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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 10 August 2021 |
| **Meeting venue:** | <https://mohnz.zoom.us/j/96507589841>  Meeting ID: 965 0758 9841 |

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| **Time** | **Item of business** | |
| 10.00am | | Welcome |
| 10.15am | | Confirmation of minutes of meeting of 13 July 2021 |
| 10.30am | | New applications (see over for details) |
| 10.30-10.55am  10.55-11.20am  11.20-11.45am  11.45-12.00pm  12.00-12.25pm  12.25-12.50pm  12.50-1.15pm  1.15-1.30pm  1.30-1.55pm  1.55-2.20pm  2.20-2.45pm | | i 21/STH/178  ii 21/STH/181  iii 21/STH/184  *Break (15)*  iv 21/STH/185  v 21/STH/187  ~~vi 21/STH/189~~ *Withdrawn by researcher*  *Break (15)*  vii 21/STH/191  viii 21/STH/192  ix 21/STH/196 |
| 2.45pm | | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |  |
| Dr Sarah Gunningham | Lay (other) | 05/07/2016 | 05/07/2019 | Present |  |
| Dr Devonie Waaka | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Present |  |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 28/06/2019 | 28/06/2020 | Present |  |
| Dr Paul Chin | Non-lay (intervention studies) | 27/10/2018 | 27/10/2021 | Apologies |  |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 19/08/2020 | 19/08/2021 | Present |  |
| Mr Dominic Fitchett | Lay (the law) | 05/07/2019 | 05/07/2022 | Present |  |

## Welcome

The Chair opened the meeting at 10.00am and welcomed Committee members, noting that apologies had been received from Dr Paul Chin.

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 13 July 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **21/STH/178** |  |
|  | Title: | HeadSMART II |  |
|  | Principal Investigator: | Prof William F Peacock |  |
|  | Sponsor: | BRAINBox Solutions, Inc. |  |
|  | Clock Start Date: | 29 July 2021 |  |

Mark Richards, Martin Than, Lorraine Skelton and Alieke Dierckx were present via videoconference 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 goal of HeadSMART II (Head injury Serum Markers and Multi-modalities for Assessing Response to Trauma) is to develop an in-vitro diagnostic traumatic brain injury (TBI) test (the BRAINBox), to aid in the diagnosis and prognosis of patients with mild TBI. This observational study includes a trauma control and healthy control groups with New Zealand enrolment restricted to TBI group totalling 1840 participants with 200 in New Zealand.

Summary of resolved ethical issues

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

1. The Committee asked for clarification on what the Brainbox device is. The researcher explained that the Brainbox is a suite of parameters designed to produce a bedside cognitive assessment tool for traumatic brain injury (TBI) symptoms.
2. The Committee requested clarification around the recruitment pathway and specified that first approach to potential-participants should not be made by the researchers in order to avoid cold-contacting. Ideally, someone part of the patient’s standard care team should ask them if they are interested in the study and pass information on. *(National Ethical Standards for Health and Disability Research and Quality Improvement, section 3, particularly para 11.7c).* The Researcher advised that while they cannot guarantee this happens all the time due to the nature of the emergency environment and turnover of shift staff, etc., it is their standard approach.

Summary of outstanding ethical issues

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

1. The Committee requested clarity on the investigator roles and who is assigned to them in this study. The researcher advised that the internationally based Professor Peacock is the coordinating investigator for the global study and that Dr Richards and Dr Than are the main co-investigators in New Zealand collectively working with other co-investigators at the Christchurch Heart Institute.

The Committee advised that in the case of international studies, a local investigator should be nominated as the coordinating investigator (CI) for the New Zealand arm of the study. *(Health and Disability Research Ethics Committees Standard Operating Procedures, para 35).* Please nominate a New Zealand-based CI and provide a current CV.

1. The Committee noted the researcher’s confirmation that the participant information sheet and consent form (PIS/CF) statement that participants will be eligible to apply for ACC is an error. Please supply an insurance certificate for sponsor cover in the event of study related treatment injury and ensure the correct compensation statement is used in the PIS/CF. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1 – 17.6).*
2. The Committee requested the supply of a data and tissue management plan (DTMP) for the lifecycle of the study to ensure the safety and integrity of participant data. This may either be incorporated into the protocol or a separate plan, but it must be study-specific and comply with *National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a and 14.17.* For guidance, please use the [Data and Tissue Management Plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/hdec-data-tissue-management-template-oct2020.docx) available on [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/).

The researcher requested clarity on what needs to be addressed in the plan to be approved by HDECs. The Committee advised that provided they tailor the HDECs DTMP template to their study requirements, which includes removing anything that is not relevant, there should not be any issues.

1. The Committee noted that tissue collection for future unspecified research (FUR) is not stated as optional, and noted that only samples collected that are required to meet the main aims of the study should be mandatory. For example, exploratory biomarker research is not required for the study and should be optional. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.57).*  The Committee requested the following;
   1. Please provide a protocol addendum that addresses the tissue collection for New Zealand participants, i.e. what is study specific (mandatory) and what is exploratory or future research (optional).
   2. Please provide a separate (optional) PIS/CF for future research, including any planned genetic / genomic assays. For guidance, please use [the Future Unspecified Use of Tissue PIS/CF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/future-unspecified-use-tissue-piscf-template.doc) available on the HDEC website.
   3. Please reconcile the information provided in the DTMP, application and PIS/CFs regarding tissue/data management for future research samples versus study specific samples. For example, the application states samples will not be sent overseas when they will, and that samples will be retained for up to 10 years whereas the protocol states that specimens will be stored indefinitely for future exploratory testing.
2. The Committee noted that the protocol states there is a maximum 96-hour window between injury and enrolment restricting the time a patient has to consider study participation. While the Committee acknowledged the time critical nature of the study, it advised that an ethical issue arises when participants are not given an opportunity to reconsider their participation because they are unable to remove their data from the study if they withdraw participation. Given this is an observational study and withdrawal of data would not affect the integrity of the research, the Committee recommended this element is reconsidered or a justification for retaining withdrawn participant’s data is provided to HDECs.
3. The Committee advised that it is important that the person consenting this group of patients with a TBI has the ability to clinically assess whether they have the capacity to provide informed consent. Please confirm that the evaluation questions that will be used for this purpose have been validated for this patient group.
4. The Committee queried if only participants who can provide independent informed consent will be enrolled in the study. The researcher advised that they do not want to exclude the group who will not be competent to consent (due to their injury) within the 96-hour window.
5. The Committee advised that substituted decision-making (where a legally authorised person consents on behalf of another person) in clinical trials is only legally acceptable in New Zealand in certain circumstances where the person has been appointed as a ‘welfare guardian’ or has Enduring Power of Attorney (EPOA). Where the patient is not competent to make an informed choice and give informed consent, and there is no person entitled to consent on their behalf (i.e. welfare guardian/EPOA), the potential participant may be enrolled in the research only if it is in the best interests of the individual, and reasonable steps taken to ascertain the views of the potential participant *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.70 – 7.71).* If the researchers choose to enrol non-consenting adults, the Committee requires the following;
   1. An ethical justification for involving adults who cannot provide their own consent *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.3)*.
   2. A justification of how the proposed method of enrolling participants who cannot provide their own informed consent is consistent with New Zealand law.
   3. That participants are given the opportunity to decide about their continued participation in the research as soon as is reasonably practical (i.e. when they regain capacity to consent). This includes the right to withdraw the data already collected about them. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.63)*
6. The Committee advised that there are other ways to aid the informed consent process with this TBI population that the researchers should consider, such as;
   1. Supported decision-making. While family members cannot consent on behalf of a participant, they can be present during discussions about the study and help the potential participant better understand their involvement. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.11 – 6.12)*
   2. Simplifying the design of the PIS/CFs to be more user-friendly for the population group the researchers wish to recruit. This includes simplifying the language, layout and including diagrams. For ideas on simplified PIS/CFs, please see the templates on the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
7. The Committee recommended the researchers resolve the uncertainty around the (consenting/non-consenting) groups they want to include in the research and provide an updated protocol detailing the process for obtaining consent, taking into account the Committee’s feedback.
8. The Committee raised concerns about participants short term ability to answer questionnaires given their head injury. The researchers responded that the questionnaires will be completed at follow up sessions from two weeks after the injury and that an abbreviated (20 min) questionnaire will be used initially to assess the participant. He added that these questions have been simplified for use with this patient group.
9. The Committee asked what measures are in place in the event questionnaire answers indicate a participant has significant mental health issues or is at risk of self-harm. The researcher said that should the research team identify at risk participants while completing the questionnaires with them, their primary care team would be engaged to discuss appropriate support services with the participant. The Committee requested participants are informed that there are questions about mental health and what will happen should their responses indicate they are at-risk; and that the safety plan is detailed in the protocol.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please make it clear that the questionnaires contain questions about mental health (as per Committee’s earlier point).
2. Please state how long samples will be kept for (page 3).
3. Please simplify the technical language used and make it easy to understand for this participant group.
4. Please remove references to future tissue research from the main PIS/CF as there will be a separate PIS/CF for this (page 3).
5. Please explain in lay language whether genetic / genomic assays will be performed as part of the mandatory testing, and whether this may include WGA. This information should also be included in the optional Future Research PISCF.
6. Please include a cultural statement about Māori views on the use of tissue for research purposes (page 3). The Committee recommended the following statement as a guide: *“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/ whānau 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 before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
7. Please state whether or not karakia is available at the time of tissue donation or destruction (page 3).
8. Please make it clear that the participant's health care provider will be informed of any abnormal results of potential clinical significance; this should be a mandatory component of study participation (page 6).
9. Please remove the optional tick boxes for GP notification in the event of an abnormal result of clinical significance; and for audit of identifiable information (page 7).

Decision

This application was *declined* by consensus, as the Committee did not consider that the study meets the *National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.17, 17.1 – 17.6, 7.57, 7.70 – 7.71, 7.3, 7.63.*

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| **2** | **Ethics ref:** | **21/STH/181** |
|  | Title: | The Topical Sevo Trial |
|  | Principal Investigator: | Dr John Barnard |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 July 2021 |

John Barnard and Jonathan Termaat were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is a feasibility trial to evaluate the efficacy and safety of topical sevoflurane applied to chronic non-healing ulcer wounds to determine its effect on pain control and wound healing. An open label study of 36 New Zealand patients with chronic skin ulcers.

Summary of resolved ethical issues

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

1. The Committee queried the justification for not including a placebo/control group in the design of this early study (i.e. how will efficacy be measured against pre-treatment pain levels). The researcher responded that due to the chronic nature of the ulcers, the symptoms that patients experience are pronounced and therefore the participants historical experience of the condition will be sufficient control for the study.
2. The Committee queried how potential participants will be referred to the research team and how they will ensure adequate separation between the clinician/researcher (dual) roles. The researcher advised there are several referral pathways within the hospital; through the in-patient pain service, vascular surgeons, kidney doctors, and wound nurses. He confirmed that these clinicians will identify potential participants and refer interested patients to the research team to discuss the study.
3. The Committee queried if there are any safety issue with storing or using this volatile medicine during the study. The researcher advised that the fluid is stored as liquid and administered as gas and there are no safety issues with storage. He added that there can be the smell of gas when administering the medicine and this is mitigated with a well-ventilated room, application of a post treatment dressing, and carbon filter masks for participant and researcher protection.
4. The Committee queried if there will be any additional study-related travel costs for participants and if they will be reimbursed. The researcher advised that to minimise disruption to participants, the research team will go to the participant and work in with the standard practice (dressing change) schedule.

Summary of outstanding ethical issues

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

1. After some discussion as to whether this type of study would be in scope of SCOTT review, the Committee recommended the researchers formally seek SCOTT’s advice on if this particular study is within scope or not. This will mitigate any potential Medsafe regulatory issues further down the line.
2. The Committee advised that the document provided is not adequate evidence of independent peer review. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26.)* The Committee requests one of the following:
   1. Please supply evidence of SCOTT approval/application (the Committee’s preference); or, if SCOTT advise that the study is out of scope
   2. Please supply an independent peer review from a suitably qualified expert usingthe [Scientific Peer Review Template](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) available on the HDEC website to address this.
3. The Committee requested the researchers’ safety plan to mitigate risks to both participants and researchers conducting home visits is detailed in the protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).* This should include a protocol for safety transporting liquid that meets legal requirements for hazardous substances.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please consider another lay title for the study which does not include the term 'topical'.
2. Please ensure the data section includes a description of how data will be de-identified, rights of access to data, and the risk of privacy / confidentiality breach.
3. Please explain that any photographs taken will not identify the participant.
4. Please replace 'National Ethical Committee' with 'Health and Disability Ethics Committee'.
5. Please remove the optional tick box for GP notification on the consent form as this should be mandatory.
6. Please remove the optional tick box for wound photography on the consent form as this is mandatory.
7. Please resolve the conflicting statements on withdrawing data on pages 6 and 9.
8. Please consider including a statement on page 6 that you will collect information on why the participant is withdrawing, if they are willing to provide it.
9. Please include more information on possible risks on page 4 such as if there are any altered sensations with sevoflurane (i.e. sensation of cold or stinging on application).

Decision

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Assc Prof Mira Harrison-Woolrych.

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| **3** | **Ethics ref:** | **21/STH/184** |
|  | Title: | Identifying multi-omic markers (genomic, epigenomic, transcriptomic) to predict risk of prostate cancer in New Zealand men. |
|  | Principal Investigator: | A/Prof Aniruddha Chatterjee |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 29 July 2021 |

Aniruddha Chatterjee and Amir Zarrabi were present via videoconference 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 will investigate genetic and epigenetic factors to predict the risk of prostate cancer in New Zealand men. 150 New Zealand participants.

Summary of resolved ethical issues

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

1. The Committee noted that the study does involve the use and disclosure of health information, which is contrary to the answer to application question G.
2. The Committee advised that health data generated in the study should be retained for a minimum of 10 years (application question r.2.5).
3. The Committee queried what will happen to tissue samples at the end of study if future unspecified research is not consented to or the participant withdraws (application question r.3.11). The researcher advised that these samples will be destroyed with an option for karakia to be performed.
4. The Committee asked if the researchers will be establishing a registered tissue bank. The researcher confirmed that they plan to establish/register a tissue bank soon and understand that this is to be undertaken in a separate HDECs application process and are not seeking permission in this study application.
5. The Committee asked if the researchers may also be responsible for ongoing clinical care of patients and, if so, how recruitment will be managed to mitigate the risk of patients feeling pressure to participate as a result of the doctor/patient relationship. The researcher advised he was not the clinician for this cohort of potential participants who have already received their treatment, through a different clinical care team and will have limited contact with them in the future. He added that after one of the clinicians has contacted the patient about the study, his research assistant will handle the recruitment process from there.

Summary of outstanding ethical issues

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

1. The Committee requested clarification around the recruitment pathway and specified that first approach to potential-participants should not be made by the researchers in order to avoid cold-contacting. Ideally, someone part of the patient’s standard care team should ask them if they are interested in the study and pass information on. *(National Ethical Standards for Health and Disability Research and Quality Improvement, section 3, particularly para 11.7c).* After some discussion with the researchers, the Committee recommended the following;
   1. Initial contact is made by letter to allow potential participants more time to digest the study information (i.e. by email or post).
   2. Ensure the letter is from a member of the participants clinical care team and introduces the research and the researcher(s) (e.g. from the clinical director).
   3. Follow up the letter with a phone call from a member of the research team.
2. The Committee noted that the participant information sheet and consent form (PIS/CF) states blood samples will be labelled with name and NHI (direct identifiers). As samples are being collected purely for research purposes, they should be de-identified at the time of collection (i.e. NHI and name removed and replaced with a participant ID code and year of birth only). It added that the data set should also be de-identified as soon as possible and prior to analysis. The researcher should maintain a separate list linking participant ID with NHI and other identifiers. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.11-12.14).* Please amend documentation accordingly.
3. The Committee requested the supply of a data and tissue management plan appropriate to the study to ensure the safety and integrity of participant data and tissue. This may either be incorporated into the protocol or a separate plan, but it must be study-specific and comply with *National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a and 14.17.* For guidance, please see the [Data and Tissue Management Plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/hdec-data-tissue-management-template-oct2020.docx) available on the HDEC website. Please ensure the template is modified to appropriately reflect the tissue and data management requirements of this study.
4. The Committee advised that the implications of test results needs to be made very clear to participants (i.e. whether results could be clinically significant to patients and their blood relatives) including what support is available to them. The researchers confirmed that the tests are exploratory only and used to understand the epigenetics landscape in New Zealand and they will not be able to predict findings of clinical significance at this point in the study. The Committee advised that this is explained to participants in lay terms in the PIS/CF.
5. The Committee recommended the researchers investigate if other prostate tissue banks already exist before establishing their own.

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

Main study PIS/CFs

1. Please review the [HDEC’s PIS/CF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) 'What happens to my information section' and incorporate relevant components into the PIS/CFs. Please ensure it aligns to your DTMP and issues such as the risk of data / confidentiality breach, access to identifiable and de-identified data and future uses of data are addressed.
2. Delete repetitive text regarding study withdrawal (page 5).
3. As information needs to be retained for 10 years, please amend ‘3 years’ statement (page 4).
4. Please amend the cultural tissue statement on page 6. The Committee recommended the following statement as a guide: *“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with genetic testing and storing your tissue should be discussed with your family/ whānau 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 before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
5. Please state what will happen to tissue samples if the participant withdraws or does not consent to future research, and whether there will be an opportunity for karakia.
6. Please explain genes and DNA in lay language.
7. Please state in lay language if whole genome testing will be performed as some participants like to know how broad the testing will be.
8. Please state whether results could be clinically significant for the participant or his blood relatives (as per Committee’s earlier point).

Future research PIS/CFs

1. Please state that future research will be related to prostate disorders only.
2. Please state in lay language whether WGA may be performed. If WGA a possibility, the risk of re-identification or DNA matching to blood relatives should be addressed.
3. Please include a Māori tissue statement that addresses unspecified genetic research.
4. Please reconsider whether you will report results of future research to participants, as this could be impractical and is not a requirement. Please make it clear to participants either way.
5. The consent form gives an option for the participant code to be stripped from samples, but this is not explained in the body of the information sheet – i.e. that they will no longer be able to withdraw their samples. Please add this to the information sheet.
6. Please fix the page numbering issue in the footer.
7. Please remove the yes/no tick boxes for items that are mandatory.

Decision

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Devonie Waaka and Mr Dominic Fitchett.

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| **4** | **Ethics ref:** | **21/STH/185** |
|  | Title: | GRIT Study |
|  | Principal Investigator: | Dr Samantha Lee |
|  | Sponsor: | University of Canterbury |
|  | Clock Start Date: | 20 July 2021 |

Samantha Lee, Lianne Woodward and Martin Kennedy were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is an adolescent extension of a continuing prospective longitudinal cohort study of New Zealand children born to mothers enrolled in methadone maintenance therapy during pregnancy. Approximately 100 teens (age 16/17) born to mothers in a methadone programme will be compared with about 110 adolescents of the same age developing normally. Mothers/caregivers in each group will also be participants in this study.

Summary of resolved ethical issues

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

1. The Committee noted the researcher’s clarification that the teenager is the primary participant, as the study is about prediction of outcomes for children, and their caregiver will only be enrolled (i.e. interviewed) if the teen agrees to participate.
2. The Committee noted the researcher’s clarification that providing saliva testing for the study is optional and the participant can remain in the study if they choose not to provide a saliva sample.
3. The Committee noted the researcher’s confirmation that the teenage participants will be interviewed separately to the caregivers to protect the privacy of the teen and requested this is made clear in the participant information sheet/consent forms (PIS/CFs).

Summary of outstanding ethical issues

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

1. The Committee noted that the application states that caregivers of the young people in this study will be providing informed consent for their participation and that of their teens. The Committee advised that as the teenagers are all aged 16 years (i.e. adults), this raises significant ethical issues. It advised that where the teenagers have capacity to provide independent informed consent, they must be allowed to do so. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.24).* It added that the participant’s caregiver can be informed that the research is taking place but the teenager, if competent, must be allowed their legal right to decide for themselves and therefore permission from the caregiver should not be sought first.
2. The Committee noted that some participants may have a restricted ability to provide independent informed consent and asked for clarity on the consenting process. The researcher advised that they will implement supported decision-making where possible but there may be a small number of participants that will lack capacity to consent because of cognitive abilities. She added that the researchers want to capture the full population of this high-risk group so that the challenges they face are not excluded from the study results.
3. The Committee advised that to enrol the 18+ non-consenting participants into research, that is in line with New Zealand law, enrolment must be in the best interests of the individual and reasonable steps taken to ascertain the views of the potential participant. Please provide an ethical justification for research that involves adults who cannot provide their own consent to HDECs that complies with *National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.70 – 7.71).*
4. The Committee advised that where the participant is incapable of giving consent and is aged 16 or 17 years, a (legal) guardian may be able to give a legally effective consent. However, these individuals still retain the right to make informed choices and give informed consent, to the extent appropriate to their level of capacity. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.10, 6.26a).*
5. The Committee advised the researchers that the method for establishing the degree to which the teen participants can provide informed consent must be detailed in the protocol as well the consenting processes. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.26).*
6. The Committee advised that as all the participants have reached the age of 16, the researchers must seek their permission (as adults) to continue to use the data that has been historically collected on them. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.20).* Given this is different to the main study, the Committee recommended it is undertaken as a separate consent process to reduce confusion for the participants and in turn safeguard the informed consent process.
7. The Committee advised that planned genetic research is poorly described in the protocol and queried what genetic factors are being investigated in the main study. The researcher clarified that they will be investigating polygenetic risk scores for psychiatric outcomes but are unsure if they will be doing any other genetic testing. The Committee advised that it is important that the participants are told exactly what genetic testing will be done in the study using language that they will understand. This includes explaining what DNA analysis is and the implications for them. Please update the PIS/CFs.
8. The Committee noted that the application stated that tissue samples would be retained for future use without consent. The Committee advised that to comply with ethical standards, optional consent must be obtained from the participant for future unspecified research. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.57).* The researchers clarified that their intention is not to undertake future research.
9. The Committee noted that interviews include disclosing sensitive information such as mental health issues and illegal behaviour and queried what measures are in place for managing any safety issues should they arise. The researcher advised that they would not report illegal behaviour that was disclosed but would discuss any safety issues or concerns with the teenage participant and support them into a referral pathway (e.g. GP). She added that there are options for seeking support in the PIS/CF (e.g. Youthline) and that they would only disclose the issues to the caregiver if the participant agrees. The Committee requested this is explained in more detail in the risk section of the PIS/CF so the participant understands what will happen if they disclose something (including when the researchers are legally obligated to report something – e.g. if causing harm to another).
10. The Committee require the supply of a data and tissue management plan appropriate to the study to ensure the safety and integrity of participant data and tissue. This may either be incorporated into the protocol or a separate plan, but it must be study-specific and comply with *National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a and 14.17.* For guidance, please see the [Data and Tissue Management Plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/hdec-data-tissue-management-template-oct2020.docx) available on the HDEC website. Please ensure the template is modified to appropriately reflect the data management requirements of this study and addresses the following:
    1. exactly what personal information will be collected and for what period, how it will be handled, who will have access to it, how it will be kept confidential, where it will be stored, and when it will be destroyed (including the recordings of the interviews);
    2. plans for return of genomic results including implication for participants and their relatives.
11. The Committee recommended this application is resubmitted to Southern HDECs to review given it is familiar with the study and the requested changes.

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

Teen PIS/CF

1. Please use the [PIS/CF templates](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) on the HDEC website.
2. Please state clearly that the caregiver cannot participate if the teen does not wish to be enrolled.
3. Please make it clear that the caregiver questionnaire is about the teen, and state whether the teen can access the caregiver's responses. Make it clear that the caregiver will not be able to access the teen's study data without express permission from the teen.
4. Please state that the teen and caregiver interviews will be conducted separately. State whether support people are permitted to be present.
5. Please ensure it is made very clear to the participant what they are signing up to, i.e. that the research team will be interviewing their school, caregiver and accessing their health and police records.
6. Please provide lay information about: what genes or genetic research is; the breadth of planned research (potential WGA); the fact that genes are shared with blood relatives; cultural issues with the donation of tissue for this type of research; sample storage; duration of retention; return of results, and opportunity for karakia. Please ensure this information lines up with the DTMP.
7. Please make notification of the GP regarding clinically significant abnormal results mandatory.
8. Please include Māori cultural support details.
9. Please include a clause in the consent form regarding video recording; this information should be in the body of the information sheet, together with information about processes to optimise confidentiality.

Decision

This application was *declined* by consensus, as the Committee did not consider that the study meets the *National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.17, 7.70 – 7.71, 6.10, 6.24, 6.20, 7.57.*

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| **5** | **Ethics ref:** | **21/STH/187** |  |
|  | Title: | 73763989PAHPB1006(Osprey) Combination of siRNA, DNA vaccine and Nucleoside Analogue for Chronic Hepatitis B |  |
|  | Principal Investigator: | Professor Edward Gane |  |
|  | Sponsor: | Janssen-Cilag Pty Ltd |  |
|  | Clock Start Date: | 29 July 2021 |  |

Edward Gane was present via videoconference 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 open label, single arm, phase 1 study aims to investigate the combination of JNJ-3989 with JNJ-0535, and nucleos(t)ide analogs (NA) for the treatment of chronic HBV infection. There are 23 participants with 4 in New Zealand.

Summary of resolved ethical issues

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

1. For future apps, please ensure technical language or acronyms are explained in the application form for the lay members to aid in their assessment.

Summary of outstanding ethical issues

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

1. The Committee advised that studies cannot share any de-identified participant information from pre-screening with the Sponsor prior to them giving consent.
2. Please ensure the receipt of overall study findings is optional for participants.
3. The Committee queried the purpose of the Platform participant information sheet and consent form (PIS/CF). After discussion the Committee stated that the message that it gives the Sponsor permission to later compare data across treatment arms/protocols was not properly explained to potential participants. This is required from the Sponsor. The Committee requested the researcher ensures the purpose of the form and its requirement is explained properly to participants.
4. The pregnant partner/pregnancy follow-up PIS/CF are to be submitted only in the event of a participant or partner pregnancy to ensure they are fit for purpose to obtain fully informed consent. They have not been reviewed or approved as a part of this submission.
5. Section 4 of Data and Tissue Management Plan (DTMP) should include the optional uses of tissue and data. Section 12.2.2 incorrectly states no future research is planned for tissue, please correct.

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

ISA PIS/CF

1. Review overall for lay-language and simplicity.
2. Describe in lay language what each of the study drugs is. The first-time study vaccine is mentioned is on p8 - and to a lay person, a vaccine is something that prevents you from getting a disease; it is confusing used in this context without explanation on what a therapeutic vaccine is.
3. Mention is made of receiving 'a NA' and 'NAs'. State how many NAs each participant gets, and how the choice of NA is determined. If NAs are standard of care, consider removing the pages of side-effects and instead state “your doctor will have talked to you about the risks of this” and present side-effects of NAs as an optional appendix.
4. Please state whether the electroporation device is approved or investigational (p4).
5. Provide a summary table showing overall study length in weeks.
6. Remove information about optional tests, procedures and genetic research/Future Unspecified Research (FUR) (e.g. p8, p11).
7. Review for repetitive statements e.g. 'take the study drug as instructed' and 'follow instructions given to you about taking the study drug'
8. Delete 'also called the AIDS virus' (p10).
9. Use lay terms to describe risks (risk section).
10. Replace Tylenol and Motrin with medications appropriate for New Zealand (p18).
11. Personal data is used inconsistently to describe all data and identifiable data. Where identifiable data is being discussed, (p23 etc) please use 'un-coded data' for clarity.
12. It is stated that: 'a request to delete your personal data cannot be fulfilled where regulations and laws that apply to clinical research require your personal data to be retained' , 'Information collected up until your withdrawal from the study will continue to be used and included in the study’ (p24) and 'The sponsor will continue to collect information from you as described in other sections of this Informed Consent Form'. Please explain why all 3 statements are required and how they differ. Please ensure that the choices of participants who are withdrawn from treatment and/or the study are formally recorded with regards ongoing collection of information.
13. It is stated that the study may be stopped if 'The study drugs being shown to work and not need further testing' and that this is a reason to remove participants from the study without their agreement. It is not ethical to do this in the setting of a therapeutic trial where a participant is receiving potentially curative treatment. Please confirm that, in this situation, participants on active drug could complete the planned course of study treatment (p25).
14. Add an optional text box for receipt of study results; this should not be a mandatory component of study entry (p30).
15. Please consider introducing and defining the study drugs immediately prior to the identifiers in the second paragraph on page 2, as opposed to the bottom of the page, and then only use the abbreviation from that point on (refer page 3).

Optional Genetic Research PIS/CF

1. State in lay language whether whole genome analysis (WGA) might be performed as part pf the testing. Please outline if there is any risk of DNA database matching/linking.
2. Provide information about identification of samples similar to what is stated in the FUR PIS/CF.
3. Include risk of sending tissue overseas.

Optional FUR PIS/CF

1. Include risk of sending tissue overseas and risk of confidentiality/privacy breach.

Optional FNA PIS/CF

1. Explain FNA risks in lay terms.
2. Include risks of sending tissue overseas and risk of confidentiality/privacy breach.

Decision

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Devonie Waaka and Mrs Helen Walker.

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| **6** | **Ethics ref:** | **21/STH/191** |  |
|  | Title: | BO42864: A Study of Pralsetinib Versus Standard of Care for Patients with RET Fusion-Positive Metastatic Non-Small Cell Lung Cancer |  |
|  | Principal Investigator: | Dr. Rajiv Kumar |  |
|  | Sponsor: | Roche Products (New Zealand) Limited |  |
|  | Clock Start Date: | 27 July 2021 |  |

Rajiv Kumar and Courtney Rowse were present via videoconference 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 aims to assess the efficacy and safety of Pralsetinib (which directly targets RET) when compared with standard of care for the first-line treatment of patients with RET fusion-positive, metastatic non-small cell lung cancer. A multicentre, phase 3, randomised, open-label study with approximately 226 participants of which 4 are in New Zealand.

Summary of outstanding ethical issues

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

1. The Committee highlighted the Foundation Medicine pre-screening test suite, that generates a genetic profile of a patient’s tumour. The Committee raised the following ethical issues for response in order to assess whether this mandatory inclusion for participants is fair:
   1. The Committee queried if the battery run for participants is the standard battery described on the Foundation Medicine website. The researcher confirmed it is, but the standard battery of tests is different in the context of the study to what is standard of care in New Zealand (DNA and RNA compared to just DNA). For this study, the RNA-based platform is important.
   2. The Committee queried if the 324 genes being tested for in the study all have known prognostic or treatment significance for solid tumours. The researcher responded that 8 of them have relevance and significance for lung cancer that have been validated. The remaining will be experimental, and that information is available to the clinician as it’s a diagnostic-grade result, not just research-grade.
   3. The Committee noted that the test suite was performed at pre-screening and many of the results were not related to study eligibility i.e. would not impact the participant’s enrolment into the study. The Committee queried the justification for assays not directly related to study eligibility to be conducted at pre-screening, and asked why the test suite was not limited to those assays required to confirm eligibility.
   4. The Committee queried if access to the database described on the Foundation Medicine website is open to any research / commercial company who pays the required fee. The researcher said they will seek clarification from the Sponsor around this and whether consent/opt-out consent is available for being on the database.
   5. The Committee queried how the Foundation Medicine links de-identified data to patients, as a third-party can re-identify data according to the Foundation Medicine website. The researcher stated that when the test is run for this study, the sample result will not be identifiable and the only people who can link the result to the study participant is study-staff. The researcher will confirm with the Sponsor that Foundation Medicine do not receive any de-identified participant health information from the Sponsor.
   6. The Committee queried if the record of the entire genome retained and is there any potential for further biomarkers to be generated from the recorded data. The researcher stated they will confirm that with the Sponsor whether Foundation Medicine keeps only the generated report, or data pertaining to the entire genome.
   7. The Committee noted there is no information on the website about retention duration of tissue, the potential for sharing of tissue with other partners, or tissue destruction. Please provide this information.
   8. The Committee queried whether there will be genetic counselling available for findings, including those that affect prognosis but are not actionable. The researcher stated that in the context of lung cancer, combinations of somatic mutations found would not indicate germ-line mutations and would not need follow-up in that regard. Please make this clearer in the pre-screening information sheet.
2. The protocol states that 'Screening tumour tissue samples, including those collected from individuals who do not enrol in the study, may be used for future research and/or development of disease-related tests or tools' (p105). This does not appear to be restricted to research related to the study drug of NSCLC, and there is no ability for patients to request that pre-screening results are not retained for these purposes. Please clarify the intended breadth of this research. There are issues with breadth of use apparent in the pre-screening, main and cross-over participant information sheets and consent forms (PIS/CF). The researcher confirmed that the scope of future research is related to the study. The Committee requested this is clearly stated.
3. In the Data and Tissue Management Plan (DTMP), please address optional secondary uses of tissue (Section 4) and archival tissue collection (Section 5).

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

Pre-Screening PIS/CF

1. Replace 'you have been selected' with 'you have been invited' (p1).
2. Explain Foundation Medicine and the report issued with much more clarity, addressing the issues regarding data and tissue management outlined above.
3. If the other tests performed may have clinical implications for the patient or his / her blood relatives, this must be clearly explained.
4. The options of receiving only clinically actionable, or actionable and non-actionable results should be presented.
5. Move the statement about sharing information with insurance companies etc to the identifiable information section (p7); this applies to all PIS/CF documents.
6. Explain what 'other data' the following statement refers to: 'Your study data may .... linked to other data collected from you'; it is unclear how the Sponsor will link de-identified study data with personal information collected from other sources.
7. Include an optional tick-box for receiving overall study results (applies to other PIS/CFs).
8. Include a section to record the participant's wishes regarding return of results other than ret-fusion, including clinically actionable and non-actionable results.
9. Please clarify and explain risks surrounding another fresh biopsy if the patient is requiring a repeat biopsy to be part of the study.
10. Please provide an indication of the chance (%) of having the RET mutation in order to help people decide if they wish to be tested for this and undergo pre-screening. In addition, please provide information on what is next for patients if they do not have the mutation after pre-screening (i.e. referred back to their oncologist who will have access to the results of their pre-screening tests).
11. Please outline on page 4 there is reimbursement of travel and parking expenses.
12. Participants should be asked on withdrawal from the main study if they wish their samples to be destroyed.

Main PIS/CF

1. Explain biomarker testing the first time the word is used and remove the explanation from the procedures table (p2).
2. Please simplify the following paragraph “Patients randomised to Arm B (investigator’s choice of SOC treatment) with documented progressive disease…” (p3)
3. Move section 1.5 to the remainder of the risks section for the study (p4) and delete repeated information.
4. Delete reference to 'or your legally authorised representative' (p6).
5. Remove lay description of biomarkers from the study procedures table; this should be fully explained elsewhere (p17). The description in the table includes reference to DNA, which must also be explained in lay terms, together with a statement about whether whole genome analysis (WGA) may be performed.
6. The Committee noted 'exploratory biomarker research' must not involve WGA and must be directly related to the study drug or disorder. Make this clear in the PIS/CF (p20). Justify whether the planned testing is consistent with NEAC Standard 14.34 (*Unless required to fulfil primary study objectives, donation of tissue for broad genetic testing (such as whole genome sequencing) should be optional for participants*.)
7. The final paragraph of page 20 equates to broad unspecified research, as does the description of some of the potential avenues of research for genome testing (p21). This must be subject to additional optional consent. Please amend to ensure that mandatory testing is confined to research directly related to the study drug / disease.
8. Ensure return of results is appropriately discussed, as noted for the Pre-screening PIS/CF.
9. Insert an optional tick-box for return of overall study results.
10. Provide space for documentation regarding return of Foundation Medicine results.
11. Participants should be asked on withdrawal from the main study if they wish their samples to be destroyed.

Crossover PIS/CF

1. Many of the points noted for the Main PIS/CF apply; amend accordingly.

Optional RBR PIS/CF

1. Participants should be asked on withdrawal from the main study if they wish their optional samples to be destroyed.

Decision

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Committee at the next full Southern HDEC meeting.

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| **7** | **Ethics ref:** | **21/STH/192** |  |
|  | Title: | INTERCEPTevar |  |
|  | Principal Investigator: | Dr Oliver Lyons |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 29 July 2021 |  |

Oliver Lyons was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study aims to evaluate the processes of a pilot multi-centre randomised controlled trial (RCT) of carbon-dioxide flushing of stent-grafts (TEVAR-CO2) versus standard saline flushing (TEVAR-S). The aim is to reduce stroke and silent brain infarcts during treatment of aortic disease, by flushing the air out of the devices (endografts) using carbon dioxide gas (CO2). An international study with 120 participants with 20 in New Zealand.

Summary of outstanding ethical issues

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

1. The Committee queried who is funding the study and who the Sponsor is. The researcher responded that this is investigator-led and there is no funding yet. The Committee requested that until other funding arrangements is obtained, please identify Otago University as the Sponsor in the participant information sheet and consent form (PIS/CF).
2. The Committee noted that the submitted evidence for independent scientific peer review is not complete enough. Further, the Committee noted that the review needs to be from someone independent from the study. The Committee referred the researcher to the [peer review template on the HDEC website.](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/)
3. The Committee stated more information around data management is required than what is available in the Protocol and PIS/CF to satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.
4. Please ensure all assessment tools (questionnaires) are uploaded for the Committee to review.
5. The Committee requested clarification around the recruitment pathway and specified that first approach to potential-participants should not be made by the researchers in order to avoid cold-contacting. Ideally, someone part of the patient’s standard care team should ask them if they are interested in the study and pass information on.
6. The Committee noted that the eligibility criteria in the protocol would exclude New Zealand participants and requires amendment.
7. Neurocognitive testing at 1 year in the protocol is not consistent with the PIS/CF. Please amend documentation for consistency.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. The Committee noted the PIS/CF is not fit for a New Zealand audience/context and recommended the researcher adapt the [PIS/CF template available on the HDEC website.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) Use of the template will aid in addressing the points outlined below.
2. Please make it clear that this is a pilot study and make it clear that feasibility is being explored, so no benefit can be promised.
3. Please clarify the MRI scans and where they will be performed.
4. A simply lay title is required, with contact details for the lead investigator at the locality, and the global study sponsor (p1).
5. It is assumed this is not the first-time patients are advised about the risk and implications of silent stroke. Please confirm as the information provided is potentially very distressing (p2).
6. Replace 'why have I been chosen' with 'why have I been invited’ (p3).
7. Give an approximate duration of each clinic and MRI visit (p3). A summary visits table is suggested showing when various procedures will be undertaken.
8. State that there may be no benefits to study participation (p5). Please amend this section to avoid over-promising benefit.
9. There is a risk that flushing with CO2 may be associated with worse outcomes (p5); this should be acknowledged.
10. State that the blood sample will be analysed overseas (and where they will be sent to) and include a Māori tissue statement (p3) *(“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/ whānau 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 before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose*.”)
11. Replace the 'what if something goes wrong section' text with the HDEC-approved ACC compensation text. Remove references to data and tissue, and to contacts in the UK.
12. The confidentiality section is not fit for purpose in New Zealand, as it references acts and data controllers that do not apply here. Critically, the Sponsor should not hold identifiable data. Refer to the [HDEC PIS/CF template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for suggested language.
13. International data transfer uses the term 'personal’ data; please instead refer to ‘coded’ or ‘un-coded’ data.
14. Rights of access, future use of data, and data risks must be addressed.
15. Please ensure all contacts provided are within New Zealand.
16. The CF is missing relevant clauses for New Zealand; please also add an optional tick-box for receipt of overall study results.
17. Clarify that its saline alone or saline in conjunction with CO2 (p3).

Decision

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Assc Prof Mira Harrison-Woolrych and Mrs Helen Walker.

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| **8** | **Ethics ref:** | **21/STH/196** |  |
|  | Title: | Polymyalgia Rheumatica (PMR) Dependent on Glucocorticoid Treatment: A Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Study ofABBV-154 |  |
|  | Principal Investigator: | Dr Mark Sapsford |  |
|  | Sponsor: | AbbVie Pty Ltd |  |
|  | Clock Start Date: | 29 July 2021 |  |

Mark Sapsform was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study aims to assess the safety and efficacy of ABBV-154 versus placebo in participants with Polymyalgia Rheumatica (PMR) who are dependent on treatment with glucocorticoids. Total of 200 participants of which 20 are in New Zealand.

Summary of resolved ethical issues

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

1. The Committee queried if participants would receive reimbursement of travel expenses. The researcher responded that reimbursement of travel expenses would be provided across all New Zealand sites.
2. The Committee noted that F in the application form is incorrect as there are no exceptions to needing to obtain HDEC approval for use of tissue. Further, responses to the use of tissue are unclear. The researcher clarified that RNA, DNA and genetic tests referred to in the application form are all optional and subject to optional consent.
3. The Committee asked how participants will be recruited. The researcher stated that recruitment for the study would be raised at department meetings, and non-study clinicians who identify potentially eligible patients will be able to approach them and gauge interest before passing study information on.
4. The Committee asked if any potentially identifying information is required to register/log in to the wearable device and other electronic devices. The researcher clarified that they do not need to login or register to use the wearable device; location is not recorded, just sleep and physical activity. An iPhone will be provided for the electronic diary, and only information required to access that device is a pin-number to open the device.

Summary of outstanding ethical issues

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

1. The insurance does not define the policy territory in the certificate. Please have New Zealand defined as the territory and resubmit this.
2. The Committee stated more information around data management is required than what is available in the Protocol and Participant Information Sheet to satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.
3. The Committee noted the justification for the use of placebo in the application form is not sufficient and required more information around with-holding standard of care. After discussion with the researcher, the Committee was satisfied that for patients defined as dependent on glucocorticoids, a taper is not withholding standard of care as its not standard of care to avoid tapering. The Committee requested this is clear in the participant information sheet and consent form (PIS/CF).
4. The Committee noted that the application states participants will not be exposed to ionising radiation above standard care, while p.1.1 lists chest x-ray and bone densitometry as study-specific procedures. The researcher stated that they will seek to use historical records where possible but may require additional screening as part of the study if none can be found. The Committee requested this is reconciled across the study documentation.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

Main PIS/CF

1. Please review for typos.
2. Please review for New Zealand context.
3. Please have a lay-friendly title and review whole PIS/CF for medical jargon and abbreviations and replace with lay-language or explanations as soon as they appear.
4. Please amend notifiable diseases to be New Zealand specific.
5. Please remove “you may have to pay for some medicines according to hospital policy”.
6. Procedure explanation is only required the first time it is mentioned.
7. In New Zealand, the collection of pregnancy information is subject to separate optional consent if it is not made as part of the main study. [HDEC have templates](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) available for the separate consent, which should only be submitted by way of amendment if pregnancy does occur.
8. Reproduction advice is scattered throughout the information sheet. Please combine this under a single header and refer to the [HDEC template around reproductive risks.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-apr20.docx)
9. Delete measurement of blood in ounces and cups (p5).
10. Include information about what a 'low risk of radiation' is equivalent to in terms of background radiation exposure (p8).
11. Give examples of commonly administered live vaccines (NZ-specific) (p11).
12. 'Even if you are no longer in the study or not receiving study drug, your study doctor will contact you to collect information about your pregnancy and pregnancy outcome'. Please note that collection of this information would be subject to additional optional consent (p14 and 'withdrawal' section).
13. Mental health problems are included in the same paragraph as allergic reactions (p14). Please separate.
14. Address use of data for future research.
15. State retention times for mandatory samples (p21).
16. If samples may be analysed in any country worldwide, this needs to be clearly stated (p21).

Optional PIS/CF

1. Please have a lay-friendly title, review whole PIS for medical jargon and abbreviations, and replace with lay-language or explanations as soon as they appear.
2. If they withdraw from the main study, please ask participants if they wish to withdraw from the optional study.
3. Explain much more clearly what genes and genetic material is, and that a person's genes are shared with blood relatives. State whether WGA may be performed.
4. Explain what pharmacokinetic samples are.
5. Explain what biomarkers are.
6. State where samples will be stored and analysed.
7. Provide information about risks of data harms (e.g. privacy breach / reidentification / sending tissue overseas).

Decision

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Devonie Waaka and Mr Dominic Fitchett.

## 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:** | 14 September 2021, 10:00 AM |
| **Meeting venue:** | ONLINE - Zoom Meeting |

1. **Review of Last Minutes**

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

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

The meeting closed at 2.50pm.