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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 22nd March 2022 |
| **Zoom details:** | https://mohnz.zoom.us/j/96507589841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Assigned Lead Reviewers** |
| 12.00-12.30pm | 2022 FULL 12093 | BP42233: A Phase 1 Study Evaluating Safety and Pharmacokinetics of RO7425781 in Relapsed or Refractory Multiple Myeloma | Dr. Peter Browett | Mrs Helen Walker & Dr Peter Gallagher |
| 12.30-1:00pm | 2022 FULL 12345 | SafePass 3 | Dr Sanjeevan Pasupati | Ms Sandy Gill & Dr Patries Herst |
| 1:00-1.30pm | 2022 FULL 11865 | Ocular Rehabilitation after Eye Damage in Aotearoa New Zealand | Dr Stuti Misra | Dr Cordelia Thomas & Ms Albany Lucas |
|  |  | ***Break (15 minutes)*** |  |  |
| 1:45pm – 2:15pm | 2022 FULL 12143 | A Study of Baloxavir Marboxil for the Reduction of Direct Transmission of Influenza from Otherwise Healthy Patients to Household Contacts | Dr Mike Williams | Ms Jessie Lenagh-Glue & Dr Peter Gallagher |
| 2:15pm – 2:45pm | 2022 FULL 12358 | Placebo-controlled study to evaluate the efficacy of mRNA-1345 vaccine | Dr Mike Williams | Dr Cordelia Thomas & Ms Julie Jones |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 22/05/2018 | 22/05/2020 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 22/05/2020 | 22/05/2023 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 22/05/2020 | 22/05/2023 | Present |
| Ms Albany Lucas | Non-lay (observational studies) | December 2021 | December 2023 | Apologies |
| Ms Julie Jones | Non-lay (intervention studies) | 22/05/2020 | 22/05/2022 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that apologies had been received from Ms Albany Lucas.

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 22nd February were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 12093** |
|  | Title: | BP42233: A Phase 1 Study Evaluating Safety and Pharmacokinetics of RO7425781 in Relapsed or Refractory Multiple Myeloma |
|  | Principal Investigator: | Dr Peter Browett |
|  | Sponsor: | Roche Products (New Zealand) Ltd |
|  | Clock Start Date: | 10th March 2022 |

Courtney Rowse and Dr Peter Browett 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. Main Study Objectives: 1. To evaluate the safety and tolerability of RO7425781 2. To determine the maximum tolerated dose (MTD) from Part 1 to define a recommended Phase II dose (RP2D) for intravenous (IV) and/or subcutaneous (SC) dosing schemes of RO7425781 3. To measure the levels of RO7425781 in the blood over time, following multiple doses 4. To assess whether RO7425781 is effective against multiple myeloma when used alone.

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 how many participants would be involved in the study. The Researcher explained that there would be approximately 5 participants as this is considered achievable for this study. More participants would be approached if they fit the inclusion criteria.
2. The Committee asked for clarification on whether the PI is the participants clinician and how the research team would manage any conflicts of interest or coercion. The Researcher confirmed that participants are under the PI’s regular care and noted that there is no benefit to the clinician if their participant takes part in the study.

Summary of outstanding ethical issues

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

1. The Committee suggested the risks of the study to be listed as an appendix at the end of the PIS to make the PIS more readable.
2. Please clarify the statement on 6 of 8 participants experiencing 11 events so that it is clear how many events a participant may expect.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| **2** | **Ethics ref:** | **2022 FULL 12345** |
|  | Title: | SafePass 3 |
|  | Principal Investigator: | Dr Sanjeevan Pasupati |
|  | Sponsor: | Emboline, Inc. |
|  | Clock Start Date: | 10th March 2022 |

Dr Sanjeen Pasputi and Ms Gypsy Francis did not present via videoconference for discussion of this application. The Committee waited 15 minutes and followed up via email before proceeding with the 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 SafePass.3 study is investigating the safety and technical performance of the improved Emboliner embolic protection catheter. The Emboliner is a temporarily-implanted aortic embolic filter which is designed to cover the aortic branch associated with the cardiac valve repair site to remove all debris created during the valve repair process. The Emboliner addresses the limitations of current devices in use with several unique features, please see Protocol TP-0686 Rev A, p 11. It is intended for use during interventional cardiology procedures, such as TAVI. In addition, the Emboliner is able to be deployed using an existing procedural access site during TAVI, so no additional procedural access is required.

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 asked for clarification on whether the device would fit any aortic size, and whether this could be an issue.
2. The Committee requested that the peer reviewer fill out the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/)
3. The Committee noted that the medical insurance does not seem protocol specific and requested to know if the total cover would be enough for this study and how much the cover would there be for a single claim.
4. Please remove the blue writing in the data management plan (DMP) and keep the information pertinent to the study.
   1. Please clarify the policies being referenced in the data governance oversight (will this be applicable to the Hamilton and Auckland sites, name the policies, please link to relevant websites).
   2. Blood samples are mentioned in the DMP. Please ensure this is addressed in the PIS.
   3. Please ensure the information on images is included in the PIS.

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

1. The Committee requested a line to be added on the very first line on page 1 to Clinical Study, such as: “…of a device which will capture particles released during heart valve surgery”.
2. Please clearly state how the device is better/different from similar devices.
3. Please provide a more lay-friendly description of the purpose of the study, like referring to “Similar technology for aortic embolic protection for TAVR” as “similar types of filters” etc.
4. Please provide detail on current standard practice in this hospital for protecting the blood stream from surgical debris.
5. Please provide information on research that has already been done using this device.
6. Please provide an image of the device forming a “hood” over the aorta on page 4.
7. Please provide more information on why pregnant women are excluded from the study and consider whether this will impact equity of access to the device.
8. Please consider using the reproductive risks template from the [HDEC website.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
9. Please be clear on whether participants will have two standardised neurocognitive assessments.
10. The Committee noted that the benefits section contains repetitive information, please review this section.
11. The Committee asked for clarification on whether the device will be available outside of the study, as the PIS contains conflicting information. Please ensure the information is consistent throughout.
12. Please add X out of 100 patients to percentages when discussing risks.
    1. Please provide further information on how many participants in New Zealand/overseas have used the device, how do these risks compare with similar devices.
13. Please rephrase the sentence in Section 3: “What do I have to mind when participating” with “What will my participation involve”.
14. Please redraft the insurance section using the HDEC template for sponsored research. It is currently very unclear and incorrect in places:
    1. Please remove the statement on not being insured whilst travelling to and from the study, as they will be covered by ACC under those conditions.
    2. Please include a paragraph explaining the insurance company and clearly state that it can cover costs if something were to happen because of the study. However, please also include a statement outlining the payment is not assured and that there may be a disputed process.
    3. Please include a statement informing participants that they should check with their own medical insurance company to ensure that participating in a trial does not invalidate their personal policy.
    4. Please remove the details about the insurance policy, they can receive these in the event of an incident occurring.
15. Under who pays for the study: Please provide a statement outlining that the sponsor (provide name) is paying for the study and that participants will not be paid for their data and will not financially benefit if the device becomes commercialised.
16. The Committee noted that the sponsors insurance must cover the participants to a high level. The medical insurance does not seem to be protocol specific. How much would each claim be covered for?
17. Under section 11, please correct the spelling mistake (withdrawal should be withdraw)
18. Under section 12, please add financial reasons to medical and scientific reasons.
19. Please provide information on where identifiable and coded data will be stored.
20. Under “what will my participation involve”: please provide information about the taking of blood samples (when and why they will be taken, what will happen to them, what types of analysis will be done, whether it is standard of care for the trial).
    1. If blood samples are part of the trial, please provide more information and include a cultural statement.
    2. Please include information on any risks associated with taking blood samples.
21. Please provide more information on images being taken during the study (what type of images, who will have access to the images, their purpose, etc), whether they will be used for reports, presentations and publications and that participants will not be able to be identified from them.
22. The Committee noted that section 12 and 15 have similar information. The information in both could be amalgamated into one section before the contact details.
23. Please place any contact information at the end of the PIS.
24. The Committee noted that the study is not taking ethnicity data. Māori data is a taonga and any research involving Maori must include ethnicity data.
25. Please clarify what will happen if a participant chooses to withdraw from the study as the information in the PIS is not consistent.
26. Please add a bullet point to the consent form that asks for consent for the blood samples to be taken and a separate bullet point for the taking of images.

**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 Patries Herst & Ms Sandy Gill.

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| **3** | **Ethics ref:** | **2022 FULL 11865** |
|  | Title: | Ocular Rehabilitation after Eye Damage in Aotearoa New Zealand |
|  | Principal Investigator: | Dr Stuti Misra |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 10th March 2022 |

Ms Janice Yeoman 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 principal aims of this study are to characterise the demographic profile of people with disfigured eyes in New Zealand and document the reasons for their eye disfigurement; to establish how people with disfigured eyes are currently rehabilitated in New Zealand by surveying eye care clinicians and people with disfigured eyes, and auditing the clinical records of people with disfigured eyes; to use observe the physiological changes that occur in a disfigured eye when it is fitted with a scleral shell prosthesis for the first time; to characterise the physiological state of disfigured eyes already fitted with scleral shell prostheses and use clinical observations to determine whether increasing the wettability of the scleral shell material can improve the health outcomes and comfort of the disfigured eye.

Summary of resolved ethical issues

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

1. The Committee queried whether the use of flyers would be appropriate in a study involving visually impaired participants. The Researcher explained that most participants in the study will be unilaterally visually impaired and that the advertisements will be printed with large fonts and keeping the designs to a minimum to it is easier to read.

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 a $30 fuel voucher as reimbursements for visually impaired participants may not be appropriate and asked the Researcher to include the option of taxi or rideshare vouchers.
2. The Committee asked for clarification on how many participants will be enrolled to the study, and how many would be expected to be children. The Researcher explained that they are aiming that the data on how many participants who may fit the inclusion criteria is currently unclear, however noted that approximately 20% of the participants would be under 20 years old.
   1. The Committee queried whether the study advertisements will read broadly enough for the purposes of the study. The Researcher explained that they will employ as many third-party organisations to use distribute the information on the study as possible.

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

1. Please briefly explain what the other parts of the study are so that if participants have an understanding of the breadth of the studies.
2. Please ensure that the language in the parents and caregivers CF are consistent (i.e., ‘you’ and ‘your child’). The consent is being gathered on behalf of the child, so please refer to the child.
   1. Please include a statement on the child’s right to withdraw.
   2. Please consider including a statement such as ‘your child will complete the survey with your assistance’.
3. The Committee noted that 12-15 year olds may be able to fill out the form without assistance. The Committee recommended a statement such as “You can fill out the form by yourself or with a parent/guardian if you wish”.
4. In the clinician DF, please refer to the ‘patients’ as ‘participants.
5. Please include a lay explanation of "osmolarity"
6. Please include a statement on a participants’ right to access and data.
7. Please include a Māori cultural statement on data being a taonga and acknowledge that you may be touching participants heads, as this is tapu.
8. Please change referring to aspects of the trial as ‘experiments’, please rephrase to ‘observational studies’ or ‘sub-studies’.
9. Please consider making the font larger.
10. Please provide more information on what will happen to the participants information in the data management plan (DMP). Please consider using the [HDEC DMP template.](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/)
11. Please check all documents for spelling or grammatical mistakes.
12. The Committee noted that some participants may be blind and requested that a braille or audio version of the PIS be made available.
13. The Committee noted that on the survey for scleral shell wearers, questions 17-19 refer to how the eye looks to the wearer. Please rephrase this section as some participants may not be able to provide this information if they have a significant visual impairment.
14. Please include a statement informing the participants that the study is towards a PhD thesis.

**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 Cordelia Thomas and Dr Patries Herst.

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| **4** | **Ethics ref:** | **2022 FULL 12143** |
|  | Title: | A Study of Baloxavir Marboxil for the Reduction of Direct Transmission of Influenza from Otherwise Healthy Patients to Household Contacts |
|  | Principal Investigator: | Dr Mike Williams |
|  | Sponsor: | Roche Products (New Zealand) Limited |
|  | Clock Start Date: | 10 March 2022 |

Dr Mike Williams and Bronwyn Gale 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 study will evaluate the efficacy of a single, oral dose of baloxavir marboxil (BXM) compared with placebo for the reduction of the direct transmission rate of influenza A or B from otherwise healthy (OwH) adult and adolescent index patients (IPs) to household contacts (HHCs).

Summary of resolved ethical issues

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

1. The Committee clarified that the increase of risk in the CDC document provided for Alaskan natives and Native Americans was potentially echoed in Pasifika and Māori populations and whilst the former was excluded from the international phase of the study, the latter would not be due to a difference in the way influenza vaccines are funded in New Zealand and the considerations of co-morbidity vs actual risk from influenza in those ethnicities.
2. The Committee clarified that the branded retention items would be covered by the sponsor and provided to the sites. None of these are intended to be inducements, please ensure these are included in D21.
3. The Committee clarified that the reimbursement travel costs were $100 per visit.
4. The Committee clarified that the indemnity was New Zealand specific.

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 how patients would be selected based on eligibility as the index patient if the household contacts were not consenting to be participants. Please, with the sponsor, determine how consenting of household participants will be managed with respect to the index patient dosing.
2. The Committee noted the restriction of dairy was a condition of the study and queried if this was wise with the inclusion of children. The Committee requests this be reviewed for necessity given there is no mention of this in the Investigators’ Brochure.
3. The Committee requires a specific plan for the management of anxiety and depression related adverse events or significant cases of distress.
4. The Committee noted that 2-3 years of age is perhaps too young to assent. Please consider the inclusion of participants from 5 years old and that consenting of index patients and household contacts should follow the same age ranges.
5. The Committee noted that there were home visits noted, please change all documentation to state that these will not occur and that site visits only will be conducted as clarified by the researcher
6. Where mention of the “Health authority in New Zealand” occurs the Committee requests this be changed to Medsafe if Medsafe is in fact what is being referenced.

The Committee requested the following general changes be made to all Participant Information Sheet and Consent Forms (PIS/CF):

1. Please ensure that filling the diary is listed as a participant responsibility.
2. Consider changing the age groupings to be Younger children and Older children, this would better support a more dynamic consent process and help remove some of the issues around appropriate language for certain groups and the removal of 16- and 17-year-olds from the “child” assent forms.
3. Please include in all assent forms for those over the age of 7 that these are full assent forms not only an assent that participants have read the PIS. Please also include in this age range the information that the participants data will be sent overseas and the location to which they will be sent.
4. Please remove tick boxes where there is not a true option involved.

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

1. Please remove “no one will be upset” from the language used and change this to something more positive.
2. Please remove the language around the Guardian as this is not necessary.
3. Please include information that the child will have their temperature taken.

Age 12-17 Participant Information Sheets and Consent Forms (PIS/CF):

1. The Committee noted that 16-17 years old can give consent as adults. Please change this consent form to 12–15-year-olds.
2. Please differentiate the requirement for pregnancy testing in those individuals who are menstruating vs. those who are not. As pregnancy testing is not relevant in individuals who are not yet capable of menstruation.

The Committee requested the following changes to the Adult Participation Information Sheets and Consent Forms (PIS/CF):

1. Please indicate what exactly must be avoided when mentioning “Certain food and medications should be avoided.”.
2. Please amend the reference to “Legally authorised representative” as this is not relevant in this study given there are no incompetent participants being enrolled.
3. Pregnancy Participant Information Sheet and Consent Form (PIS/CF): the committee will consider this when it actually happens and is submitted as an amendment

**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 Peter Gallagher and Ms Jessie Lenagh-Glue.

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| **5** | **Ethics ref:** | **2022 FULL 12358** |
|  | Title: | Placebo-controlled study to evaluate the efficacy of mRNA-1345 vaccine |
|  | Principal Investigator: | Dr Mike Williams |
|  | Sponsor: | PPD Global Limited & Moderna TX, Inc. |
|  | Clock Start Date: | 10th March 2022 |

Dr Mike Williams 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 safety and tolerability of the mRNA-1345 vaccine as also aims to demonstrate the efficacy of a single dose of mRNA-1345 vaccine in the prevention of a first episode of RSV-associated lower respiratory tract disease (RSV-LRTD) as compared with placebo within the period of 14 days post-injection up to 12 months post injection.

Summary of resolved ethical issues

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

1. The Committee clarified that in the event a participant does not have a smartphone or device that can access the eDiary that one will be provided.

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 letter from Medsafe noted that the General Practitioner (GP) should be told if individuals are participating. If this is the case, then the option for a GP to be consented should be removed as it should be mandatory.
2. The Committee noted that the statement “After the study tests are completed, some of your samples may be stored for up to 20 years and may be used for future research purposes if permitted by local regulations. The samples will remain the property of Moderna. You will not be told of additional tests, nor will you receive results of any of these tests.” needs to be amended as in NZ the participant must give separate consent for unspecified future use of samples as per NEAC guidelines.
3. The Committee queried the lack of a Māori tissue or data statement in the Participant Information Sheet. The Committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of any tissue samples removed. The cultural issues associated with sending your samples or data 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.”*

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

1. Please proof-read for missing words and context.
2. Please clarify what samples will be taken for FUR and if it is nasal swabs *and* blood or if it would only be blood samples.
3. Please remove mention of antibody assessment in the FUR as this is a main study process.

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

1. On page 2 please delete the HDECs review statement is it is incorrect and the correct statement is included under point 16.
2. On page 4 please remove the statement informing the number of participants may change dependent on RSV infection in the community.
3. On page 4 please explain all abbreviations in full the first time they are mentioned.
4. Please reword “Attend to your visits” to ensure it reads correctly.
5. Please detail a structure as to how the consent will be recorded if they are consented over the phone, should this not be the case then it may be more appropriate for this to be removed.
6. On page 8 please note that use of depression and anxiety questionnaires requires a plan for addressing an adverse event or significant distress.
7. Please review for spelling and grammar.
8. On page 25 please amend the statement on Moderna stopping the participation at any point for any reason.
9. Please amend the pregnancy statement in participants over 60 as this is unnecessary.
10. Please amend the tissue statement to note what types of tissue will be collected and where it will be sent overseas.
11. Please simplify the PIS to be clear and simple for participants, more along the lines of the brochures provided.
12. Please amend point 2, “The use of a safe and effective” please delete ‘safe and effective’ as that has not yet been determined.
13. Please remove “The total number of participants in Phase 3 of the study will depend on the number of cases of RSV infection in a particular region and the number of participants in Phase 2 of the study.”, otherwise the reference to phase 2 should be removed as it has no context.
14. Please add more information to explain the randomization process
15. Please delete ‘personal’ from the page 2 statement “Personal information already…” as this reads currently as if this data is not study-related.
16. Please rephrase “It is recommended to tell your health care provider about your participation in the study.” to reflect the consent which says that the GP will be contacted to inform them of study participation.
17. Please change ‘fit’ to eligible in the statement, “whether you are fit to take part in this study”.
18. “If you decide to leave the study early for any reason, you will be asked to be followed for your safety and complete all the follow-up procedures.” – this won’t make sense to a participant, it makes it sound like they are physically followed. Please rephrase to say they will be contacted for safety follow-up rather than followed.
19. Please include a statement prior to mention of the provision of a thermometer to participants that states how and where the temperature should be recorded.
20. Please include more information regarding the physical exam, to align with the information from the protocol, particularly as the head is touched and assessed which is tapu for Maori: “The full examination will include assessment of skin, head, ears, eyes, nose, throat, neck, thyroid, lungs, heart, cardiovascular, abdomen, lymph nodes, and musculoskeletal system/extremities.”
21. Please include incidence of adverse reactions or potential risks and the expected frequency of these in a “1-in-10” format if they are available.
22. Under costs for taking part header, please delete “or your insurance company.”
23. Please amend the statement “The Sponsor may pay for the reasonable and necessary costs associated with this care.” as it is the sponsors responsibility to pay for care following an Adverse Event. This should be Will not may.
24. Please do not include the initials and date of birth in the de-identified data that will be stored.
25. Please delete the statement, “However, in order to protect the scientific value of the study, your right to access these data may be delayed until the study data have been analysed, unless required to be made known earlier by local law.” as the participant has a right to access and correct their data in New Zealand.
26. Please remove mention of the FUR unless stating that it is optional and will be consented as such.
27. Please delete the statement “When the study is finished, you may write to the study doctor to request information about yourself that was collected during the study. Unless prevented from doing so for legal or ethical reasons, the study doctor will give your reasonable access to this information. “
28. Please review the statement “All personal information that you provide will be kept completely confidential.” As under use of technologies it says that confidentiality by the vendor cannot be guaranteed and this is either unnecessary or should be reviewed.
29. Please ensure data storage timelines reflect the NZ requirements as laid out by NEAC 12.13.
30. Information being sent overseas is not properly covered in the body of the PIS.
31. Please specify data risks as they are not clearly covered. Please refer to the [HDEC template](https://ethics.health.govt.nz/assets/HDEC-data-tissue-management-template-Oct-2021.docx) for this section.

The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):

1. Please ensure data storage timelines reflect the NZ requirements as laid out by NEAC 12.13.

**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 Cordelia Thomas and Ms Julie Jones.

## General business

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

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| **Meeting date:** | 26th April 202 |
| **Zoom details:** | To be determined |

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 3pm.