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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 24 September 2019 |
| **Meeting venue:** | Room GN.7, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:10pm | Confirmation of minutes of meeting of 27 August 2019 |
| 12:30pm | New applications (see over for details) |
| 12:30 – 12:55pm  12:55 – 1:20pm  1:20 – 1:45pm  1:45 – 2:10pm  2:10 – 2:25pm  2:25 – 2:50pm  2:50 – 3:15pm  3:15 – 3:40pm  3:40 – 4:05pm | i 19/CEN/153  ii 19/CEN/154  iii 19/CEN/155  iv 19/CEN/156  v 19/CEN/158  vi 19/CEN/159  vii 19/CEN/167  viii 19/CEN/164  ix 19/CEN/165 |
| 4:05pm | General business:  Noting section of agenda |
| 4:10pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Apologies |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |
| Dr Sarah Gunningham | Lay (other) | 05/07/2019 | 05/07/2022 | Present |
| Ms Helen Davidson | Lay (ethical/moral reasoning) | 06/12/2018 | 06/12/2021 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Mrs Helen Walker.

The Secretariat noted that it would be necessary to co-opt a Chairperson from another HDEC in accordance with the Standard Operating Procedures. Dr Sarah Gunningham confirmed her eligibility and was co-opted by the Secretariat as Chair of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 27 August 2019 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **19/CEN/153** |  |
|  | Title: | NP40435: Dose Escalation and Expansion Study Of PD-1/TIM-3 Bispecific Antibody In Patients With Advanced And/Or Metastatic Solid Tumours. |  |
|  | Principal Investigator: | Dr Sanjeev Deva |  |
|  | Sponsor: | Roche Products (New Zealand) Limited |  |
|  | Clock Start Date: | 12 September 2019 |  |

Potential conflicts of interest

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

Dr Sarah Gunningham noted that she was part of Southern HDEC that had previously declined this application.

Summary of Study

1. This is a first in human, open label, multicenter, Phase I, dose-escalation and expansion study designed to evaluate the efficacy, safety, tolerability and PK of a novel PD-1/TIM-3 Bispecific antibody, RO7121661, administered by IV infusion as a single agent. The study will consist of 2 Parts (A and B). New Zealand will only be participating in Part B. Data from Part A will be used to select the best dose and schedule for testing in Part B.
2. Part B (Tumour-Specific Expansion Cohorts): Participants with specific tumour types, e.g., non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC) or melanoma will receive RO7121661. Part B will determine the effect of RO7121661 on these tumour types.

Summary of resolved ethical issues

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

1. The Committee stated that any new data relevant to part B of the study should be sent to HDEC to review as a study Amendment

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

1. The Committee stated that the study documentation should be amended to clarify whether small-cell lung cancer is included in this study.
2. The Committee requested that page seven of the PIS is amended to include a photograph or diagram that demonstrates the differences between CT and MRI scanning.
3. The Committee stated that the PIS should be amended to include a table and timetable of visits.
4. Please amend the PIS to add a box at the beginning of the document, stating that this study is a first in humans trial
5. Please amend references to “health authorities” to New Zealand- specific organisations, e.g. Medsafe
6. Please amend page four of the PIS to state whether the numbers of participants listed is the New Zealand sample or the international sample
7. Please amend page four of the PIS to ensure that the correct numbers for study arm, and total study population are written.
8. Please amend page five of the PIS as information about side effects of the study drug is not applicable for this section.
9. Please amend the consent form to offer a lay-summary of results to participants if they wish to receive one
10. Please remove the cultural statement for sending tissue samples overseas from its current location in the PIS and add it to the section titled “what happens to my samples”.

Decision

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

* Please refer to the suggested changes to the Participant Information Sheet and Consent Forms written above

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| **2** | **Ethics ref:** | **19/CEN/154** **(Closed)** |  |
|  | Title: | MK-1308 in combination with Pembrolizumab in Advanced Solid Tumours (MK-1308) |  |
|  | Principal Investigator: | Dr Sanjeev Deva |  |
|  | Sponsor: | MSD |  |
|  | Clock Start Date: | 12 September 2019 |  |

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.

The Researcher requested that the Minutes for this review are closed for commercial reasons. The Committee agreed and upheld the Researcher’s request.

Decision

This application was *provisionally approved* by consensus.

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Peter Gallagher and Ms Helen Davidson.

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| **3** | **Ethics ref:** | **19/CEN/155** |  |
|  | Title: | ANBL1821: Testing the addition of Eflornithine (DFMO) to therapy in people with neuroblastoma (NBL) that has come back or has not responded to treatment. |  |
|  | Principal Investigator: | Dr Tristan Pettit |  |
|  | Sponsor: | Children's Oncology Group |  |
|  | Clock Start Date: | 12 September 2019 |  |

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. Despite improvements in therapy, relapse, refractory, or progressive neuroblastoma (NBL) patients still have poor outcomes. The previous COG study, ANBL1221, demonstrated an overall response rate of 41.5% for relapsed or refractory NBL patients treated with irinotecan, temozolomide, and dinutuximab. Patients generally responded well to dinutuximab/irinotecan/temozolomide, but over half did not respond. This study seeks to improve patient response rates by adding DFMO to dinutuximab/irinotecan/temozolomide. DFMO may improve the anti-tumour activity of the dinutuximab/irinotecan/temozolomide regimen by depleting polyamines, enhancing chemosensitivity, and improving dinutuximab response. DFMO may also help decrease the pain caused by the dinutuximab.

Summary of outstanding ethical issues

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

1. Please clarify whether identifiers that will be recorded on study documentation include initials and date of birth, or if it is just study numbers (discrepancy between application form and study documentation).

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

1. The Committee stated that the PIS should be amended to include a table of visits that the participant is expected to attend for this study.
2. The Committee stated that the PIS needs to clarify whether the tissue bank being used is outside of New Zealand; if so, extra information about that tissue bank, and a cultural statement for tissue being sent overseas, is required.
3. Please reconcile page 21-23 of the main PIS and the FUR-specific PIS, to make it clearer to the reader what future research they are consenting to, which future research is optional and which is mandatory, and which future research is specified and which is unspecified. Please note that separate consent is only required for specified research, whereas one consent is required for all FUR. Please label all Future research consent forms (both specified and unspecified) accordingly.
4. Please amend page nine of the main PIS to clarify whether there is any risk associated with a mother breastfeeding a baby who is being treated with the study medication.
5. Please amend the PIS to clarify that a Certificate of Confidentiality was received by the United States Federal Government, as New Zealand does not have a Federal Government.
6. Please amend page three of the PIS to specify what tests and imaging is done, possibly added to a table in the appendix for clarity.
7. Please amend PIS to clarify that how many years in total recruitment will take place.
8. Please remove the USA contact number from page twelve of the PIS
9. Please add to the PIS information about personal health information of participants being forwarded to the participant’s GP, to reflect what is written in the Consent Form.
10. Please add a cultural statement to the FUR reconsent at sixteen-years PIS/CF.
11. Please amend the PIS/CF for continued participation upon reaching age of consent to ensure that participants will receive the original, full PIS at this time.
12. Please amend reconsent at sixteen years old, as this does not require parental consent.
13. Please add a table of visits to the PIS for 11 to 15-year-olds
14. Please amend the Child Assent Form for children ages eleven to fifteen, to ensure that language such as “relapsed” and “recurrent” are not used interchangeably.
15. Please add illustrations or other visual aids to PIS and Assent Forms for seven to ten-year-olds.

Decision

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

* Please confirm what identifiers will be used in study documentation
* Please refer to the requested changes to the PIS and Consent Forms listed above

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Patries Herst and Dr Cordelia Thomas.

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| **4** | **Ethics ref:** | **19/CEN/156** |  |
|  | Title: | Klippel-Trenaunay Syndrome (KTS) Study |  |
|  | Principal Investigator: | Dr Swee Tan |  |
|  | Sponsor: | Gillies McIndoe Research Institute |  |
|  | Clock Start Date: | 12 September 2019 |  |

Dr Swee Tan was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. To study the demographics, possible causation and anatomical distribution of the disease and associated anomalies in patients with Klippel-Trenaunay Syndrome (KTS) referred to the Centre for the Study & Treatment of Vascular Birthmarks,based at the Plastic, Maxillofacial & Burns Unit at the Hutt Hospital, Wellington, New Zealand.
2. The study will also focus on identifying potential complications of KTS including venous thromboembolism and its possible association with persistent embryonal vein.

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 recommended that the HDEC template be used for the PIS/CF to ensure patients have enough information to give informed consent.
2. The Committee stated that Māori consultation is required for health research in New Zealand.
3. The Committee stated that more information regarding participation in future unspecified research is necessary.
4. The Committee stated that independent scientific peer review must be carried out, using the HDEC template.
5. Please amend the protocol to include a safety plan for any safety issues that may arise from the administration of the Quality of Life Questionnaire.

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

1. The Committee stated that if children are to be included in this study, then separate age-appropriate assent forms are necessary.
2. The Committee stated that PIS and Consent Forms should be amended to reflect that legal guardians cannot provide consent on behalf of adults who are not able to provide consent for themselves in New Zealand.
3. The Committee stated that, if participants are to be added to an existing database or registry, then this must be included in the PIS.
4. The Committee stated that the PIS/CF should be amended to clarify what type of compensation participants receive how much it is worth, and under what circumstances it is received by participants.
5. Please clarify in the PIS what types of tissue are being collected, including storage and disposal/return of tissue protocols.

Decision

This application was *declined* by consensus as the Committee did not consider that the study would meet the following ethical standards:

* Please amend the information sheet and consent forms, taking into account the suggestions made by the Committee (Ethical Guidelines for Observational Guidelines (2012) para 6.10)
* Research involving Māori participants should be developed in consultation with a Māori representative (Ethical Guidelines for Observational Guidelines (2012), para 4.4)
* In order to meet established ethical standards, health and disability research must be scientifically valid (Ethical Guidelines for Observational Guidelines (2012), Appendix)
* All observational studies should be conducted according to written protocols that state the aims of the study, the data needed and how the data will be collected, used and protected (Ethical Guidelines for Observational Guidelines (2012), para 5.11)
* Please include a safety response plan for the event that a participant’s answers to the psychological health questionnaire raise concern for their well-being (Ethical Guidelines for Observational Guidelines (2012), para 5.5)

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| **5** | **Ethics ref:** | **19/CEN/158** |  |
|  | Title: | LIBRETTO-201 EAP |  |
|  | Principal Investigator: | Professor Mark McKeage |  |
|  | Sponsor: | Southern Star Research Pty Ltd |  |
|  | Clock Start Date: | 12 September 2019 |  |

Potential conflicts of interest

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

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

Summary of Study

1. This is a multi-center Expanded Access Program (EAP) for LOXO-292 to provide the investigational product to site-based investigators who are treating patients 18 years of age or older who have locally advanced or metastatic solid tumors with RET activation.
2. The study consists of a screening evaluation to confirm eligibility for patients and a treatment phase during which patients will initiate and be administered LOXO-292 with assessment visits conducted weekly for the first month, then approximately every 1-3 months or as needed for safety monitoring or standard of care needs. An end of treatment visit will be completed approximately 7 days after the last LOXO-292 dose administration followed by a safety assessment approximately 28 days after the end of treatment visit.
3. As an EAP, this program is not designed to assess the effectiveness of LOXO-292. Data collection will be limited to information needed to determine eligibility, describe patient demographics and exposure, collect
4. Safety information and meet regulatory reporting requirements. Statistics will be summarised descriptively.

Summary of outstanding ethical issues

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

1. Please confirm whether any tissue or identifiable information from this study is being sent overseas.
2. Please provide more information about payment of expenses via bank account and whether this is compulsory.
3. If patients are given the PIS for treatment beyond disease progression, please confirm that they will have the original PIS available as well.
4. Please provide evidence of independent peer review, using the template found on the HDEC website.
5. The Committee noted that the cultural section of HDEC application forms is to communicate any facts and statistics about the disease in question and its impact on Māori (if known), not to reference the Treaty of Waitangi.

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

1. The Committee stated that the table of tests found in the protocol should be added to the PIS.
2. The Committee stated that the section of the PIS on reproductive risks should be amended to reflect the standard wording on the HDEC website.
3. The Committee stated that pages nine and eleven of the PIS repeat content on “new findings”. Please combine these sections and remove language alluding to whether any new information will affect participants’ willingness to continue in the study.
4. Please amend page two of the PIS to state that participants are joining this study to test the safety of the drug, not because of limited treatment options.
5. Please add a pregnant partner form if participants who might have children are to be included.
6. Please amend page ten of the PIS that states participants may be able to be reimbursed, to state in definite terms whether they will or will not be reimbursed, and how much the reimbursement amount will be.
7. Please amend page twelve of the PIS to more clearly communicate how study insurance can be accessed by participants, should they need it.
8. Please amend the start of the PIS, to explain what RET cancer and the study drug is, before explaining what the research is.
9. Please amend PIS to replace reference to regulatory agencies with New Zealand specific information.
10. Please amend the PIS to clarify that 300 participants are taking part in this project worldwide, and the relative number of those who are based in New Zealand.
11. Please confirm that the study cannot be stopped for commercial reasons in New Zealand and amend the PIS accordingly.
12. Please amend references to law to New Zealand law
13. Please add a cultural statement to the PIS, using the HDEC website and PIS template for guidance.
14. Please add more information about any tissue samples being sent overseas to both the PIS and Consent Form.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the Committee
* Please confirm whether any tissue or identifiable information from this study is being sent overseas.
* Please provide more information about payment of expenses via bank account and whether this is compulsory.
* If patients are given the PIS for treatment beyond disease progression, please confirm that they will have the original PIS available as well.
* Please provide evidence of independent peer review, using the template found on the HDEC website.

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Patries Herst and Dr Sarah Gunningham

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| **6** | **Ethics ref:** | **19/CEN/159** |  |
|  | Title: | Use of non-invasive ventilation in de-novo acute hypoxaemic respiratory failure |  |
|  | Principal Investigator: | Dr Dilip Jayasimhan |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 09 September 2019 |  |

Dr Dilip Jayasimhan was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Current guidelines make no recommendations regarding the use of non-invasive ventilation (NIV) in patients with acute respiratory failure not caused by heart failure. There is mixed evidence regarding the efficacy of NIV in this setting. Some systematic reviews suggest a reduced rate of intubation and invasive mechanical ventilation with the use of NIV; however, there is significant heterogeneity in the trials assessed. Some studies suggest a worse outcome in those who fail a trial of NIV who go on to be intubated and mechanically ventilated.
2. The Researchers intend to retrospectively analyse the use of NIV for patients with the above condition and assess outcomes with propensity matching to determine if there is increased mortality in those who fail a trial of NIV.

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 stated that this study should be looking for specific data points so that information can be anonymised upon receipt by the Researchers.
2. The Committee stated that patients should be contacted to consent to their data being used in this study, as it is significantly different to the reason why their information was initially recorded.
3. The Committee stated that if consent is not to be sought, then the Researchers must make a case that complies with the HDC Code of Rights.
4. The Committee confirmed that the study in its current form would constitute health research, as the breadth of information being gathered by the researchers means that it would not qualify as an audit or related activity.
5. The Committee stated that the practical limitations described were insufficient to waive the need for informed consent.
6. The Committee stated that the possibility of increased patient anxiety (due to researcher not knowing the answers to research questions) is insufficient reason to waive consent for this study.

Decision

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

* Unconsented health research must comply with New Zealand law (Ethical Guidelines for Observational Guidelines (2012), para 1.9)

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| **7** | **Ethics ref:** | **19/CEN/164** |  |
|  | Title: | The Effects of Infraslow Neurofeedback on Anxiety and Depression (ISAD) |  |
|  | Principal Investigator: | Tyson Perez |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 12 September 2019 |  |

Tyson Perez was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This current study aims for the first time to 1) use full-band EEG to compare whole-brain activity and connectivity in healthy people to people with anxiety and/or depression and 2) target key areas within the brain's resting-state networks in people with anxiety and/or depression using a novel type of neurofeedback called infraslow neurofeedback (IS-NFB).
2. Neurofeedback is a non-invasive therapy designed to teach individuals to self-regulate brain activity.

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 two Participant Information Sheets. The Researcher stated that they are two arms of one study.
2. The Committee queried how the clinical arm of the study would be recruited. The Researcher stated that posters and advertisements would be used.

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 stated that the HDEC templates for study documentation should be used for this study.
2. The Committee stated that, rather than using deception, any participant biases or expectations can be managed by using a randomised and blinded research design.
3. The Committee stated that, to avoid stigmatisation, every participant should receive the same compensation.
4. The Committee stated that a safety plan should be put in place for participants completing mental health questionnaires.
5. The Committee stated that independent peer review should be performed using the HDEC template.
6. The Committee stated that a screening process for recruiting participants with anxiety and/or depression is necessary.

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

1. The Committee stated that the PIS for both healthy and clinical arms of the study should describe in greater detail the aims of the study, and the role of each group in the study.
2. The Committee stated that reference to saliva samples on page three of the PIS for healthy participants should be removed if they are no longer being collected.
3. The Committee stated that if time of day was the only important factor in when sessions for healthy participants occur, this should be stated in the PIS.
4. The Committee stated that the PIS should include how sweat responses will be collected and assessed.
5. The Committee stated that the description of unexpected side effects on page three of the healthy participant PIs should be removed, as healthy participants are not receiving any treatment.
6. Please use the ACC statement found on the HDEC PIS template.
7. Please remove the cultural statement for tissue samples being sent overseas, unless tissue samples are being sent overseas.
8. Please change reference to HDEC to ensure the correct regional HDEC is being referred to.
9. Please amend the PIS to include information on the notification of the participant’s GP, to match with what is stated in the Consent Form.
10. Please amend the PIS to state the restricted activities at the start of the PIS.
11. The Committee stated that the clinical group PIS should include information about the questionnaires, particularly that they are questionnaires on anxiety and depression.
12. Please remove images of brain slices from the PIS, unless extra explanation of this image and its relevance to the study is given.
13. Please add a flow chart or table to the PIS to communicate exactly what participants are expected to do.
14. Please amend the PIS to state any side effects of treatment, rather than just serious side effects.
15. Please amend the PIS to state what the protocol is for participant data if they withdraw from the study.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Guidelines (2012), para 6.13)
* All intervention studies should be conducted according to written protocols that state the aims of the study, the data needed and how the data will be collected, used and protected (Ethical Guidelines for Intervention Guidelines (2012), para 5.41)
* Please include a safety response plan for the event that a participant’s answers to the psychological health questionnaire raise concern for their well-being (Ethical Guidelines for Intervention Guidelines (2012), para 6.62)

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| **8** | **Ethics ref:** | **19/CEN/165** |  |
|  | Title: | RSV MAT-004 - a research study to vaccinate pregnant women against RSV and assess the incidence of RSV associated events in the children born to these mothers |  |
|  | Principal Investigator: | Dr Thorsten Stanley |  |
|  | Sponsor: | GlaxoSmithKline |  |
|  | Clock Start Date: | 12 September 2019 |  |

Potential conflicts of interest

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

Dr Cordelia Thomas declared that she has had professional contact with Dr Thorsten Stanley. The Committee decided that this would not amount to a conflict. No other potential conflicts of interest related to this application were declared.

Summary of Study

1. GlaxoSmithKline is testing a new vaccine for pregnant women to protect their babies against RSV. This is the first time that this vaccine will be given to pregnant women. Two doses of the vaccine will be tested: 60µg and 120µg. These doses have been given safely to about 125 women who were not pregnant. The study is being done to make sure the new vaccine is safe for pregnant women and their babies, find out how well the vaccine can boost antibodies in pregnant women, if these are transferred to the baby and if so, how long the antibodies stay in the babies’ blood.
2. It also aims to find out how often pregnant women visit a health care provider and how often their babies get sick, due to a cold-like illness.
3. About 150 healthy pregnant women and their babies will take part in the study around the world.

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 stated that, if samples are being kept for thirty years, children will need to reconsent once they have turned 16; the original PIS should be made available to them at this time as well.
2. Please confirm that the guardians’ consent for samples from the baby will only be completed once the baby is born.
3. The Committee stated that more information is required on whether the collection of umbilical cord blood will have any impact on use of umbilical cord blood for future treatments that the baby may receive.
4. The Committee also requested further information about who will be collecting umbilical cord blood, and what information the person collecting the sample will be provided with if they are not part of the study team.
5. The Committee stated that a more urgent safety plan should be put in place for the mother, should she report any potential risks in the daily diary.
6. Please remove dates of birth from samples after the hospital tests are completed, so that samples are completely deidentified when sent overseas.

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

1. The Committee stated that greater detail should be added to the start of the PIS, explaining what RSV is and that adults are highly likely to have already encountered the virus.
2. The Committee stated that the HDEC template for PIS/CF should be followed as appropriate.
3. Please amend page three of the PIS to state approximately how many of the 150 participants will be based in New Zealand, in addition to the other countries in which this study is taking place.
4. Please amend page six of the PIS to state that participants do not need to give a reason to withdraw from the study.
5. Please amend page eleven of the PIS to state that laboratories where samples are stored is in New Zealand, or explicitly name any other country if applicable.
6. Please add a cultural statement to all PIS for samples being sent overseas.
7. Please provide clarification on the statement on page 14 of the PIS, which states that the study sponsor will ensure privacy and security of the baby’s personal information when it is held by a third party, as the study sponsor should not be receiving any personal information about the baby.
8. Please amend page 12 of the PIS to reflect that all information leaving New Zealand is fully deidentified
9. Please amend page 16 of the PIS, to replace “local supervisory authority” with “privacy commissioner”.
10. Please remove the sentence in the PIS that states unlawful posession of baby’s personal information can lead to compensation, as this does not apply to a New Zealand context.
11. Please clarify the amount of reimbursement that participants will receive, as written on page 19 of the PIS, and state in definite terms that participants will be reimbursed.
12. The Committee stated that the information in the Consent Form regarding access to the baby’s personal information from the GP after withdrawal from the study, should be first described in the PIS. This should also explicitly state whether this is optional or compulsory for participants.
13. Please amend the “withdrawal from study” section, as the Committee consider the continuation of collection of medical records to equal continued participation in the study.
14. Please amend the statement that says any information released by doctors, hospitals or laboratories etc. will remain confidential, as the Committee has concerns about whether this can be guaranteed by the Sponsor.
15. Please add specific agreement for sending samples overseas to the Consent Form
16. Please provide a time-frame in which participants must advise the study doctor that they have become pregnant.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Guidelines (2012) para 6.13)
* All intervention studies should be conducted according to written protocols that state the aims of the study, the data needed and how the data will be collected, used and protected (Ethical Guidelines for Intervention Guidelines (2012) para 5.41)
* Please include a safety response plan for the event that a participant’s answers to the psychological health questionnaire raise concern for their well-being (Ethical Guidelines for Intervention Guidelines (2012) para 6.62)

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| **9** | **Ethics ref:** | **19/CEN/167** |  |
|  | Title: | (duplicate) REOPEN 2 STUDY. A study of intranasal OPN-375 in participants with chronic sinusitis without nasal polyps |  |
|  | Principal Investigator: | Dr Dean Quinn |  |
|  | Sponsor: | Covance New Zealand Ltd. |  |
|  | Clock Start Date: | 19 September 2019 |  |

Potential conflicts of interest

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

Dr Sarah Gunningham noted that she was part of Southern HDEC that had previously declined this application.

Summary of Study

1. The purpose of this study is to compare the efficacy of intranasal administration of twice-daily doses of 186 and 372 μg of OPN-375 (fluticasone propionate) with placebo in subjects with chronic sinusitis without nasal polyps.
2. Approximately 399 subjects will be randomly assigned to receive OPN-375 186 μg or 372 μg, or placebo (133 subjects in each treatment group); subjects will be randomized using a 1:1:1 ratio.
3. The expected participation period for a subject is approximately 26 weeks, including a pretreatment phase consisting of a Screening visit followed by a 7- to up to 21-day single-blind placebo run-in period and a 24-week double-blind treatment phase.

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 sufficiently addressed all issues raised by the HDEC where it was previously reviewed.

Decision

This application was *approved* by consensus.

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 22 October 2019, 12:00 PM |
| **Meeting venue:** | Room TBC, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington, 6011 |

1. **Problem with Last Minutes**

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

The meeting closed at 4:00pm.