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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 15th November 2022 |
| **Zoom details:** | https://mohnz.zoom.us/j/96507589841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12.30-1.00pm | 2022 FULL 13730 | BJT-778-001: A Study to Evaluate BJT-778 in Healthy Participants and in Participants with Hepatitis B Virus (HBV) and Hepatitis D Virus (HDV) Infection | Professor Ed Gane | Dr Andrea Forde & Ms Catherine Garvey |
| 1.00-1.30pm | 2022 FULL 13608 | IN002011 : A Study to Evaluate a new mRNA COVID-19 Vaccine (IN002.5.1) in Comparison with an Approved mRNA COVID-19 Vaccine | Dr Corey Selwood | Dr Sotera Catapang & Dr Leonie Walker |
| 1.30-2.00pm | 2022 FULL 13667 | PCT in the ICU - a retrospective study | Dr Jaqueline Hannam | Dr Kate Parker & Mr Jonathan Darby |
| 2.00-2.30pm | 2022 EXP 13822 | Kawakawa and its impact on inflammatory markers | Dr Farha Ramzan | Mr Derek Chang & Ms Catherine Garvey |
| 2.30-3.00pm |  | Break 30 Minutes |  |  |
| 3.00-3.30pm | 2022 FULL 13508 | The Co-Pilot trial: Closed loop in children and youth with type 1 diabetes and high-risk glycaemic control | A/Prof Ben Wheeler | Ms Jade Scott & Dr Leonie Walker |
| 3:30pm-4:00pm | 2022 FULL 13681 | Measuring and strengthening immunity to measles in young adults fully immunised in childhood | Professor Peter McIntyre | Dr Andrea Forde & Mr Jonathan Darby |
| 4:00pm-4:30pm | 2022 FULL 12179 | MER-XMT-1536-3: Study of Upifitamab Rilsodotin as Post-Platinum Maintenance Therapy for Participants with Platinum-Sensitive Recurrent Ovarian Cancer | Dr Michelle Wilson | Dr Kate Parker & Dr Leonie Walker |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mr Derek Chang | Non-lay (Intervention studies) | 08/07/2022 | 08/07/2025 | Present |
| Dr Kate Parker | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey | Lay (the Law) (Chair) | 19/03/2019 | 19/03/2022 | Present |
| Dr Sotera Catapang | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Apologies |
| Dr Leonie Walker | Lay (Ethical/Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, apologies had been received from Mr Jonathan Darby.

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 18th October 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 13730** |
|  | Title: | BJT-778-001: A Study to Evaluate BJT-778 in Healthy  Participants and in Participants with Hepatitis B Virus (HBV)  and Hepatitis D Virus (HDV) Infection |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | Novotech Biotechnology |
|  | Clock Start Date: | 3rd November 2022 |

Professor Ed Gane, Courtney Rowse, Holly Thirwall, Nicole Arreola and Nicole Griffiths 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 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 application was submitted to the Standing Committee on Therapeutic Trials (SCOTT) for review.
2. The Committee clarified that there would be some inclusion/recruitment of Hepatitis Delta (D) participants as well as the cohort of Hepatitis B.
3. The Committee clarified that there were no chimpanzee models as these are no longer permitted in European and North American practice.
4. The Committee noted that there was no direct benefit for the drug in participants due to the mechanism of the drug itself.
5. The Committee clarified that the Delta patients would be recruited from within the clinic’s pre-existing population as well as in communities of Samoan and Kiribati populations in New Zealand and that this would be managed as required for the study population. The Committee clarified that there would be suitable arrangements for travel for participants outside of Auckland and no recruitment of people unable to be followed up should they be required to leave the country. The Committee suggested that this be updated in the application.
6. The Committee clarified that the offshore sites would update and keep in contact with the New Zealand sites via the Sponsor to ensure that dosing and number of participants is correct with particular regard to sentinel dosing.
7. The Committee notes that cohort C1 does not exist and that this is intentional due to the dosing.

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 that the sponsor signatures be done with a person’s signature rather than the general “Mr Novotech Regulatory”.

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

1. Please include the overseas laboratory details i.e., location, name of lab etc. as is included in the optional PIS.
2. Please remove reference to cohort C1.
3. Please ensure the protocol reflects any particular recruitment and consent arrangements for the Hepatitis D cohort.

**Decision**

This application was *approved* 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 13608** |
|  | Title: | IN002011: A Study to Evaluate a new mRNA COVID-19 Vaccine (IN002.5.1) in Comparison with an Approved mRNA COVID-19 Vaccine |
|  | Principal Investigator: | Dr Corey Selwood |
|  | Sponsor: | Shenzhen Shenxin Biotechnology Co., Ltd (doing business as InnoRNA) |
|  | Clock Start Date: | 3rd November 2022 |

Dr Chris Wynne, Courtney Rowse and Holly Thirwall 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 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 scientific validity of the investigated vaccine and the Moderna vaccine would be reviewed by SCOTT. The Committee clarified that the terms of the provisional approval of the Moderna vaccine would be considered by SCOTT in the review of the research drugs.
2. The Committee noted that older populations would be studied in later phases of the study particularly given the importance of these vaccines in older populations in COVID-19 prevention.
3. The Committee clarified the use of a comparator due to the lack of a naïve population because of widespread infection and high uptake of vaccines.
4. The Committee clarified the limits and purposes of access to identifiable information as listed in the PIS and confirmed that this largely meant access to identifiable data kept and viewed on site.
5. The Committee clarified that National Medical Products Administration (NMPA) SOPs would be used in accordance with the locality.
6. The Committee clarified the follow up and recall protocol for serious adverse events.
7. The Committee clarified that the screening would look into the respiratory system of smokers and that if there was a chance there would be a negative effect with drug they would not be included in the study.
8. The Committee clarified the arrangement of the subgroups as per the protocol.
9. The researcher clarified that the address of the laboratories would not be included in the Protocol as per standard.

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 the use of the Moderna as a comparator vaccine given this vaccine is provisionally approved in New Zealand. The Committee requested that the SCOTT review be provided for review once it becomes available. The researcher clarified that both Pfizer and Moderna have been in global use and have licensure in most jurisdictions. However, Pfizer is not available for use as the comparator. Therefore, the study is using the alternative mRNA vaccine.
2. The Committee requested that the advertising be made clearer and in line with the radio ads regarding the study only being conducted in Christchurch.

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

1. Please clarify agencies that may have access to the identifiable information for the sake of transparency, particularly in respect of Governments and government agencies.
2. Please clarify the use of rapid antigen testing (RAT) as necessary and if appropriate the possibility of polymerase chain reaction (PCR) testing.
3. Please ensure that the amount of blood being taken is consistent between the Protocol an information sheets.

**Decision**

This application was *approved* 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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| **3** | **Ethics ref:** | **2022 FULL 13667** |
|  | Title: | Modelling procalcitonin for bacterial infections in the intensive care - a retrospective study |
|  | Principal Investigator: | Dr Jacqueline Hannam |
|  | Sponsor: |  |
|  | Clock Start Date: | 3rd November 2022 |

Dr Jacqueline Hannam 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 resolved ethical issues

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

The Committee had no further comments or queries regarding the study and noted that this resubmission was completely satisfactory.

**Decision**

This application was *approved* by consensus.

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| **4** | **Ethics ref:** | **2022 EXP 13822** |
|  | Title: | Kawakawa and its impact on inflammatory markers |
|  | Principal Investigator: | Dr Farha Ramzan |
|  | Sponsor: |  |
|  | Clock Start Date: | 3rd November 2022 |

Dr Farha Ramzan and Dr Chris Pook 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 resolved ethical issues

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

1. The Committee noted that consultation with Māori was being undertaken and the study was developed by a Māori organisation and would be for their benefit.
2. The Committee clarified that the Kawakawa product was collected by Wakatū Incorporation for the purposes of the project and conducted the food standard microbiology testing.
3. The Committee clarified that the data will be owned by Wakatū due to the rights to IP in the therapeutic uses and cultural uses and significance of the kawakawa for Māori. No IP claims will be made by the Liggins Institute or University of Auckland. Any publication manuscripts will be viewed by Wakatū prior to the publishing and reasonable changes may be made by them in consultation with the researchers.
4. The Committee noted that the information provided to Wakatū will be de-identified.
5. The Committee clarified how the standardisation of the pharmaceutical compounds has occurred and the use of a single batch for the investigation product in this research.

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 comments raised in the peer review had not been responded to in the application. The endpoint rationale and the observation of inflammatory markers have previously been investigated but not published at this point. The sample size was noted by the peer reviewers as not being sufficient to account for gender, BMI, age and ethnicity. Please address this in the response either by referring to this as a pilot study or by increasing the number of participants.
2. The Committee noted that there was no toxicity study for this powdered product and that as there has been no prior trials and no current plans for monitoring the possible adverse effects on participants given the perceived low dose and low risk the PIS should acknowledge this.
3. The Committee requested that the details of the product including relevant production and manufacturing standards be included in the protocol.
4. The Committee requested clarification as to whether this study is investigator led or if this is a commercially sponsored study, and in particular requested detail of the data rights and commercial interests in the study of Wakatū. This will need to be updated in the protocol and if the study is in the benefit of the commercial entity, then it will require sponsor status and there will need to be insurance provided for this purpose. ACC will not cover participants for injury in this study if it is commercially sponsored.
5. Please clarify in the protocol as to who exactly was part of the cultural consultation process.

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

1. Please amend to use more lay-friendly language.
2. Please clarify that the screening is a formal visit to the site and no screening or pre-screening will be done remotely.
3. Please clarify what will occur to the data in the case of screening failure.
4. Please use layman terms for random and post-prandial.
5. Please include amount of blood sample taken per visit and total amount of blood sample for the study.
6. Please clarify what will occur if any abnormal results are found.
7. Please specify who the funder, the sponsor is and the sourcing of the kawakawa in the information sheet.
8. Please acknowledge who Wakatū are and their role in the information sheet.
9. Please state clearly how many capsules may be given to participants.
10. Please clarify what each of the 3 study interventions are.
11. Please standardise use of placebo or control for consistency.
12. Please explain the term “double blinded”.

**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 Mr Derek Chang and Ms Catherine Garvey.

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| **5** | **Ethics ref:** | **2022 FULL 13508** |
|  | Title: | The Co-Pilot trial: Closed loop in children and youth with type 1 diabetes and high-risk glycaemic control |
|  | Principal Investigator: | A/Prof Ben Wheeler |
|  | Sponsor: |  |
|  | Clock Start Date: | 3rd November 2022 |

Alisa Boucsein and Associate Professor Ben Wheeler 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 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 cohort would not be able to access the funded pump due to their glycaemic control. The researcher noted that any provision after the study would be due to better glycaemic control achieved in the trial.
2. The Committee clarified that the study is investigator initiated despite provision of the equipment by the device manufacturer (insulin pump and CGM).
3. The Committee queried if there would be cultural competency in the consenting staff should there be a need for this. The Researcher noted there may be availability of this.
4. The Committee noted that the reasoning for exclusion of pregnant people in the study was potentially problematic. The researcher noted that there were independent studies being conducted by other researchers in the field in pregnant participants. The manufacturer has made a ruling to not permit this cohort to participate in this particular study. The researcher specified that any people becoming pregnant on the study would be assisted to access a government funded device.
5. The Committee clarified that there would likely not be provision of the same device for adults after the study but there would be the ability to move on to the government funded devices (pumps) while participants were likely to have to wholly or partly fund the CGM devices.

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 provision of the assent forms for the younger group of children
2. The Committee requested clarity in the data management plan, protocol, and participant information sheets (PISs) as to what will happen to data, how and where it will be stored and for how long and who specifically will have access to the data.
3. The Committee requested provision of some form of reconsent form for individuals turning 16 during the study. The mechanism for reconsenting these participants should be outlined in the adolescent assent form and in the PIS for parents/guardians. The Committee confirmed that reconsent may be carried out remotely if carefully documented and access to discussion with study staff prior to reconsent could occur remotely.
4. The Committee requested the following changes to the Data Management Plan (DMP):
   1. Please include information as to the data management around the actigraph, namely how this data is downloaded and where to and what form this data is stored and used in and who has access to it.
   2. Please review for redundant information left over from the template.

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

1. At the start of the PIS, please clarify the design of the study including a clear statement that the study is in two parts.
2. Please clarify what CGM stands for.
3. Please amend the information sheet titles to be consistent with the protocol or vice versa.
4. Please provide a modified diagram of the study schema as it appears in the protocol, this should be made lay friendly.
5. Please address the inability to promise provision of the device after the study.
6. Please make a note of the reconsent process.

**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 Leonie Walker and Ms Jade Scott.

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| **6** | **Ethics ref:** | **2022 FULL 13681** |
|  | Title: | Measuring and strengthening immunity to measles in young adults fully immunised in childhood |
|  | Principal Investigator: | Professor Peter McIntyre |
|  | Sponsor: |  |
|  | Clock Start Date: | 3rd November 2022 |

Professor Peter McIntyre and Melanie Millier 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.

Dr Andrea Forde declared a potential conflict of interest and the Committee decided that no action was necessary and that they would continue with their discussion with Dr Forde present.

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 intradermal device was not currently licensed in New Zealand. The nebulizer was licensed in New Zealand but not for the use of vaccine administration.
2. The Committee clarified the routine reporting requirements and the additional steps around this with the mobile phone based reporting to regulatory members of the team.
3. The Committee clarified that the assay device would be producing results for measles, mumps, rubella and varicella and that this would be conducted overseas.
4. The Committee noted that the population was vulnerable.
5. The Committee clarified that the potential participants are enrolling in courses with a clinical component for which they are required by the university course providers to be vaccinated and have evidence of immunity to various diseases including measles .
6. The Committee clarified that the MMR vaccine is free for any of the students through student health centres.
7. The Committee clarified the documents had been received by SCOTT and that SCOTT responded to the applicants noting that SCOTT review was not necessary for this study, as the MMR is a licensed medicine in ANZ, and that SCOTT therefore had no objection to the study .
8. The Committee clarified that the screening tests would involve a blood sample to be taken and that the residual specimens would then be utilised should the participant consent to the specimens to be released to the researchers for use.
9. The Committee noted that the protocol was labelled ‘Draft’ and requested the final protocol be uploaded.

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 that the protocol not contain the phrase “HDEC has approved the study protocol.” The ethical aspects of the study may be approved by HDEC but the protocol is not reviewed by HDEC.
2. The Committee queried which students would be required to have these vaccines. This should be included in the protocol and participant information sheet.
3. The Committee queried that Meningococcal poses a similar threat to this population and should be addressed in the submission as this can be as vital in prevention. Please clarify how this may interact with the study.
4. The Committee requested clarification of the follow-up approach, who will be doing so, what information will be provided to the participant and what access to records the university health centre will have. These issues are to be addressed in the protocol.
5. The Committee requested that any communications that may be used in recruitment and follow-up of participants be provided for review as they are produced.
6. The Committee requested membership details and a charter for the monitoring Committee for the sake of clarity around access to data in whatever form it may be in. This should also be clarified in the Protocol.

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

1. Please clarify the data that will be going overseas and what conditions the assay may identify.
2. Please amend SCOTT approval statements to note that this was not required for this study.
3. Please clarify specifically where anatomically the vaccine will be administered.

**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 Andrea Forde and Catherine Garvey.

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| **7** | **Ethics ref:** | **2022 FULL 13730** |
|  | Title: | MER-XMT-1536-3: Study of Upifitamab Rilsodotin as Post-Platinum Maintenance Therapy for Participants with Platinum-Sensitive Recurrent Ovarian Cancer |
|  | Principal Investigator: | Dr Michelle Wilson |
|  | Sponsor: | Mersana Therapeutics |
|  | Clock Start Date: | 3rd November 2022 |

Vivian Sun, Dr Michelle Wilson, Eshwini Tadiyal, Erika Keeton, Dr Bob Burger and Rita Lemming 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 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 best practice in New Zealand was observation. Treatment availability does not differ in New Zealand from other countries; however, some treatments are not publicly funded.
2. The Committee noted that SCOTT has approved the study.
3. The researchers confirmed that the study would be delivered publicly but there would be Sponsor funding for the resources used.
4. The Committee noted that pre-screening will only rarely require further biopsy as most participants will have had prior surgeries or biopsies that tissue can be taken from.
5. The Committee clarified that the quality-of-life questionnaires would be conducted prior to meeting clinicians but would be seen and reviewed. These would also be independently assessed through other standard of care checks external to that questionnaire.
6. The Committee clarified that the standard of care detection of any psychological distress would be utilised and followed up with promptly by the treatment team as is standard practice.

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 that the CI indemnity be provided for review.
2. The Committee queried and requested that the application be updated to show that the study does have potential therapeutic benefit, as currently it does not state this.
3. The Researcher noted that the dosage was altered after the application was submitted. The Committee requested that this be amended where necessary.
4. The Committee requested that clarity be provided around treatment options as currently stated in the participant information sheet. Specifically, please state that there are other treatment options available in New Zealand, albeit unfunded options.
5. The Committee requested that recruitment be led by the study nurse and not by the treating clinician and that this be detailed in the protocol.
6. The Committee noted that ethnicity data is required to be collected in New Zealand Clinical trials. Please amend this in the Protocol.
7. The Committee requested detail on who would be on the independent review board at Mersana.
8. The Committee noted that the reasons the study can be stopped cannot be solely for commercial purposes and that this should be clearly defined for the sponsor.
9. The Committee requested to remove references to sections in the Data Management Plan that are no longer relevant but have been retained in the template.

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

Main PIS/CF:

1. Please define the NaPi2b channels in lay terms the first time it appears.
2. Please clarify what an ECOG score is in lay terms for participants.
3. Please provide a time frame for the return of study results.
4. Please clarify that there are no “funded” alternatives for this condition.
5. Please specify that “you will be” reimbursed instead of “may be”.

Pre-screening PIS/CF:

1. Please clarify that the participants may request for their sample to be destroyed.

**Decision**

This application was *approved* 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).*
* 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).*

## General business

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

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| **Meeting date:** | January 2023 |
| **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 4:23 pm.