheet for the sub-study.
3. The Participant Information Sheet for the main study indicates that participants must withdraw in writing, however, in New Zealand verbal withdrawal is legally binding and any withdrawal of consent form must be optional.
4. Please clearly state in the Participant Information Sheet whether participants samples can be withdrawn if they decide to not continue their participation in the study.
5. Please include a statement regarding the requirement to use contraception in the Consent Form, the Committee suggests the following statement *‘I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy.’*
6. Please replace the study title on the Participant Information Sheet with a shorter title, the Committee suggests that ‘VICTORIA’ would be suitable.
7. Please do not refer to the main Participant Information Sheet in the Participant Information Sheet for the sub-study, specifically the sub-study Participant Information Sheet should either have its own statement about compensation and the availability of ACC.

Decision

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

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*).

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| **5** | **Ethics ref:** | **16/STH/119** |
|  | Title: | The MINIMIZE-AF Study |
|  | Principal Investigator: | Professor Richard Troughton |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 August 2016 |

Professor Richard Troughton 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 the use of spironolactone for the treatment of paroxysmal (intermittent) atrial fibrillation.
2. This study will recruit participants with previously implanted implanted cardiac device that can record the occurrence of atrial fibrillation, this is primarily to allow accurate recording of instances of atrial fibrillation.
3. Participants will be randomised to either the spironolactone or placebo treatment, and occurrences of atrial fibrillation will be measured throughout the study to compare the study groups.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether the study results will be generalizable, given that all participants will have some type of more serious heart condition requiring an implanted pace maker device and that most patients with paroxysmal AF do not require an implanted device. The Researcher explained that this initial study is primarily a proof of concept and if spironolactone is shown to have benefit in this population (in whom occurrences of AF can be measured very precisely), future studies will include a broader range of participants.
2. The Committee questioned whether any participants may be on drugs that could adversely interact with the study drug, in particular digoxin, which is used for the treatment of AF. There is a potential interaction between spironolactone and digoxin which may increase drug levels and it may be necessary to monitor digoxin levels in some participants. The Researchers agreed that this was a possibility and that they will investigate further and consider monitoring for such interactions during the study. .

Summary of ethical issues (outstanding)

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

1. Some technical terms in the Participant Information Sheet are not explained, please revise to ensure each technical term is explained the first time it is used.
2. Please revise the Participant Information Sheet to remove typographical and grammatical errors.
3. Please revise the main Participant Information Sheet to remove any optional aspects of the study (for example, collection of tissue samples for genetic research) and include these in separate information sheets and consent forms. This helps to ensure it is clear what is optional.
4. Please be clear that tissue will be sent overseas as part of the optional sub-study, but that this tissue is not being sold.
5. Please state the maximal allowable dose in the Participant Information Sheet and clarify that participants will be given a much lower dose.
6. Please include contraception information for male participants in the Participant Information Sheet.
7. Please include information on all possible drug interactions in the PIS and explain what action may need to be taken if any such interactions occur.

Decision

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

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*).

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| **6** | **Ethics ref:** | **16/STH/121** |
|  | Title: | A Single and Multiple Dose PK-PD study of ketamine in healthy volunteers and patient cohorts |
|  | Principal Investigator: | Professor Paul Glue |
|  | Sponsor: | Douglas Pharmaceuticals America Ltd |
|  | Clock Start Date: | 04 August 2016 |

Professor Paul Glue, Dr Tak Hung and Linda Folland 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.

Dr Nicola Swain declared a potential conflict of interest. The Committee decided to allow her to stay in the room but not participate in the discussion or decision making for this application.

Summary of Study

1. The purpose of this study is to investigate the safety and tolerability of ketamine when administered orally (in the form of a 60 mg tablet formulation).
2. Traditionally ketamine is administered as an injection and is quick acting. This study will investigate an oral tablet form of ketamine as a controlled release formulation (takes longer to release in the body).
3. This study will be conducted in 5 cohorts with different dose levels.
4. Cohorts 1-3 will be conducted in healthy volunteers, Cohort 4 will be conducted in 12 patients with either treatment resistant depression or treatment resistant anxiety, Cohort 5 will be a fasting/fed crossover study conducted in 12 healthy participants.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether the dosing of participants in this study will be staggered. The Researchers clarified that within cohorts, participants would not have staggered dosing, but one cohort will be dosed and their results reviewed by the independent data safety monitoring group before the next cohort begins dosing. The Committee agreed that this is acceptable as this is not a new medicine.
2. The Committee raised concerns about the potential for participants to develop an addiction to Ketamine due to their exposure during this study. There is potential for misuse of ketamine as it is a medicine known to produce a “high” in some people and is easily available online. The Researchers explained that they feel there is a minimal risk of this due to the slow release they expect from oral Ketamine giving less of a high, they do not expect a pleasurable high from such a low dose. The Committee questioned whether they would be monitoring the level of “high” experienced by participants. The Researcher stated that they currently did not have a plan to do so, but could provide a validated questionnaire to participants in the first two cohorts and if these participants were reporting experiencing a significant high they could re-evaluate the dosing of the following cohorts. The Committee agreed that this would be suitable.
3. The Committee questioned whether participants in cohort 4, with treatment resistant depression, would have to stop current medications. The Researcher clarified that they remain on all existing medication.
4. The Committee questioned whether participants in cohort 4 will be well enough to provide informed consent. The Researcher assured the Committee that they would be.

Summary of ethical issues (outstanding)

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

1. The Committee noted that limited information on expected side effects listed in the Participant Information Sheet. The Researcher explained that the side effects are known for injected ketamine but they expect that oral ketamine may have different side effects. The Committee stated that some information on possible side effects should be listed in the Participant Information Sheet, however, this could include a statement explaining that these are the known side effects for injected ketamine and are expected to differ for oral ketamine.
2. The Committee recommended that the risks are listed in a bullet point format in the Participant Information Sheet.
3. Please ensure the Cohort name is more prominent on the Participant Information Sheet.
4. Please revise the inclusion and exclusion criteria in the Participant Information Sheet to reduce the technical wording and make it more accessible for lay participants.

Decision

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

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*).
2. Please provide further information on the questionnaire that will be provided to participants, including a copy of what participants will be given.

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

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| **7** | **Ethics ref:** | **16/STH/104** |
|  | Title: | Ketamine therapy among patients with treatment-resistant depression |
|  | Principal Investigator: | Professor Paul Glue |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 July 2016 |

Professor Paul Glue 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.

Dr Nicola Swain declared a potential conflict of interest. The Committee decided to allow her to stay in the room but not participate in the discussion or decision making for this application.

Summary of ethical issues (resolved)

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

1. The Committee questioned how the dose level was determined for this study. The Researcher clarified that participants are dosed based on their weight.
2. The Committee questioned how long participants are monitored post dosing. The Researcher stated that participants are monitored for 2 hours.
3. The Committee questioned whether participants will provide informed consent before completing screening questionnaires. The Researcher confirmed this is the case.
4. The Committee noted that the application form had been incorrectly completed and indicated that no unexpected findings could be found, however it is possible that they may be found.

Summary of ethical issues (outstanding)

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

1. The Committee stated that the Participant Information Sheet supplied with this application is poor.
2. Please add page numbers and footers to the Participant Information Sheet.
3. Please move any information on optional aspects of the study, such as Future Unspecified Use of Tissue to separate Participant Information Sheets and Consent Forms, the Committee suggested that these are developed in line with the HDEC template.
4. Please emphasise in the Participant Information Sheet that participants should not drive or operate heavy machinery. Please also clarify that participants will have taxis paid for so they do not need to drive.
5. Please remove the information defining ‘placebo’ in the Participant Information Sheet as this study does not use a placebo but rather an ‘active control’ and this terms should be used and explained instead.
6. The Committee noted that participants must be told what the active control is and fully informed of its possible risks and side effects. Please ensure this is added to the Participant Information Sheet.
7. Please clarify in the Participant Information Sheet how long participants will be in the study as currently it states that the study runs for 3 years, however, participants are only in the study for 8 weeks. The Committee noted that participants do not need to know the expected timeframe for the complete project, just how long their participation would be.
8. Please add another heading to the Participant Information Sheet for the risks associated with blood tests to ensure they are clear.
9. Please add a separate section in the Participant Information Sheet for the reproductive risks and ensure information is included for men and women.
10. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: *You may hold beliefs about a sacred and shared value of 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.”*
11. The Committee noted that the Participant Information Sheet does not need to justify the study design and any references should be removed.
12. Please include information on withdrawing from the study in the Participant Information Sheet, this should include information on whether tissue and data can be withdrawn.
13. Please revise the Participant Information Sheet to ensure clarity for lay participants.
14. Please remove tick boxes from the Consent Form for all statements that are not truly optional, meaning that a participant could select ‘no’ and still participate in the study.
15. Please notify all participants’ GPs of their participation in the study, this should be included in the Participant Information Sheet.

Decision

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

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*).

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

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| **8** | **Ethics ref:** | **16/STH/111** |
|  | Title: | Early Ketamine PK-PD |
|  | Principal Investigator: | Professor Paul Glue |
|  | Sponsor: |  |
|  | Clock Start Date: | 28 July 2016 |

Professor Paul Glue 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.

Dr Nicola Swain declared a potential conflict of interest. The Committee decided to allow her to stay in the room but not participate in the discussion or decision making for this application.

Summary of ethical issues (outstanding)

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

1. The Committee noted that this study involves very early blood draws post dosing and a number of blood draws in quick succession to determine why Ketamine works so quickly. The Committee identified that it may be difficult to draw these blood samples due to the strain on veins, however, they did not feel this posed a significant safety risk but rather a practical issue.
2. The Committee stated that the peer review provided with this application was of poor quality and did not include any comments by the peer reviewer about what was considered. Please provide further evidence of the peer review process.
3. Please emphasise in the Participant Information Sheet that participants should not drive or operate heavy machinery. Please also clarify that participants will have taxis paid for so they do not need to drive.
4. 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.”*
5. Please add information to the Participant Information Sheet about the risks associated with taking blood samples.
6. Please remove tick boxes from the Consent Form for all statements that are not truly optional, meaning that a participant could select ‘no’ and still participate in the study.

Decision

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

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*).

## General business

1. The Committee noted the content of the “noting section” of the agenda.

1. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 20 September 2016, 12:00 PM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

The following members tendered apologies for this meeting.

Mrs Angelika Frank-Alexander

1. **Problem with Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

The meeting closed at 4:15pm