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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 August 2020 |
| **Meeting venue:** | Zoom Meeting ID: 965 0758 9841 |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.15pm | Confirmation of minutes of meeting of 28 July 2020 |
| 12.30pm | New applications (see over for details) |
| 12.30-12.55pm  12.55-1.20pm  1.20-1.45pm  1.45-2.00pm  2.00-2.25pm  2.25-2.50pm  2.50-3.15pm  3.15-3.30pm  3.30-3.55pm  3.55-4.20pm  4.20-4.45pm | i 20/CEN/179  ii 20/CEN/185  iii 20/CEN/186  *Break (15 minutes)*  iv 20/CEN/187  v 20/CEN/191  vi 20/CEN/190  *Break (15 minutes)*  vii 20/CEN/188  viii 20/CEN/192  ix 20/CEN/193 |
|  |  |
| 4.45-5.00pm | General business:  Noting section |
| 5.00pm | Meeting ends |

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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) | 22/05/2015 | 22/05/2020 | Present |  |
| Dr Patries Herst | Non-lay (intervention studies) | 22/05/2015 | 22/05/2020 | Present |  |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Apologies |  |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 22/05/2015 | 22/05/2020 | Present |  |
| Ms Helen Davidson | Lay (ethical/moral reasoning) | 06/12/2018 | 06/12/2021 | Present |  |
| Ms Julie Jones | Non-lay (intervention studies) | 22/05/2020 | 22/05/2022 | Present |  |
| Dr Jill Wilkinson | Non-lay (observational studies) | 22/05/2020 | 22/05/2023 | Present |  |

## Welcome

The Chair opened the meeting at 12pm and welcomed Committee members, noting that apologies had been received from Cordelia Thomas

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 28 July 2020 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **20/CEN/179** |  |
|  | Title: | Hospital based assessment of depression and psoriasis |  |
|  | Principal Investigator: | Dr Karen Koch |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 13 August 2020 |  |

Karen Koch was present by 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. Psoriasis is an auto-inflammatory condition associated with numerous comorbidities. The prevalence of co-morbid depression in patients with psoriasis ranges from 20 to 60%. A growing body of evidence suggests that inflammation is involved the pathogenesis of depression. Depression in psoriasis may relate to multiple factors, including the disfiguring nature of the condition, inflammation, medical and other treatments. Factors that may alter the risk of depression include psoriasis affecting the hands, feet or face (as opposed to other body areas), younger age of onset, co-morbid arthritis and certain immune-modulating (biologic) drugs. The aim of the study is the examine prevalence of depression in patients with psoriasis at Waikato Hospital and to identify predictors of depression in patients.

Summary of resolved ethical issues

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

1. The Committee queried if this study was for the purpose of attaining a qualification. The researcher clarified that it is not.
2. The Committee stated that for future applications, the benefit to Māori component of the application form should provide statistics or anecdotal evidence in relation to the study.
3. The Committee advised the Researcher that relevant Māori cultural issues for this research would include the potential for whakamā in participants. The Committee requested the Researcher become familiar with this concept and be mindful of this for future applications.

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 at what point the researcher can determine if a participant was depressed based on the questionnaires. The researcher explained that standard practice is that a score of 10 is indicative of pathological concern. The Committee explained that as this is now data collected for research, this needs to be explained in the participant information sheet.
2. The Committee requested that the researcher ensure they have sought permission for the use of questionnaires they wish to use in the study.
3. The Committee queried if the telephone call to participants by research assistants would be a cold call or discussed prior to their clinical. The researcher clarified that they are likely the participant’s clinician and may have prior knowledge of it. The Committee requested the approach for this is considered, noting their concern that the first approach may be from someone they do not know.
4. The Committee stated that it will require to see the script for the telephone conversation.
5. The Committee clarified that in the protocol references to ‘pin’ to be code instead to avoid confusion.

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

1. The Committee recommended the researcher refer to the HDEC template here for guidance on completing the participant information sheet and consent form for missing sections outlined below (<https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates>)
2. Please amend to include more information about what data is being collected, where the data comes from, what is happening with that data, security measures for storing the data, and how long it is kept for. Note that health information must be kept for 10 years.
3. Under “What will my participation in the study involve?”, please add “with your permission, other information will be completed by the doctor…”
4. Add approximate time to complete the questionnaires
5. Include an outline of the safety plan in place if a participant returns information that suggests they are depressed and/or at risk. “*If the information you provide in the questionnaire suggests you are severely depressed, we will discuss this with you. It might be necessary to contact the mental health services at the hospital for further assessment.*”
6. Include statement on what rights a participant has to access and correct their information (see template for guidance).
7. Please include a statement on plans for publishing, including clarification that data will not be identifiable once published.
8. Amend the word “telephonic’ to telephone in the participant information sheet and consent form
9. Please remove consent for contacting GP in the consent form
10. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).
11. Under “Who do I contact?”, please amend your name to read First then Last name for clarity.

Decision

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

1. Please provide the Committee with a script for the telephone conversation between someone on the research team and potential participant.
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 Jill Wilkinson and Helen Walker

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| **2** | **Ethics ref:** | **20/CEN/185** |  |
|  | Title: | Trametinib in Neurofibromatosis-associated Tumours (TiNT) |  |
|  | Principal Investigator: | Dr Andrew Dodgshun |  |
|  | Sponsor: | ANZCHOG |  |
|  | Clock Start Date: | 13 August 2020 |  |

Andrew Dodgshun and Kirstie Copeland were present by 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. Neurofibromatosis type 1 (NF1) is a genetic disorder in children that can cause a number of medical complications, including development of large nerve tumours (Plexiform Neurofibromas) or tumours of the nerves that control vision (Optic Pathway Gliomas). The TiNT clinical trial will test the effect of a new medicine, trametinib, in reducing the growth of NF1-associated tumours and also improve quality of life through reducing pain and visual deterioration and improving behaviour and neurodevelopment.

Summary of resolved ethical issues

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

1. The Committee queried if there would be future unspecified research using this study’s data. The researcher clarified that there would not be.
2. The Committee queried if the researchers would be including participants as young as 3 months old. The researcher responded that they would, however unlikely it would be, and that safety data is gathered for that age group. The researcher added that younger age groups would not be expected to fill in questionnaires.
3. The Committee noted that as the protocol states that pregnancy would be followed up, a future amendment would need to be submitted to add a pregnancy participant information sheet/consent form if pregnancy of a participant were to occur.

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 insurance certificate provided is about to expire and an updated one needs to be submitted to the Committee.
2. The Committee stated that no data or safety plan has been documented for responses to questionnaires that indicate severe depression or concern for safety. In addition, no information has been documented in the protocol on who is collating this information, how soon this is being collated, and who is acting on it. The researcher responded that each site has a child psychologist responsible for the receipt and collation of information, with the addition of three in person assessments. The researcher stated they would consult with their central neuro-psychology team to identify which questionnaires have content that needs to be flagged for more immediate screening or processing, which the Committee agreed to.
3. The Committee noted that a list of questionnaires has been included but the Committee need to sight them.

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

1. Amend ‘regular doctor’ on page 6 of the treatment participant information sheet to specify regular Oncologist
2. On page 7 of the treatment participant information sheet, please outline examples of soap substitutes e.g. sorbolene for clarity.
3. On Page 15 of the treatment group and page 9 of the control group Participant/Parent or Guardian Information sheets, note that all health research in New Zealand involving humans is not reviewed by HDEC. Please remove first sentence under “Who has reviewed the clinical trial”, and add a sentence referring to the role and review of SCOTT for this medicine.
4. The statement “I understand that the study treatments would be harmful to an unborn child and agree to avoid falling pregnant or causing a pregnancy, while I am on treatment, and for an agreed time after the end of treatment.” In the treatment participant information sheet needs to be reworded as this is also aimed at parents/guardians. Please also add a simplified version of this to the assent forms.
5. Please amend the wording under “Do I have to take part” in the 11-15 assent form to be consistent with the 7-10 assent form.

Decision

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

1. 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).*
2. Please supply updated evidence of ACC-equivalent compensation available to all participants in the event of injury during the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
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 Patries Herst and Helen Davidson

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| **3** | **Ethics ref:** | **20/CEN/186** 51:30 |  |
|  | Title: | Choosebetweenamab |  |
|  | Principal Investigator: | Prof Peter Wark |  |
|  | Sponsor: | John Hunter Hospital |  |
|  | Clock Start Date: | 13 August 2020 |  |

James Fingleton was present by 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.

Julie Jones declared a conflict of interest. The Chair decided to let Julie stay but not participate in discussion.

Summary of Study

1. Patients with severe asthma seen in the severe asthma clinic will sometimes be eligible for the biological agents omalizumab or mepolizumab based on the result of blood tests. Mepolizumab and omalizumab are both licensed and funded in New Zealand. Omalizumab and Mepolizumab work differently but there are some people who would be eligible for either medication. The medications are never given together so the clinician needs to decide which to give. The purpose of this study is to run a trial in which people who in this situation will be randomised to receive either Mepolizumab or Omalizumab and compare outcomes.

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 for future applications, the response in the application form for benefit to Māori should include statistics or data on incidence in Māori, if any.
2. The Committee queried the link between GSK and their right to review outcome prior to publication. The researcher clarified that they are providing access to the medication in Australia and will not be able to prevent publication regardless of the outcome.
3. The Committee asked for clarification if participants under 18 will be included as stated in the protocol. The researcher clarified that participants over 18 years will be included in New Zealand.
4. The Committee queried if the health information is being retained for 5 or 10 years. The researcher responded that it will be kept for 10 years.

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 withdrawal is not required to be in writing and the participant should not be required to complete a form after withdrawing, and the researcher can do that on their behalf. This should be reflected in the participant information sheet.

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

1. Please amend under “What will happen to information about me?” on page 7 and in the consent form to include information that data will be sent overseas, and if this data is de-identified and who will have access.
2. Please review the information sheet for technical language, amending for lay terms where possible.
3. On Page 6, please amend statements under “What if I withdraw from this research study” to remove the requirement for participant to have to complete follow-up form.
4. On Page 8, the Committee noted that all research in New Zealand involving humans is not reviewed by HDEC, and the wrong guidelines have been references. Please remove the first sentence, and refer to the updated guidelines (*National Ethical Standards for Health and Disability Research and Quality Improvement (2019))*
5. Please amend to add information about if data will be de-identified, what data is required for phone calls, what data is being used for, and that data is being retained for 10 years. Please refer to the HDEC template for guidance (<https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates>)
6. Please include information about the John Hunter Hospital, their role in research, and that this is an international study.

Decision

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

1. 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 Sandy Gill and Peter Gallagher

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| **4** | **Ethics ref:** | **20/CEN/187** |  |
|  | Title: | YO42137: Stage II/III esophageal squamous cell cancers following concurrent chemotherapy and radiation therapy |  |
|  | Principal Investigator: | Dr Richard North |  |
|  | Sponsor: | Roche Products (New Zealand) Limited |  |
|  | Clock Start Date: | 13 August 2020 |  |

Richard North, Michelle Raitak and Charlie Stratton were present by videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a phase 3, double-blinded, placebo-controlled, randomised multicentre study designed to evaluate the efficacy and safety of Tiragolumab + Atezolizumab compared with Placebo in patients with locally advanced oesophageal squamous cell carcinoma.

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 standard of care and approach to participants is inconsistently documented. The researcher clarified that the study happens after standard of care is provided and they as their clinicians will approach patients during chemotherapy asking for their interest in the study. As standard of care is typically no treatment, the researcher reassured the Committee that there is no withholding of treatment in the placebo arm.
2. The Committee queried if a one-year course is considered a full treatment regime, and for justification for the time frame. The researcher responded that standard of care post-treatment if any is provided is typically a year as set by oncologists.
3. The Committee stated their concern that no information in the participant information sheet outlines the content of the questionnaires or any plan if responses to measures of depression would cause concern. The researcher clarified that the study doctors in their role as oncologists monitor the participants closely and would be able to monitor that risk through this method.

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 the researcher confirm with the sponsor that the insurance provided is study specific.

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

1. The Committee requested that there were no ‘yes / no’ tick box on the consent forms. Please confirm if any clauses are optional with the sponsor.
2. The Committee noted that all research in New Zealand involving humans is not reviewed by HDEC. Please amend the HDEC reference under “What happens if I am injured?” to clarify that HDEC only approve the ethical aspects of the study, and add a sentence referring to the role and review of SCOTT for this trial.
3. Please amend the HDEC email to [hdecs@health.govt.nz](mailto:hdecs@health.govt.nz)
4. Please add an option in the consent form for the participant to receive a summary of the study results if this will be available.
5. Please add a statement in the PIS that participants have the right to access information and correct information.
6. Please amend the pregnant partner participant information sheet and consent form to also include pregnant participants in the event a participant becomes pregnant.
7. The Committee noted that in the event of collecting an infant’s health information after birth, the child’s guardian can also consent, not just the mother.
8. Please review and amend sheets for typos and spelling mistakes.
9. Please add a statement outlining the content of the questionnaires and what current plans are in place for monitoring and addressing concerns with answers that may indicate depression in a participant.

Decision

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

1. 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)*
2. please confirm with the sponsor that the insurance is study specific. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1)*

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| **5** | **Ethics ref:** | **20/CEN/191** |  |
|  | Title: | PIVOT-12 |  |
|  | Principal Investigator: | Dr Richard North |  |
|  | Sponsor: | PPD/Nektar |  |
|  | Clock Start Date: | 13 August 2020 |  |
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Richard North and Lesley Goodman was present by videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is an open label (participant’s treatment is known) study that will evaluate the efficacy and safety of bempegaldesleukin plus nivolumab (immunotherapy drug), compared with nivolumab after complete resection of melanoma in patients at high risk for recurrence.

Summary of resolved ethical issues

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

1. The Committee noted the answer to P.4.1. in the application form was inappropriate and requested the Researcher be mindful of this for any future applications. The Committee explained that the Treaty of Waitangi should not be cited as a health benefit and equal access to participate for Māori should not need to be stated as this is the default expectation. The Committee recommended including any statistics of the prevalence of the disease in Māori (or an explanation if unknown) when answering P.4.1. for any future applications.

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 data should be kept for 10 years following the child turning 16 in the event of pregnancy during the trial. Discussion outside of the meeting that was permitted by the researcher concluded that the need for re-consent would not be applicable to this study, but data should still be retained for 10 years following the child turning 16 (total of 26) (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.28)*

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

1. Please highlight the lay-title more prominently
2. Please add a compensation statement in the Optional Tumour Biopsy participant information sheet/consent form (PIS/CF) to match the Main PIS/CF
3. Please review all information sheets for spelling and grammar
4. The Committee noted that the pregnant partner PIS/CF needs to include a statement that data is going overseas.
5. Please ensure that the pregnant partner PIS/CF and the Pregnancy Follow-up PIS/CF are split into 2 separate documents, with consent for baby’s health information to be signed only after the birth.
6. On Page 4 of the Main PIS/CF, please remove the Lost to follow-up reference.
7. Please add to the consent form: “I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy.” Or equivalent language.
8. Equivalent consent forms statements don't appear available regarding the following:
   1. "I have been given sufficient time to consider whether or not to participate in this study."
   2. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed." - this clause may be acceptable to exclude as it is stated in the PIS that data will be used and does not appear to be an option for this study.
   3. "I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
   4. "I understand the compensation provisions in case of injury during the study."
   5. “I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy”
   6. "I understand my responsibilities as a study participant."
   7. "I wish to receive a summary of the results from the study."
9. On Page 27, please reword the statement “your study doctor or hospital will be paid for including you in this study” to state the hospital is compensated for recruitment.
10. In the main PIS, please highlight on page 21 for the male participants to inform their partner for risks to pregnancy.

Decision

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

1. 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 Sandy Gill and Julie Jones

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| **Ethics ref:** | **20/CEN/190**  **(CLOSED)** |
| Title: | A Phase 1 Study of mRNA-5671/V941 as Monotherapy and in Combination with Pembrolizumab |
| Principal Investigator: | Dr Sanjeev Deva |
| Sponsor: | MSD |
| Clock Start Date: | 13 August 2020 |

Sanjeev Deva, Sophie Goodger, Valmir Silva, Justin Mavin, and Scott Bannan was present by 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.

**CLOSED SESSION**

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 Sandy Gill and Patries Herst.

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| **7** | **Ethics ref:** | **20/CEN/188** |  |
|  | Title: | A Study Evaluating the Safety, Tolerability, and Pharmacokinetics of HB0017 |  |
|  | Principal Investigator: | Dr Christian Schwabe |  |
|  | Sponsor: | Syneos Health |  |
|  | **Ethics ref:** | **20/CEN/188** |  |

Christian Schwabe and Courtney Rowse were present by 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. HB0017 is a monoclonal antibody that is intended for the treatment of inflammatory conditions such as psoriasis and psoriatic arthritis. The study aims to test the safety and tolerability in healthy volunteers of HB0017 at different doses, the levels of the drug in the blood over time, and the body's immune response (in terms of producing antibodies against the drug, called antidrug antibodies or ADAs).

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 how the researcher plans to recruit into the study. The researcher responded that they have a database of people who have expressed interest in participating in clinical trials. The first approach will be to send an email to those in the right age bracket for interest.

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

1. The Committee noted in the Main PIS that all research in New Zealand involving humans is not reviewed by HDEC. Please amend the HDEC reference under “Approval by ethics committee” to clarify that HDEC only approve the ethical aspects of the study, and add a sentence referring to the role and review of SCOTT for this trial.
2. Please amend the HDEC email to [hdecs@health.govt.nz](mailto:hdecs@health.govt.nz)
3. Please remove the last bullet point in the consent form as it is a duplicated statement.

Decision

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

* 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).*

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| **8** | **Ethics ref:** | **20/CEN/192** |  |
|  | Title: | AK119-101: A study assessing single doses of the investigational drug AK119-101, in healthy adults. |  |
|  | Principal Investigator: | Dr Chris Wynne |  |
|  | Sponsor: | Novotech NZ Ltd |  |
|  | Clock Start Date: | 13 August 2020 |  |

Chris Wynne was present by 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. AK119 is being developed for the treatment of COVID-19.This is the first study of AK119 in humans to further inform clinical development of AK119. The trial aims to assess how safe and well-tolerated single doses of AK119 are, measure levels of AK119 in the blood over time, following a single dose (pharmacokinetics), and measure the body's immune response to a single dose of AK119 (immunogenicity).

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 about the excess of $2500 in the insurance certificate, and if participants would be expected to pay this. The researcher clarified this is a cost the sponsor would also cover.

Decision

This application was *approved* by consensus

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| **9** | **Ethics ref:** | **20/CEN/193** |  |
|  | Title: | BGB-11417-101 |  |
|  | Principal Investigator: | Dr Henry Chan |  |
|  | Sponsor: | Beigene Aus Pty Ltd |  |
|  | Clock Start Date: | 13 August 2020 |  |

Henry Chan and Leo Gonzalez-Perez was present by videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a multicenter, Phase 1, open-label, dose-finding, first-in-human study of BGB-11417 alone and in combination with zanubrutinib. The study is comprising of Monotherapy Dose Finding and Expansion Cohorts with BGB-11417, as well as Combination Cohorts with Zanubrutinib for Dose Finding and Expansion in patients with CLL/SLL.

Summary of resolved ethical issues

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

1. The Committee queried if there would be any standard treatments participants would have to stop in order to participate due to the answers on the application form around progressing treatment. The researcher responded that there is currently no standard treatment for this, and currently there is no alternative for effective treatment in New Zealand.
2. The Committee noted the answer to P.4.1. in the application form was patronising and requested the Researcher be mindful of this for any future applications. The Committee explained that the Treaty of Waitangi should not be cited as a health benefit and equal access to participate for Māori should not need to be stated as this is the default expectation. The Committee recommended including any statistics of the prevalence of the disease in Māori (or an explanation if unknown) when answering P.4.1. for any future applications.
3. The Committee advised the Researcher that relevant Māori cultural issues for this research would include the potential for whakamā in participants. The Committee requested the Researcher become familiar with this concept and be mindful of this for future applications.
4. The Committee stated that for future applications to ensure the CI CV has a record of GCP training

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 no medical indemnity was provided, and this will need to be uploaded.

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

1. All PIS/CFs inconsistently state that samples are going overseas and where they will be going to. Please ensure this is consistent across all participant information sheets and consent forms.
2. Please include an option in the consent forms about the provision of study findings to participants or their families after study completion.

Decision

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

1. 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).*
2. Please provide evidence of professional indemnity held by the CI (*Standard Operating Procedures for Health and Disability Ethics Committees (SOPs), para 42.7*)

After receipt of the information requested by the Committee, a final decision on the application will be made by Helen Walker and Jill Wilkinson

## 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 September 2020, 12:00 PM |

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**

Discussion arose around ensuring CI indemnity, safety plans for depression questionnaires and New Zealand territory-specific insurance which the Chair agreed to discuss with the secretariat before next meeting.

The meeting closed at 4.45pm