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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 13 February 2018 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 11:30am | Welcome |
| 11:35am | Confirmation of minutes of meeting of 01 February 2018 |
| 11:45am | New applications (see over for details) |
|  | i 18/STH/38  ii 18/STH/40  iii 18/STH/26  iv 18/STH/27  v 18/STH/29  vi 18/STH/30  vii 18/STH/34  viii 18/STH/35  ix 18/STH/36  x 18/STH/24  xi 18/STH/25 |
|  | Substantial amendments (see over for details) |
|  | i 16/STH/168/AM01 |
| 4:00pm | General business:   * Noting section of agenda |
| 4:15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 27/10/2015 | 27/10/2018 | Present |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Apologies |
| 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 |
| Mrs Stephanie Pollard | Non-lay | Co-opt NTB | Co-opt NTB | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Fiona McCrimmon | Lay (the law) | 27/10/2015 | 27/10/2018 | Present |
| Dr Anna Paris | Lay (other) | 24/08/2017 | 24/08/2020 | Present |
| Dr Kate Parker | Non lay | Co-opt NTA | Co-opt NTA | In attendance |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that apologies had been received from Dr Sarah Gunningham and Assc Prof Mira Harrison-Woolrych.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Mrs Stephanie Pollard and Dr Kate Parker 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.

## Confirmation of previous minutes

No minutes of previous meetings were available to confirm.

## New applications

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| **1** | **Ethics ref:** | **18/STH/38** |
|  | Title: | GS-US-389-2024 A Phase 2 Study to Evaluate the Safety, Tolerability and Antiviral Activity of GS-9688 in Patients with Chronic Hepatitis B |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 01 February 2018 |

Ed Gane and Chin Kuh 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. 50 people will be enrolled in the study looking at the investigational drug. This drug is thought to be curative for Hepatitis B. There are also optional genetic testing and optional Future Unspecified Use of Tissue. Also uploaded is an optional PK study and optional leukephersis sub-study.

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 participants will be informed post-study whether they have received treatment or placebo. The Researcher confirmed that they would be told.
2. The Committee questioned whether study participation would prevent participants participating in future therapeutic Hepatitis B studies. The Researcher explained that they would still be eligible and participants in the Phase 1 trial would also be eligible to participate in this study.
3. The Committee questioned whether participation in the sub-study is being paid at a higher rate than participation in the main study. The Researcher explained that participation in the sub-study is quite invasive and participants are unlikely to be able to return to work the same day as participation, making the time commitment higher than it may first appear.
4. The Committee questioned how the numerous Participant Information Sheets are presented to participants. The Researcher clarified that after explaining the main Participant Information Sheet to participants the person completing enrolment will go over the possible sub-studies with participants.

Summary of ethical issues (outstanding)

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

1. Please clarify in the Participant Information Sheet that participants would remain eligible to participate in future therapeutic studies.
2. Please replace the term ‘subject’ with ‘participant’ in all participant facing documents.
3. Please consider simplifying the schedule of assessments table
4. The current level of detail in the Participant Information Sheet is likely to be confusing for most lay participants, please simplify these documents.
5. The Participant Information Sheet gives no indication of potential curative or therapeutic benefit, although it is important to not overstate the possible benefits of study participation some indication of the potential effects of the study drug can be given.
6. Please explain that participants will be informed after the study whether they were randomised to the active or placebo arm.
7. The form’al protocol title should be removed from the Participant Information Sheet as participants only need to know the lay title.

Decision

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

* 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:** | **18/STH/40** |
|  | Title: | Mitochondrial dysfunction and radiotherapy for rectal cancer |
|  | Principal Investigator: | Dr Jesse Fischer |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 February 2018 |

Dr Jesse Fischer 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 Waaka declared a potential conflict of interest, the Committee decided to allow her to remain in the room but not participate in decision making for this study.

Summary of Study

1. This study investigates whether mitochondrial activity be used to identify a potential marker of therapeutic response to radiotherapy for rectal cancer.

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 formal Māori cultural consultation has been undertaken. The Researcher confirmed that it has.
2. The Committee noted that the peer reviewer mentioned possible slow and difficult recruitment and questioned how this will be addressed. The Researcher explained that although they know it may be difficult to recruit participants they believe they can recruit sufficient numbers for statistical significant even if they cannot meet their recruitment aims.
3. The Committee questioned how participants will be initially approached, noting their preference that participants are initially approached by a member of their clinical care team. The Researcher explained that they can have a nurse make the initial approach and if participants are interested the researcher will complete the enrolment process.
4. The Committee questioned the screening process. The Researcher explained that he would screen the colonoscopy lists and identify potential participants, for the nurse to then approach. The Committee noted that as the researcher is not a member of the clinical team, and would be accessing the health information without consent solely for the purposes of research, that this access must be justified to the Committee.
5. The Committee explained that under Rule 11(2) of the Health Information Privacy Code (HIPC) the disclosure of identifiable health information without consent is allowed for (ethically approved) research if it is not desirable or practicable to obtain individual authorisation. The Committee noted that, although the obligation to meet the requirements of the HIPC lies with the agency that holds the information, the Committee cannot approve a study if it does not comply with New Zealand law.
6. The Committee discussed whether it was desirable to obtain individual authorisation, the Committee agreed that if practicable it is desirable to obtain consent from individual participants prior to accessing their identifiable health information.
7. The Committee discussed whether it is practicable to obtain consent prior to identifiable health information being accessed by researchers. The Researcher explained that they had considered a number of potential methods for identifying potential participants without the researcher having access to identifiable health information, including having the health information screened by a member of the potential participant’s clinical care team instead of by the researcher. However, the Researcher explained that in their opinion none of the methods they had considered would be practicable, for example if they relied on each participant’s clinician to refer them to the study this would be likely to produce variable referrals from different clinician’s interpretations of the inclusion criteria (impacting the scientific validity of the study), and it would also not be practical as the clinicians would not have the time to screen all patients to identify those who may be eligible for study participation.
8. The Committee explained that overall they felt that it was not practicable to obtain consent from individual participants before identifiable information is disclosed to the researcher. The Committee noted that the agency that holds this information will need to ensure that the requirements of the HIPC are met before disclosing this information.
9. The Ethical Guidelines for Observational Studies states at Paragraph 6.43:

*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:*

* + - *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*
    - *there would be no disadvantage to the participants or their relatives or to any collectives involved; and*
    - *the public interest in the study outweighs the public interest in privacy.*

1. 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.
2. The Researcher explained that they believe there is solid justification for the study as it is investigating an important clinical question and would potentially offer improved care for future patients. Further the Researcher explained that he has sought to minimise the access to information without consent and minimise any distress experienced by participants due to the method of recruitment.
3. The Committee questioned whether it would be possible for participants to be recruited without the researcher screening their health information. The Researcher explained that due to the number of clinicians in the unit it would not be possible to rely on these clinicians to screen and identify potential participants, and relying on the triage system could reduce the scientific validity of the study.

Summary of ethical issues (outstanding)

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

1. Please combine the additional Participant Information Sheet page for Māori participants into the main Participant Information Sheet
2. The information sheet has information for Dr Fischer, then the consent form switches to Professor Frizelle, please change this to be consistent throughout. Both researchers can be referenced throughout and the contact numbers for both should be included in the Participant Information Sheet.
3. Please add page numbers to the Participant Information Sheet.
4. Please clarify in the Participant Information Sheet that the study is being conducted for the researcher’s studies.
5. Please revise the statement in the Participant Information Sheet about a ‘diagnosis being made’ to ‘results being available’ as this is likely to reduce distress for participants.
6. 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.”*
7. Please don’t collect ethnicity on the consent form, this is not a data collection form.

Decision

This application was *approved* by vote, with 6 for and 1 against, and Dr Fiona McCrimmon dissenting, subject to the following non-standard condition:

* 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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| **3** | **Ethics ref:** | **18/STH/26** |
|  | Title: | Strategies to prevent age related eye diseases |
|  | Principal Investigator: | Professor Paul J Donaldson |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 01 February 2018 |

Professor Paul J Donaldson 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 Kate Parker declared a potential conflict of interest, the Committee decided to allow her to remain in the room but not participate in decision making for this study.

Summary of Study

1. This study seeks to investigate whether animal research on age related eye disease translate to humans.

Summary of ethical issues (resolved)

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

1. The Committee questioned the consent process for tissue stored in the eye bank. The Researcher explained that when families consent to tissue being donated to the eye bank they are given the option of the tissue being used for research, only tissue donated with consent for research will be used in this study.
2. The Committee questioned the response to the question in the application form asking the researcher to identify ethical issues posed by the study, as this was answered ‘not applicable’. The Researcher apologised for poorly answering this question. The Committee explained that in future applications more care must be taken to identify potential ethical issues such as the risks of confidentiality breach.
3. The Committee questioned where tissue stored for Future Unspecified Use of Tissue will be kept. The Researcher explained that it will be stored in the Auckland Regional Tissue Bank, which is HDEC registered.
4. The Committee questioned if there are any questionnaires or surveys involved in the study and the researcher confirmed that there are none.
5. The Committee questioned whether Māori cultural consultation has been undertaken. The Researcher explained that this was required for their programme grant. The Committee noted that this is not a box ticking exercise and is important, especially for a study involving the use of tissue.

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 questioned whether comments for the peer review are available for this study. The Researcher explained the peer review process and noted that no protocol specific review had been undertaken. The Committee requested evidence is provided of scientific peer review for this study, the Committee suggested that the HDEC template is used to obtain the peer review (*Ethical Guidelines for Intervention Studies* Appendix 1).

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

1. Please clarify in the Future Unspecified Use of Tissue Participant Information Sheet that tissue will only be used for eye related studies.
2. Please add a footer to participant facing documents including page and version numbers.
3. Please ensure formatting, including text spacing is consistent throughout participant facing documents.
4. Please revise the first paragraph of the Participant Information Sheet to improve lay readability.
5. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: *“You may hold beliefs about a sacred and shared value of 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.”*
6. Please refer to the ‘principal’ investigator, not the ‘principle’ investigator.
7. 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.”*
8. Revise confidentiality section in light of HDEC Participant Information Sheet template.
9. Please see the HDEC template for the required contact details and ensure these are in the Participant Information Sheet.
10. Please revise the Consent Form to include a section for the enrolling clinician to sign, indicating that the participant has had the study explained to them and understands study involvement.
11. Please remove the yes/no columns from the Consent Form for all statements that are not truly optional, meaning that a participant could respond ‘no’ and still participate in the study.
12. Please remove the statement about retaining samples from the main Consent Form, this should only be included in the optional Future Unspecified Use of Tissue Participant Information Sheet.
13. Please ensure the Consent Form references the correct HDEC, this study is being approved by the Southern HDEC.
14. Please state very early in the Participant Information Sheet what participation involves.
15. The Committee requested that the font size of the Participant Information Sheet is increased to assist participants with impaired eyesight to read the information.

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 evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).

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

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| **4** | **Ethics ref:** | **18/STH/27** |
|  | Title: | Visualisation rate of duodenal ampulla with and without a capped wide-viewing gastroscope |
|  | Principal Investigator: | Dr Wayne Bai |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 February 2018 |

Dr Wayne Bai 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 ethical issues (resolved)

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

1. The Committee questioned how long it will take to recruit for this study. The Researcher stated that they believe they can recruit for the study in a few months.
2. The Committee questioned how the study is being funded. The Researcher explained that there is no funding for the study.
3. The Committee noted that the application form incorrectly indicates that the study uses Kaupapa Māori research methodology.
4. The Committee questioned the stopping criteria for the study. The Researcher explained that they will conduct a statistical analysis every 100 participants and can use this information to stop the study if necessary.
5. The Committee questioned whether the peer review comments about potential delay have been responded to. The Researcher explained that the comments were in references to a possible reduction in patient treatment delay if the study technique is successful.
6. Please ensure the purpose of the study is more clearly stated in future applications.

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 explained to the researcher that the application form should be answered in lay language and not ask the committee to refer to the protocol.
2. The Committee questioned the need for 400 participants in a feasibility study, please provide further justification for this in a feasibility study.
3. The Committee questioned how participants would be approached about the study. The Researcher explained that the Participant Information Sheet would be sent to potential participants by the booking clerk. The Committee explained that if the first time participants hear about the study is by post then the Participant Information Sheet must be of very high quality and be accompanied by a well written invitation letter, which has not been provided.
4. Please provide more information about Māori cultural consultation for this study.
5. The Committee noted that the application form indicated that the study has independent data safety monitoring. The Researcher explained that they just have routine hospital monitoring. The Committee requested that this information is provided accurately in future, adding that it is important that this study has some specific adverse event monitoring and this should be added to the study protocol. Every intervention study should have appropriate oversight of the conduct of the study to ensure the safety of the participants and the integrity and validity of the study data (Ethical Guidelines for Intervention Studies paragraph 6.38).
6. Please ensure that health information is retained for 10 years post collection, not 10 years post patient recruitment.

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

1. The Committee stated that the Participant Information Sheet needs to be completely re-written, please use the template to guide this revision. Please ensure that the Participant Information Sheet is reviewed by some lay people before resubmission to HDEC.
2. Please remove or revise references to cancer in the Participant Information Sheet as the current wording is likely to alarm participants and make them concerned that they may have cancer.
3. Please add a picture or diagram to help explain the different study treatments.
4. Please remove the yes/no columns from the Consent Form for all statements that are not truly optional, meaning that a participant could respond ‘no’ and still participate in the study.
5. Please clearly explain current standard of care in the Participant Information Sheet.
6. Please clearly state in the Participant Information Sheet what happens if the papilla can’t be seen during the study. It must be clear for participants that continuing to look for the papilla, longer than they would for standard care, could increase the time the procedure takes.
7. The Participant Information Sheet currently provides information both on what happens in standard care and what happens in the study, please revise this to only explain what happens in the study as information on standard care should be provided elsewhere and this will help make it clear for participants how study participation differs from standard care.
8. Please ensure the Participant Information Sheet clearly explains randomisation.
9. Please revise the Participant Information Sheet as it currently states that no personal information is being collected, however this is incorrect as clinical details are being collected.
10. Please clarify in the Participant Information Sheet how the risks of standard care are increased by study participation.
11. Please clarify in the Participant Information Sheet whether any other aspect of the participant’s care could be affected by study participation.
12. Please clarify in the Participant Information Sheet that there is no expected benefit to participants.
13. Please review the Participant Information Sheet for typographical and grammar errors.
14. A footer containing version number and date to be included in the Participant Information Sheet.
15. Please change "Please read and understand all the pages" to "Please make sure you have read and understand all the pages..."
16. 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.”*
17. 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.”*
18. Please remove the yes/no columns from the Consent Form for all statements that are not truly optional, meaning that a participant could respond ‘no’ and still participate in the study.

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*).
* Please ensure that the application form is completed more carefully in future applications.
* Please respond to the outstanding ethical concerns detailed above.

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| **5** | **Ethics ref:** | **18/STH/29** |
|  | Title: | EXTEND-IA TNK - Part 2 |
|  | Principal Investigator: | Dr Teddy Yuan-Hao WU |
|  | Sponsor: | The Florey Institute of Neurosciences and Mental H |
|  | Clock Start Date: | 01 February 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. This is part II of a II-part study and will investigate superiority of tenecteplase 0.4mg/kg v 0.2 mg/kg in achieving reperfusion post ischaemic stroke in patients proceeding to endovascular clot retrieval.
2. The principal ethical issue is obtaining consent in acutely unwell individuals requiring time-critical treatment, and the inclusion of non-competent adults in the study.
3. The Committee commended the high quality of the 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 the researchers have put forward a good argument for the inclusion of non-competent adults, and have specifically stated that each individual will be included only if the clinician believes it is in that individual's best interests to participate. The Committee stated that they are comfortable that this criteria can be adequately assessed given the available literature and interim results (study Part I).
2. The Committee stated that the frequent review to re-assess competency is commended.
3. The Committee noted that ethnicity should be collected as part of this study.
4. The Committee questioned the involvement of family, whanau, and EPOAs in the study. The Researcher confirmed that they will not be providing consent on behalf of the participants, but if available will be consulted regarding whether the participant would want to participate in the study if able to participate in the study.
5. The Committee questioned whether consulting with family could delay this time sensitive treatment. The Researcher explained that they have time available to consult with family if they are available, the Researcher noted that this has worked well in the previous study.

Summary of ethical issues (outstanding)

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

1. 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.”*

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/30** |
|  | Title: | Co-designing a self harm app |
|  | Principal Investigator: | Associate Professor Sarah Hetrick |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 01 February 2018 |

Associate Professor Sarah Hetrick 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 ethical issues (resolved)

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

1. The Committee noted that in the application form it is indicated that Māori cultural review is not required for this study, but this is incorrect. The Researcher explained that cultural review has already been undertaken and this question in the application was answered incorrectly.
2. The Committee commended the quality of the safety plans for the study, noting that they are some of the best they have seen.
3. The Committee noted that as this study involves group workshops that confidentiality cannot be maintained and this must be clearly explained to participants.
4. The Committee questioned whether the workshops are all being facilitated by suitably qualified professionals. The Researcher confirmed that they are.
5. The Committee questioned when participants will sign the Consent Form. The Researcher explained that they will verbally explain the study to participant over the phone when inviting them to participate, then again before the workshop where they will provide written informed consent.
6. The Committee questioned whether all participants will be over 16 years old. The Researcher confirmed that they would be.
7. The Committee questioned whether the study exclusion criteria are sufficient to protect participants. The Researcher explained that they have used these exclusion criteria in similar studies before and found them to be suitable.
8. The Committee questioned how support would be provided for participants who become distressed during study participation. The Researcher explained that as participants will be recruited through clinical services they will be able to refer them back to these services as required.

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 questioned the suitability of the peer review for this study. The researcher explained the peer review process undertaken. The Committee requested that further peer review for this specific study protocol is undertaken, they suggested that the HDEC peer review template would be useful in providing this evidence.

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

1. Please fix formatting issues in the Participant Information Sheet.
2. Please check the headings and footers of the information sheets to ensure they are correct.
3. Please revise the Participant Information Sheet to remove all typographical errors.
4. Please add to Participant Information Sheet how info will be kept, where it will be kept, and for how long and how identifiable it will be.
5. Please update the study title on all participant facing documents to clarify that this is an app for self-harm prevention.
6. Please ensure the study title is correct on all participant facing documents.

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)*

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

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| **7** | **Ethics ref:** | **18/STH/34** |
|  | Title: | NOX66 and Palliative Radiotherapy in Patients with Late Stage Prostate Cancer |
|  | Principal Investigator: | Dr. Chris Wynne |
|  | Sponsor: | Noxopharm |
|  | Clock Start Date: | 01 February 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.

Dr Devonie Waaka declared a potential conflict of interest, the Committee decided to allow her to remain in the room but not participate in decision making for this study.

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 peer review template uploaded did not include any comments from the reviewer. Although this study is being reviewed by SCOTT and no separate evidence of peer review needs to be uploaded, it would be better in future applications to ensure that all documents uploaded are complete.
2. The Committee questioned the tissue storage planned during and after this study. The Researcher explained that tissue would be stored for use in this study, and that this could include future tests related to the study drug. The Committee stated that this is acceptable as these tests are specified in the Participant Information Sheet, however, storage for this testing indefinitely is not acceptable, a 5 year limit for tissue storage was agreed.
3. The Committee noted that although the withdrawal of consent form can be used that this cannot be mandatory. The Researcher confirmed that this is optional and participants can withdraw verbally.
4. The Committee noted that the response provided to the question in the application form regarding potential cultural issues does not identify the use of tissue as a potential cultural issue. Please ensure this question is answered more fully in future.

Summary of ethical issues (outstanding)

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

1. Please add a 5 year time limit for tissue storage to the Participant Information Sheet.
2. Please add a tick box to the consent form for the optional tissue use for this study.
3. Please remove the statement that says ‘indefinite for studies related to the study drug’ from the Participant Information Sheet.
4. Please provide more specific information in the Participant Information Sheet about where tissue collected for this study will be stored.
5. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of 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 *approved* by consensus, subject to the following non-standard condition:

* 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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| **8** | **Ethics ref:** | **18/STH/35** |
|  | Title: | SAPPHIRE |
|  | Principal Investigator: | Dr Alan Pithie |
|  | Sponsor: | Janssen-Cilag (New Zealand) Limited |
|  | Clock Start Date: | 01 February 2018 |

Dr Alan Pithie and Liane Dixon 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.

Dr Devonie Waaka declared a potential Conflict of Interest, the Committee determined it was suitable for her to fully participate in the consideration of this application.

Summary of Study

1. This is a phase III placebo-controlled study assessing efficacy of pimodivir in addition to standard of care in treatment of acute influenza A. 25 participants in NZ, with intention to include adolescents and the elderly.
2. Participants will be recruited in the ER within 72 hours of symptom onset before going to wards.

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 participants will have time to consider their participation in the study, given that the recruitment is time sensitive. The Researcher explained the time available to participants to consider participation, stating that there is time between initially presenting and having a diagnosis confirmed and this time can be used to consider participation.
2. The Committee questioned whether the nasal swab will need to be redone for participants who had it as part of standard care. The Researcher confirmed that it would not need to be redone.
3. The Committee questioned whether the initial approach will be made by a member of the clinical care team. The Researcher confirmed it would be.
4. The Committee questioned whether all participants would be able to provide informed consent. The Researcher explained that some participants will be under 16 and may need to have parents’ consent on their behalf, but this will be determined on an individual level and all adults will consent for themselves.
5. The Committee questioned whether participants injured in this study may need to seek compensation from the study sponsor from outside New Zealand. The Researcher explained that this is not their understanding and they will support any participants who need to seek compensation from the study sponsor.

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 Sheets provided appear to be the generic international trial ones and more care should be taken in future to revise these before submission to HDECs. In future, before submission to HDECs please ensure all participant facing documents are revised for lay readability and to meet New Zealand standards.
2. The Future Unspecified Use of Tissue Participant Information need to be totally separate from the main Participant Information Sheet.
3. Please add a heading to emphasise the Māori cultural tissue statement.
4. Please give the study a short lay title on all participant facing documents, for example ‘a study of a new treatment for influenza’.
5. Please revise the Participant Information Sheet to indicate that samples tested in the study may be used for participants care, currently it indicates that they won’t be.
6. Please remove the statement from the Participant Information Sheet about participants possibly being found eligible for another study.
7. Please revise the contraception section of the Participant Information Sheet, a template is available at ethics.health.govt.nz.
8. Please add a separate section for obtaining consent after birth if it is intended to collect information on children of participants or their partners.
9. Please remove mention of indefinite tissue storage from the Participant Information Sheets, tissue storage needs to be time limited.
10. Please replace the term ‘ward’ from parent information sheets as this term is not used in New Zealand.
11. Please reduce or condense the information contained in the Participant Information Sheet as this is likely to overwhelm participants.
12. Please clarify in the Participant Information Sheet that participants in both arms will receive standard care.
13. Please revise formatting of the Participant Information Sheet as currently the body text merges with footers.
14. The Committee queried the lack of a Māori tissue statement in the main 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.”*
15. Please remove the interpreter box from participant facing documents and replace with a statement about interpreters being available on request.

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 Devonie Waaka and Dr Anna Paris.

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| **9** | **Ethics ref:** | **18/STH/36** |
|  | Title: | (duplicate) STATEC: Selective Targeting of Adjuvant Therapy for Endometrial Cancer |
|  | Principal Investigator: | Doctor Bryony Simcock |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 February 2018 |

Peter Sykes 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 ethical issues (resolved)

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

1. The Committee questioned whether study participation may result in standard care being withheld from participants. The Researcher explained that not all patients currently have their lymph nodes removed, although most do in Christchurch as it is offered to most patients as part of standard care.
2. The Committee questioned what would happen if someone had strong preferences regarding the removal of their lymph nodes. The Researcher explained that participants have plenty of time to consider whether they want to be in the study and if they have strong preferences about their care they will not be enrolled in the study.
3. The Committee questioned whether data will be collected on how many participants withdraw from the study or decline participation due to preferences on having their lymph nodes removed or not. The Researcher confirmed that they will collect this data.

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 diagram in the Participant Information Sheet is confusing and the pathways should be revised to clearly state that it is referring to ‘if cancer is found…’.
2. Please remove the information on sentinel lymph glands form the diagram in the Participant Information Sheet.
3. Please clarify in the Participant Information Sheet that most patients in Christchurch opt to have their lymph nodes removed as part of standard care, but study participation may result in participants being randomised to not have their lymph nodes removed.
4. The Participant Information Sheet is quite hard to understand, please consider where improvements to lay readability can be made. It may be useful to have some lay people read the Participant Information Sheet and indicate any sections they find confusing, before it is given to potential participants.
5. The term ‘apparent’ in the Participant Information Sheet is likely to confuse participants as although it is the correct technical term it is likely to offer more confusion than clarity to participants, this term should be removed from participant facing documents.
6. Please state at the start of the Participant Information Sheet that the lymph glands referred to in the study are in the pelvis.

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 Nicola Swain and Ms Raewyn Idoine.

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| **10** | **Ethics ref:** | **18/STH/24** |
|  | Title: | Comparison of the blood levels of two forms of isotretinoin capsule in healthy male volunteers under fasting conditions. |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas Pharmaceuticals America Ltd |
|  | Clock Start Date: | 01 February 2018 |

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

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

1. The Committee discussed whether it was acceptable for the study to only include male participants. The Committee agreed that this is acceptable due to the risks to a foetus if any participants were to become pregnant.

Summary of ethical issues (outstanding)

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

1. In the Participant Information Sheet the inclusion/exclusion list is not lay friendly, please revise this list to only include the criteria that participants could know about, not criteria that will be identified in screening. General statements like ‘we will review your medications to check if you are eligible’ could be useful here.
2. Please reference the correct HDEC in the Participant Information Sheet, this study is approved by the Southern HDEC.
3. Please state in the Participant Information Sheet that specialist clinical support is available in the event that participants experience adverse psychological effects. The Committee noted that it is essential that this support is available if needed.

Decision

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

* 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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| **11** | **Ethics ref:** | **18/STH/25** |
|  | Title: | Comparison of the blood levels of two forms of isotretinoin capsule in healthy male volunteers under fed conditions. |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas Pharmaceuticals America Ltd |
|  | Clock Start Date: | 01 February 2018 |

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

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

1. The Committee discussed whether it was acceptable for the study to only include male participants. The Committee agreed that this is acceptable due to the risks to a foetus if any participants were to become pregnant.

Summary of ethical issues (outstanding)

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

1. Please state in the Participant Information Sheet that a vegetarian breakfast is not available.
2. In the Participant Information Sheet the inclusion/exclusion list is not lay friendly, please revise this list to only include the criteria that participants could know about, not criteria that will be identified in screening. General statements like ‘we will review your medications to check if you are eligible’ could be useful here.
3. Please reference the correct HDEC in the Participant Information Sheet, this study is approved by the Southern HDEC.
4. Please state in the Participant Information Sheet that specialist clinical support is available in the event that participants experience adverse psychological effects. The Committee noted that it is essential that this support is available if needed.

Decision

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

* 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

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| **1** | **Ethics ref:** | **16/STH/168/AM01** |
|  | Title: | Deprescribing in Aged Residential Care |
|  | Principal Investigator: | Dr Claire Heppenstall |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 February 2018 |

Dr Claire Heppenstall 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 Amendment

1. This amendment is requesting inclusion of participants unable to 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. The Committee explained that proxy consent is not acceptable for health research in New Zealand and the only acceptable method for enrolling participants unable to provide their own informed consent is under Right 7(4) of the HDC Code of Rights. The Committee explained that for this condition to be met participation in the study must be in the individual best interest of each participant. The Committee stated that this argument could be made for this study, as receiving specialist advice on medications is likely to benefit participants. However, this argument was not made well in this amendment and would need to be clearly explained separately.
2. The Committee questioned whether the study aims can be met by the inclusion of participant unable to consent, noting that the primary purpose of the study is to investigate how many patients take up the offer of a specialist review, as well as how many GPs make changes based on the review recommendations. The Committee pointed out that if participants are unable to consent they will also be unable to decide whether or not to take up the medication review. The Committee suggested that if they were included in the study they would need to be considered a separate group where all participants who are unable to consent receive the medication review, and the study only investigates whether their GPs make the suggested changes. The Committee noted that this would require a revision of the protocol.
3. The Committee noted that both the ability to consent and whether participation is in best the individual’s best interests must be determined by a clinician, however this cannot be determined by the participants’ GP as this would compromise study validity as the outcome measures for these participants would be whether or not the GP took up the medication review suggestions.
4. The Committee suggested that due to the number of protocol changes that would be required to include participants unable to consent in this study that it may be better submitted as a new study, the Committee explained that they are supportive of the study and hope that if it is submitted as a new study this is submitted back to the Southern HDEC.

Decision

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

* The Committee notes 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.
* Studies involving participants unable to provide informed consent must be undertaken in accordance with Right 7(4) of the HDC Code of Rights. People are entitled to make free and informed decisions about their participation in a study (Ethical Guidelines for Intervention Studies paragraph 6.8).
* If the inclusion criteria of the study are to be changed to include participants unable to provide informed consent this will necessitate changes to the study aims and outcome measures for this group, the current study protocol is not suitable for this purpose and will need to be revised to ensure study validity. Scientific soundness is ethically important. Projects without scientific merit needlessly expose participants to risk and misuse their time, and waste resources (Ethical Guidelines for Intervention Studies paragraph 5.5).

## 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 March 2018, 08:00 AM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

The following members tendered apologies for the April meeting.

* Dr Nicola Swain, Dr Fiona McCrimmon, and Dr Devonie Waaka

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