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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 01 June 2021 |
| **Meeting venue:** | <https://mohnz.zoom.us/j/96507589841>  Meeting ID: 965 0758 9841 |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:15pm | Confirmation of minutes of meeting of 04 May 2021 |
| 12:30pm | New applications |
| 12:30 – 12:55pm  12:55 – 1:20pm  1:20 – 1:45pm  1:45 – 2:00pm  2:00 – 2:25pm  2:25 – 2:50 pm  2:50 – 3:15pm  3:15 – 3:40pm | 21/NTB/123 Kate/Stephanie  21/NTB/124 Susan/Leesa  21/NTB/125 John/Stephanie  [break]  21/NTB/126 Kate/Stephanie  21/NTB/128 Susan/Leesa  21/NTB/129 John/Stephanie  21/NTB/131 Kate/Leesa |
| 3:40pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |  |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | Present |  |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |  |
| Mrs Leesa Russell | Non-lay (intervention studies),  Non-lay (observational studies) | 14/12/2015 | 14/12/2018 | Present |  |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |  |
| Ms Susan Sherrard | Lay (consumer/community perspectives) | 19/03/2019 | 19/03/2022 | Present |  |

## Welcome

The Chair opened the meeting at 12pm and welcomed Committee members.

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 04 May 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **21/NTB/123** |  |
|  | Title: | VICTOR |  |
|  | Principal Investigator: | Dr Claire Hemmaway |  |
|  | Sponsor: | University of Birmingham |  |
|  | Clock Start Date: | 20 May 2021 |  |

Dr Claire Hemmaway and Kerry Walker 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.

Leesa Russell declared a conflict of interest and was excused from discussion.

Summary of Study

1. This phase 2 study is a trial for patients with acute myeloid leukaemia, with a particular gene mutation. Participants will be randomised to receive a new drug called venetoclax, combined with low dose cytarabine (VEN+LDAC), or the standard of care intensive chemotherapy regime. The first participants enrolled are older (who do badly with this disease) and if the interim analysis is favourable, the drug will be offered to younger patients. One hundred and fifty-six participants in three countries,16 of which are in New Zealand.

Summary of resolved ethical issues

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

1. The Committee advised that with Leesa Russell stepping out of the meeting due to a conflict of interest with this application, the Committee would not be quorate. The Committee advised that it would provide feedback on the application at this meeting as per the usual approach but would require a member from another HDEC to review the application and confirm the decision. The Committee recommended this approach to minimise the delay in sending a decision to the researchers, and this was agreed.
2. The reviewer has confirmed the Committee’s decision and their comments are included within these minutes.
3. The Committee congratulated the researchers on a well written application and was pleased to see an extensive peer review led by United Kingdom experts with consumer input recognised.
4. The Committee noted that the study was presented as a collaborative study rather than commercial. The Committee queried that the balance of benefit will not be attributed to the manufacturer of the study drug. The researchers confirmed that the sponsor supplies the study drug only and does not have a role in the study beyond this. The researchers added that the sponsor will not have access to the study data.
5. The Committee asked the researchers what the rationale for choosing a non-inferiority study design is. The researchers responded that the data from the previous phases of the trial indicate that receiving this drug combination is equally effective or better. However, the new treatment may have other advantages that make it preferable to standard care such as a reduction in toxicity, hospitalisation, and death, and an increase in quality of life (e.g. treatment would mostly be administered as outpatient care when currently it is inpatient care (5 months). The researchers advised that they have designed the study this way to prove this. The Committee was comfortable with this response.
6. The Committee noted that finding funding for the trial in New Zealand is currently underway by the research team.
7. The Committee noted the researchers’ confirmation that there is no additional cost, outside of standard of care treatment, to patients to participate in this study.
8. The Committee queried if extra bone marrow samples are required for the study. The researchers responded that the standard of care treatment has evolved over the last year due to the recognition that early intervention is beneficial for people with this particular gene mutation. The result of the change in standard of care treatment means that participants will not undergo any more bone marrow aspirations than they would receive off trial.
9. The Committee noted that the protocol states that molecular screening will be separate for New Zealand patients. The Committee queried why there is no consent form for this. The researchers clarified that molecular screening does not require consent because it is part of standard care. The researchers added that the only difference is that study participants’ screening results will be expedited.
10. The Committed advised that they would normally request that the Patient Information Sheet and Consent Form include the approved reproductive/contraception wording from the [HDEC template for reproductive risks](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-apr20.docx); however, considering the study population, the Committee was comfortable with the reduced content.
11. The Committee noted that the Patient Information Sheet and Consent Form includes an interpreter box and queried if being able to speak English is a requirement for the questionnaires. The researchers advised that their normal approach is to use an interpreter for the consenting process and that they would have the questionnaires translated into some other prevalent languages. The latter is only for those who do not understand English.

Summary of outstanding ethical issues

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

1. The Committee queried if a person will be precluded from the study if they do not speak a language that the questionnaires are available in. The researchers responded that the trial is niche and this is unlikely to occur; however, they will clarify this scenario with the sponsor who licenses the questionnaires.
2. The Committee queried why the frequencies of side effects associated with daunorubicin are stated as unknown in the Patient Information Sheet and Consent Form. The Researcher advised that the drug has been used for long enough that they will be able to provide some predictions for side effects to participants.
3. The Committee recommended that participants are given the opportunity to discuss their thoughts about participation with a member of the research team who is not involved in the participant’s clinical care, at some stage during the recruitment process. This mitigates the risk of patients feeling pressure to participate given the existing doctor-patient relationship.

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

MAIN PIS/CF

1. Please clarify, on page 10, that the pregnancy testing will happen before the start of each cycle.
2. Please see page 12 and note that some health information must be retained for at least 10 years.
3. Please amend page 12, noting that people other than the researchers may have access to identifiable information, including Sponsor study monitors, Sponsor personnel in the event of audit, the participant’s general practitioner in the event of an abnormal result of clinical significance, and the Medical Officer of Health in the event of a positive test for HIV or hepatitis.
4. Please amend the item on the consent form to an optional ‘Yes/No’ tick box offering a summary of study results. The Committee advised that it is important to make all elements of being involved in the study, as easy as possible for participants.
5. Please state the randomisation ratio (1:2) so that participants understand the chances of getting into a study arm.
6. Please separate the bone marrow and quality of life questionnaires with additional bullet on page 3.
7. Please include predictions for frequency of side effects of daunorubicin on page 9 (e.g. 1 in 20 chance of…).

FUR PIS/CF

1. Please state in lay language, whether future research may involve genomic research, and whether this could include whole genome amplification.
2. Please clarify how long you are storing samples for (e.g. application says 15 years after study end but consent form states indefinitely).
3. Please note that samples cannot be anonymous (as is currently described in the FUR PIS/CF) as they were originally labelled with participant IDs. If participant ID is stripped from the samples, so there is no link back to the participant or their data from the main study (i.e. they are anonymised), then this should be clearly stated.
4. The consent form is confusing around the option for identity to remain with the sample, followed by a mandatory statement about removing identify and the consequences for withdrawal. Please review these and simplify them into clear questions so they are easy to understand.
5. Please explain the limitations around withdrawal in the body of the information sheet (e.g. you will not be able to withdraw your information after the point where the data has been anonymised).
6. Please make it clear that due to the link being broken, participants cannot request the withdrawal of samples from future research.
7. Please indicate whether or not there will be opportunity for karakia at the time of tissue disposal.

Decision

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

* Please address all outstanding ethical issues requested by the Committee.
* 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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| **2** | **Ethics ref:** | **21/NTB/124** |  |
|  | Title: | Havening feasibility and acceptability for adolescents |  |
|  | Principal Investigator: | Dr Josephine Stanton |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 20 May 2021 |  |

Dr Josephine Stanton was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is an exploratory study of a new psycho-sensory therapeutic intervention called Havening for adolescents admitted to an acute mental health inpatient unit with concerns about suicidal risk. The study includes questionnaires for youth, whānau and treatment staff. Thirty-five New Zealand participants (20 youth, plus whānau and staff).

Summary of resolved ethical issues

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

1. The Committee advised that approaching young people in acute mental distress to be involved in a study without their guardian present would not be appropriate in a research setting. The researcher responded that the guardian would be spoken to prior to discussing the study with the participant.
2. The Committee noted the researcher’s confirmation that Havening is not standard of care, however the Medical Council of New Zealand and her employers have approved the use of Havening, a novel therapy, as a medical 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 noted that the application has been presented as an observational study; however, agreed that it is in fact an intervention study as the treatment is being offered to patients as a non-standard of care treatment.
2. The Committee advised that there are specific ethical standards for research *(*[*National Ethical Standards for Health and Disability Research and Quality Improvement*](https://neac.health.govt.nz/national-ethical-standards/)*)* and operating procedures that support the ethical standards ([*Standard Operating Procedures for HDEC*](https://neac.health.govt.nz/national-ethical-standards/)). The Committee recommended that researchers new to clinical research become familiar with these standards as it will guide the research study design and conduct.
3. The Committee stated that a treatment that is not standard of care is considered a new treatment and treated as a first-in-human trials and as such is subject to specific ethical guidelines and standards.
4. The Committee added that its role is to review how well a research proposal meets these ethical standards, the standard operating procedures and other relevant regulatory requirements. As such, the Committee must work within these frameworks when reviewing research studies.
5. The Committee advised that because the application has been presented as an observational study, crucial information required to assess an intervention study is missing from the application. Because of this, significant changes to the study are required, and the Committee agreed the study therefore is likely to be declined today.
6. The Committee suggested using the remaining time to discuss what an approvable intervention study application that meets the HDEC requirements would look like. The researcher agreed with this approach.
7. The Committee advised that as the study population involves vulnerable participants (legal minors who may be under deep mental distress), the ethical issues are more complex. The Committee advised that the reason for this is to protect the vulnerable/unwell from unnecessary research by first testing the intervention on a healthy population and making a case for why the research is necessary.
8. The researcher advised that her argument for undertaking a study with this group is that it is the group she works with in her clinical practice and she believes the Havening therapy will be beneficial for this patient group.
9. The Committee stated that the researcher’s access to a particular patient population is not sufficient to justify research within a vulnerable population. The Committee added that, were the researcher adamant that the research had to be conducted with this vulnerable population, a more compelling justification is needed for why the research cannot initially be done in adults who are less unwell, to obtain an evidence base for doing a larger study involving a more unwell population. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.2).*
10. The researcher stated that there is no previous research that has been done on Havening and her hope was to begin giving a consumer voice to the therapy that could be published in a journal and eventually have the treatment available to anyone, not just those who can afford to pay for it. The researcher added that she planned to do this through the work she does with the (vulnerable) population she services. She added that she does not have time to commit to a long research process that includes working with another (healthy) population.
11. The Committee suggested the researcher consider obtaining support from other groups that do research in similar areas (e.g. neuroscience or other psychotherapies) where she may get access to resources (e.g. other research investigators) that could assist her in undertaking a study like this.
12. The Committee recommended that an escalation breakout protocol for when/if participants become distressed should be included for the current study as well as an emergency management plan for dealing with a participant in crisis (e.g. behaves violently).
13. The Committee recommended the application clarifies who is being recruited and how they are being chosen (e.g. age ranges, family for interviews, staff) and who will be present during the Havening sessions, etc. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.9).*
14. The Committee advised that the inclusion criteria mentions participant groups but does not say what would exclude someone from being able to take part in the study (e.g. age limit, particular conditions such as requiring dialysis). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8).*
15. The Committee advised that consideration needs to be given to how a participant’s competency to consent will be assessed and if they cannot consent for themselves, if they would be excluded or would there be supported consent for people in acute mental distress. Please include guidelines in the protocol for managing the consenting process, including how the decision of competency will be made and how it will be communicated to participants/family). *National Ethical Standards for Health and Disability Research and Quality Improvement, section 6 (Ethical management of vulnerability) and 7 (Research with adults who cannot provide informed consent).*
16. The Committee noted that the measures described in the application/protocol states that qualitative information will be collected as and when appropriate and then the Havening is applied ‘when the investigator thinks it is appropriate’. The Committee advised that for research, the measures need to be more clearly defined, such as the frequency and duration of the intervention (e.g. one-hour long session fortnightly for six weeks). In addition, the Committee expects the measures would include pre and post surveys with check-ins before and after treatment, as well as some effectiveness or acceptability measures. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15)*
17. The Committee advised that the protocol will need a section on management of whānau participation and requested that this is thought through in more detail and documented. For example:
    1. If a family member is to sit in on the therapy session, how will the consent process be managed for the family member and the participant.
    2. What kind of questions the family member will be asked about the participant and how the participant agrees to have their information shared with the family member.
18. The Committee advised that the protocol must include a process for reconsenting participants as adults if they turn 16-years-old during the study.
19. The Committee noted that the protocol suggests a Kaupapa Māori design, however that the application (question p.4.4) says that it is not. The Committee advised that Kaupapa Māori methodology does not appear to be reflected in the current protocol and recommended that it is either built into the protocol or mention of it is removed. Please refer to definition of Kaupapa Māori research in the *National Ethical Standards for Health and Disability Research and Quality Improvement, section 3.*
20. The Committee requested that the researcher consider how to manage the conflict of interest of being both the clinician and the researcher. This should also be addressed in the protocol. This is to mitigate any pressure for participants to take part in the study which may be present due to the doctor-patient relationship. For example, during the recruitment process potential participants are given the opportunity to talk with a member of the research team that is not involved in their clinical care. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.24, 6.13 – 6.16).*
21. The Committee noted that the researcher is intending to recruit staff that she works with and queried, similar to the previous point, how the researcher will ensure staff do not feel compelled to take part. The researcher advised that participation will be offered to many staff and she will be unaware of who is recruited into the study.
22. The Committee acknowledged that while there is some anonymity in numbers and the approach set out by the researcher may be acceptable, it is recommended that the justification for how the potential power imbalance would be mitigated needs to be clearly detailed in the protocol (i.e. how confidentiality of staff will be retained and how she will ensure staff do not feel compelled to take part).
23. The Committee recommended the researcher records a plan for how she will handle incidental findings (i.e. observations of potential clinical significance that are unexpectedly discovered in research). Normal practice includes the researcher informing the participant’s clinician and therefore consideration needs to be given to how this process will be managed given the clinician/researcher conflict of interest. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.48).*
24. The Committee recommended the protocol includes information about how the treatment is used in a clinical context including what the existing standard of care treatments are.
25. The Committee asked for the inclusion of a plan for managing adverse events related to Havening. For example, how will researchers identify if participants are doing worse than those not receiving Havening and ensuring those participants are receiving equity of care in addition to the research they are involved in. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.30 – 11.33).*
26. The Committee recommended including information in the protocol on the administration of Havening as well as developing a training manual for the therapist detailing how the touch therapy is to be administered (e.g. frequency, duration, where to touch, where not to touch, technique to ensure consistency, escalation process, etc.)
27. The Committee noted that the peer reviewer suggests the District Health Board (DHB) policy on touch should be referred to but is not in the current protocol. The Committee recommended that, as an action of assurance, the protocol references the DHB’s position on both touch therapy and experimental and holistic treatment.
28. The Committee noted that there was only one peer review submitted and require the supply of a second in independent peer review. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
29. The Committee requires a data management plan to ensure the safety and integrity of participant data that specifies the health information being collected and how it is being analysed. This may either be incorporated into the protocol or a separate plan, but it must be study-specific and comply with *National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a.* For guidance, please see the [Data Management Plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) available on the HDEC website.
30. The Committee requested a sponsor is identified in the application (a.5.1). That is, the organisation that is taking responsibility for the study which may be different from the funder.
31. The Committee stated that the number of participants in the study is not clear and this needs to be consistent across all study documentation. The researcher advised that it is difficult to estimate as she is unsure, at this stage, how many patients, family members and staff would be chosen to participate.
32. The Committee recommended that the application (question b.4.4) states how the researcher plans to use the data in the future. Please see the guidelines on future unspecified research (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.25).*
33. The Committee advised that the answer to application question r.2.1 should be ‘yes’ (the study involves reviewing or screening health information, for example in order to identify potential participants).
34. The Committee noted that application question on benefit to Māori (p.4.1) states that Māori have a high proportion of admittance for acute mental health and requested that this answer addresses how the study is tailored to this population. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.1 – 3.6).*
35. The Committee noted that answer to application question p.3.2.2.2 needs to address how assent will be obtained from children.
36. The Committee noted the interview questions for children have been supplied and the questions for staff and family would also need to be provided to HDEC.
37. The researcher asked if she could use data collected from administering Havening in her regular medical practice for research in a years’ time, for example, or whether she would still not get permission to do research on this (vulnerable) population that she provides clinical care for.
38. The Committee advised that if the researcher used a treatment on patients for a year and decided to undertake a retrospective audit to see if the treatment was administered the way it should be, this could be an acceptable approach. However, a requirement with this approach is that, as it is evaluating the effectiveness of a treatment, there must be a control group.
39. The researcher advised that the purpose of this study is not to determine the efficacy of the Havening technique, rather to give it a consumer voice as this does not currently exist. The researcher asked that if she offered this to her patients as an optional treatment as part of her regular practice, could she then do a case series and if that would be considered observational.
40. The Committee advised that the researcher may choose to write up cases about her patients as a clinician and share them with other clinicians and this would not require HDEC review as it is not considered research. However, to make this into a truly observational research study, it would require undertaking a series of interviews with cases/people who are receiving Havening already as standard of care with another practitioner. The Committee suggested that a valuable place to begin may be with the population who are paying for the treatment, to gain their experience and grow the consumer voice from there.
41. The Committee stated its appreciation of the researcher’s good intentions to help her patients and acknowledged that the research approval pathway may feel like a barrier to achieving this. However, there are several options available if the researcher chooses to proceed with the study.
42. The Committee suggested that the researcher ask her contact at the DHB to contact Leesa Russell to discuss this study and the options available.

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

1. Please create a PIS/CF for staff.

*Family Whānau PIS/CF*

1. Please make it clearer who the Family Whānau PIS/CF is for (i.e. family members of all participants and not just for guardians consenting on behalf of minors).
2. Please format the document consistently.
3. Please simplify the description of Havening in the ‘what is Havening’ section.
4. Please review the section about interpreters and state that not speaking English is an exclusion criterion (or amend the section if non-English speakers are included).
5. Please include the role of the person when using first names of staff/research team.
6. Please include what the questionnaires are about in the ‘What will my participation in the study involve?’ section.
7. Please make it clear that Havening is on offer for research and it may or may not benefit patients. Please frame it so that participants know that participating in the study is to help understand the treatment better and whether or not it helps people.
8. Please include who pays for the study and the name of the trust (if it is being funded).
9. Please review the [HDEC PIS/CF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) 'What happens to my information section' (recently updated) and incorporate relevant components into the PIS/CF. Please explain the types of information that may be shared with other parties, such as new information about mental health revealed in a session (incidental findings), and how it would be handled. This would also include information about the process for contacting Child & Family Unit and the key worker and what information will be shared with them and when (if they consent).
10. Please explain the conflict of interest(s) in the study, such as the researcher/clinician divide, and include information about how the interaction between these two roles will be managed.
11. Please remove the ‘Yes/No’ tick boxes on the consent form unless the items are truly optional.

*Young person (16-years-old and over)*

1. Please make changes as per the Family Whānau PIS/CF.
2. Please include ages on both the Young Person and Younger Person PIS/CFs to make it easier to differentiate between them.
3. Please more clearly explain what the Havening procedure is, including a more specific description of the gentle touch, i.e. what parts of the body will be touched and how, etc.
4. Please make it clear that the participant can bring a support person to the sessions if they wish.
5. Please make it clear that should the participant tell the researcher something they consider to be dangerous (e.g. where they may harm themselves or another person), that the researcher will notify their treating clinician of this.
6. Please replace the last two consent items regarding legal rights with the approved wording from the [HDEC PIS/CF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc).
7. Please revise the future unspecified research consent section to ensure the HDEC criteria is being met as referenced previously. Please refer to PIS/CF templates on future research available on the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/).

*Younger person (12-15-years-old)*

1. Please make changes as per the Family Whanau PIS/CF.
2. Please include ages on both the Young Person and Younger Person PIS/CFs to make it easier to differentiate between them.

Decision

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

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| **3** | **Ethics ref:** | **21/NTB/125** |  |
|  | Title: | Youth on Dialysis Survey |  |
|  | Principal Investigator: | Dr Mark Marshall |  |
|  | Sponsor: | Faculty of Medical and Health Sciences |  |
|  | Clock Start Date: | 20 May 2021 |  |

Dr Mark Marshall was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a cross-sectional exploratory study of all dialysis patients in New Zealand aged 15-24-years-old. This study aims to map participants' physical and psychosocial health and unmet needs in this area. This is in preparation for developing a tailored virtual reality intervention, which is intended to enhance their physical and psychosocial skills.

Summary of resolved ethical issues

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

1. The Committee asked for clarity on whether those who have diminished capacity are excluded from the study or whether supported decision making could be an option for this group. The researcher advised that they are not planning to include people with diminished capacity (who cannot consent for themselves by completing the survey). The researcher stated that he is not certain that the exclusion of data for this demographic would influence the mean/median data for the majority. He added that the longer-term requirements in terms of the virtual reality intervention will require people to be able bodied and able minded to participant in the trial.

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 agreed that the application submitted was good and, as noted by the researcher in the application, the main ethical issue is around obtaining assent from the 15-year-old participants.
2. The Committee advised that the ethical standards support young people consenting for themselves provided they adequately comprehend what their research participation involves and the risks associated with it. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.23 – 6.30).*
3. The Committee acknowledged that this particular group of 15-year-olds are extremely health literate and agreed that they have the capacity to understand the questions being asked of them in the survey and therefore are able to consent for themselves.
4. The Committee queried what the role of the parent is in the study or if the questionnaire will go directly to the 15-year-old to complete. The researcher confirmed that the questionnaire will be provided directly to the 15-year-old.
5. The Committee noted that while there are no ethical issues with competent 15-year-olds agreeing to the research without parental consent, there may be complaints from parents who have an issue with this approach, and that this potential risk may be something the researcher wishes to consider.
6. The Committee queried if the researcher will know the identity of the parents and whether they would want to be actively involved in the consenting process for their 15-year-old. The researcher responded that they would be able to get advice from the local investigators (from each District Health Board) on which parents to approach for consent if required.
7. The Committee agreed that formal parental consenting is excessive for an observational study of this kind and a letter to parents explaining the process should be sufficient to mitigate this risk.
8. The Committee requested that an updated protocol for 15-year olds is provided to HDEC that addresses the assent versus consent discussion.
9. The Committee requested greater detail on the management of participant data throughout the research lifecycle. *National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a.* Please use the [Data Management Plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) available on the HDEC website as a guide. Please ensure identifiable and coded data are distinguished and describe the process for linking data and de-identifying data.
10. The Committee stated that separating the Data Management Plan from the protocol for the study will increase the likelihood that the data procedures (particularly around linking) will be consistently followed by the different parties involved, thereby ensuring the safety and integrity of participant data.
11. The Committee stated that the flyer advertisement teases later phases of the research that are not mentioned in the PIS/CF and recommended the flyer focuses on the current phase of the study only. The Committee, therefore, requested the following changes:
    1. Please remove the text about virtual reality (VR) experiments (e.g. ‘The future is coming!’). The Committee suggests using the questionnaire as an opportunity to invite respondents to volunteer for the VR intervention.
    2. Please amend the pictures in the header and the ‘become a volunteer’ to be more relevant to the current study phase.
    3. Please amend the statement ‘Received information from the study on how everyone else is doing’ to be clearer about what this means. E.g. ‘Receive a summary of the survey results’.

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

1. Please remove the Accident Compensation Corporation statement in the PIS/CFs as there is no chance of treatment injury with a questionnaire.
2. Please include a one-line statement saying that the study is being conducted as part of attaining a PhD qualification.
3. The Committee advised that the last sentence is inaccurate as the data will be linked to participants.
4. The Committee advised that the description of the data linking does not adequately cover the quantum of data being gathered about individuals (i.e. ‘collecting a small amount of info from your most recent health records about your medical condition. These results will not be linked to you’). Please incorporate more detailed information on page 3 regarding the management of data collected during the study that aligns with the Data Management Plan and describes exactly what health data is being linked. This will also include how long data will be stored (e.g. 10 years after the youngest participant turns 16). For guidance, please refer to the 'What will happen to my information’ section of the [HDEC PIS/CF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc).
5. Please revise the statement ‘These results will not be linked to you’ as this is not accurate. For guidance, please see the wording in the ‘What will happen to my information’ section in the [HDEC PIS/CF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc).

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Stephanie Pollard and Mr John Hancock.

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| **4** | **Ethics ref:** | **21/NTB/126** |  |
|  | Title: | CK-301-301: Phase 3 study on Cosibelimab (CK-301) in Participants with Non-Small Cell Lung Cancer |  |
|  | Principal Investigator: | Dr Dean Harris |  |
|  | Sponsor: | Checkpoint Therapeutics, Inc. |  |
|  | Clock Start Date: | 20 May 2021 |  |

Dr Dean Harris was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Cosibelimab (CK-301) is a fully human monoclonal antibody of IgG1 subtype that directly binds to Programmed Death-Ligand 1 (PD-L1) and blocks its interactions with the Programmed Death-1 (PD-1) and B7.1 receptors. Normally, PD-L1 binds to PD-1 or B7.1 to stop an immune response and prevent autoimmunity/promote self-tolerance. Cancer cells are able to express PD-L1 and can use this to evade the body’s immune response. An anti-PD-L1 antibody, such as cosibelimab, could prevent PD-1/PD-L1 binding and reactivate the anti-tumour immune response.
2. Clinical studies have shown that blockade of the PD-1/PD-L1 pathway by monoclonal antibodies can enhance the immune response and result in anti-tumour activity. PD-L1 is the primary PD-1 ligand that is up-regulated in solid tumors, where it can inhibit cytokine production and the cytolytic activity of PD-1+, tumour-infiltrating CD4+ and CD8+ T cells. 1,2,3 These properties make PD-L1 a target for cancer immunotherapy. In addition, by retaining a native Fc-region, cosibelimab may also be capable of mediating antibody-dependent cell-mediated cytotoxicity of tumour cells.
3. In this trial, cosibelimab in combination with chemotherapy will be compared with chemotherapy alone in subjects with advanced or metastatic non-squamous, non-small cell lung cancer have not previously received systemic therapy. The primary objective of this trial is to evaluate the antitumor activity of cosibelimab in combination with chemotherapy compared with chemotherapy alone using Overall Survival.

Summary of resolved ethical issues

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

1. The Committee referred to a.1.6 of the application where the researcher has stated there are ‘no ethical issues’ The Committee requested that the researcher does not state this in future because there will likely always be ethical issues involved in a study.
2. The Committee referred to page 11 of the Participant Information Sheet with regards to ‘Pregnancy Risks’. The Committee queried the rationale behind the time difference for women being prohibited from egg donation four months post-study and men are prohibited from sperm donation six months post-study. The researcher stated that this is likely a global study standard and given that sperm and eggs are affected differently.

Summary of outstanding ethical issues

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

1. The Committee noted that the researcher’s Medical Council of New Zealand practising certificate expired on 31 May 2021. The researcher stated that this has since been updated and the trial nurse will provide an updated copy. The researcher also confirmed that this document was not his Medical Protection Society indemnity certificate. A copy of that is already available on the portal.
2. The Committee noted that the researcher included a form for withdrawal of participation. Withdrawal is not required in writing and participants may just say when they wish to withdraw. The Committee requested that the word ‘optional’ be added to the header of that form.
3. The Committee acknowledged that the Data and Tissue Management Plan (DTMP) was good and easy to follow. However, at 12.2.1 of the DTMP, it says ‘no future unspecified research is planned for data collected in this study’. This is inconsistent with page 16 of the Participant Information Sheet which states that there may be future unspecified research. The researcher stated that they do not envision the use of data for future unspecified research, but future research may occur after the outcome of this trial. Please reconcile the DTMP with the Participant Information Sheet for consistency and clearly outline what the plans are.
4. The Committee noted that the DTMP states that tumour tissue will be stored for a maximum of 5 years and then either returned to site or destroyed. However, the Participant Information Sheet is silent on this and the Consent Form states that tumour tissue will be destroyed overseas. The researcher stated that they would arrange for tissue to be returned to and destroyed in New Zealand. To that effect, the Committee requested that the researcher amends the Consent Form and adds information in the Participant Information Sheet.
5. The Committee asked if it is possible for karakia at the time of donation or destruction of any of the samples. The researcher stated that karakia is likely not possible at the time of donation but may be possible at the time of destruction for samples that are returned to New Zealand. The Committee requested that this is made clear and added to the Participant Information Sheet. If karakia is possible, include information that there may be an opportunity but that it would be done as per standard District Health Board process. However, if karakia is not possible, please state this clearly.
6. The Committee referred to page 8 of the Participant Information Sheet and noted that the risks around the study drug need to be quantified better. The researcher clarified that this section was written before they had the data on the recent clinical study of the study drug. The Committee also noted that there are some adverse event profiles and risks in the Investigator’s Brochure which are not included in the Patient Information Sheet. Please include quantification in the Patient Information Sheet and a statement that there is ‘limited safety information’ currently available. Please also review the Investigator’s Brochure again to see if anything is missing in the description of risks in the Participant Information Sheet.

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

1. At page 1, please remove the word ‘limited’ in relation to treatment options.
2. At page 2, please explain the ‘2:1’ ratio as some participants may not know what this means.
3. At page 4, please remove the word ‘race’. This is not a concept used or approved of in New Zealand.
4. At page 7, please replace ‘any other research study’ with ‘clinical trial’ because participants could be involved in qualitative research without having their results impacted.
5. At page 10 under the medication heading ‘Cisplatin’, please include numbers for the risks. Generally, participants prefer risks to be quantified in real numbers rather than percentages; however, you can also leave some percentages. Please also check the numbers and percentages for risks for the other medication headings because they are currently inconsistent.
6. At page 12 under the heading ‘Computer tomography (CT) Scans’, it is unclear what a ‘1.26%’ risk of developing cancer means. For risks of radiation, this is better expressed in terms of connection to background radiation. Please clarify this and provide more background information.
7. At page 16 under the heading ‘Rights to Access Your Information and Results’, please note that this study is not blinded so access to study-specific information cannot result in withdrawal. Please amend the current information accordingly.
8. Please include a statement in the Consent Form that blood samples will be sent and destroyed overseas.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made 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 Mrs Kate O’Connor and Mrs Stephanie Pollard.

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| **5** | **Ethics ref:** | **21/NTB/128** |  |
|  | Title: | TaCAS-FU trial |  |
|  | Principal Investigator: | Dr VIVIAN FU |  |
|  | Sponsor: | Medical Research Institute of New Zealand |  |
|  | Clock Start Date: | 20 May 2021 |  |

Dr Vivian Fu and Dr Harry McNaughton were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is a long-term follow up study of participants from an original Taking Charge After Stroke study (TaCAS) in 2016 to 2017. The TaCAS study showed that a simple treatment – one or two Take Charge sessions – started within 16 weeks for people with a new stroke, improved quality of life and independence 12 months after the stroke compared to people who did not receive that treatment. That study involved 400 people in New Zealand.
2. This Taking Charge After Stroke Follow-up (TaCAS-FU) study aims to see whether the positive effect of the TaCAS intervention is still present between four and five years after the stroke. The information will be gathered via a questionnaire for participants from the prior study although may include family members/care givers if needed, to provide data on those who cannot provide their own.
3. The researchers will contact the participants by mail, seeking consent to acquire health outcome information for a small subset of the original outcome measures (survival, health-related quality of life, independence, living situation). These will be collected on paper (return mail), electronically (online database), or by telephone (following written consent).

Summary of resolved ethical issues

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

1. The Committee noted there were no issues with data management for this study. However, the Committee advised that it standardly requires a data management plan as part of an application and the researchers are encouraged to provide one for any future applications.
2. The Committee noted that the participant invitation letter is included with the Participant Information Sheet and Consent Form. Usually the invitation letter should be a separate document; however, the Committee acknowledged that the researchers will be sending out the documents altogether to participants by mail.

Summary of outstanding ethical issues

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

1. The Committee referred to the statement at page 3 of the Patient Information Sheet about participants having experienced improved quality of life and independence 12 months post-stroke with the TaCAS prior study intervention, compared to those who did not receive that intervention. The Committee considered that current statement might negatively influence responses to the questionnaire. Participants may feel they missed out on treatment that was helpful to those who did receive it. The Committee suggested alternative wording such as, ‘There were differences between the groups at 12 months and this study wants to see if those differences have been sustained’.
2. The Committee did not consider that the peer review obtained by the researchers was independent because the reviewer is in a related study. The Committee requested a new peer review and asked the researchers to ensure that the reviewer uses the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2020.docx).
3. The Committee noted that the researchers will use a tiered process of obtaining consent. The Committee advised that every clinical trial has its own screening process and at least three attempts are usually made to contact potential participants by phone who have been screened. It is reasonable for this study to obtain verbal consent.
4. The Committee asked how the researchers will know that participants are competent to consent post-stroke if they are obtaining verbal consent. The researchers stated they will speak to potential participants and the beginning of the phone call and determine what they understand and have insight into the reason for the phone call. The researchers will ask whether the information was received and it has been read and understood, then proceed from there. The phone call will not be purely formal. There will be general assessment to determine if there is enough insight for the participant to proceed. The Committee also noted that the researchers are specialists in their area and experienced with determining competency, without needing to see the participant. Please put this plan in the Protocol and clearly explain how competency will be determined.
5. The Committee also asked that the researchers consider the option for participants to take a photo of their signed consent form and send this to the researchers.
6. The Committee requested inclusion of a well-documented method/process of recording consent and how it was obtained. This should also include a section on the Consent Form, or on a separate page, using the following or similar wording: ‘I, [member of research team], spoke to [participant] at [time and date]. I read the consent form to the participant, and I will post a separate copy to them to ensure they receive one. The participant verbally agreed to undertake the study procedures and we will proceed with the survey. We agreed for the survey to take place at [time and date] by [delivery mechanism i.e. Zoom/phone call]’. Please also refer to the [NEAC Standards](https://neac.health.govt.nz/national-ethical-standards/part-two/) around verbal consent.
7. The Committee discussed the approach for participants who are unable to consent/have diminished capacity. The researchers stated that participants are usually staying in some type of institutional care/living. The researchers stated that phone calls will usually go through to a nurse’s station before they may speak to participants themselves. There would be communication at that point which would determine whether the participant can speak. If not, that would end the researchers’ attempt to speak with the participant. The Committee then asked, if the researchers are unable to consent a participant, what the process is for keeping them included in the study. The researchers stated they would ask the nurse who is caring for the patient, or a family member a few simples questions, including whether the participant is receiving full time care/support, where the participant is living (institutional care or not), whether the participant is alive, and then the ranking score which requires just two questions (whether the participant is bed-bound or mobile). The Committee noted that this information will still be about caregivers/family members’ perception so while the information is factual, the Consent Form and Protocol need to be clear that their opinion is being sought about the participant.
8. In relation to the above point, the Committee requested that for non-consenting participants, their family members be consented on a separate family/whānau consent form. This will need to make clear that the participant was part of the prior study, the researchers are aware that the participant is no longer able to provide information about their life, so the family/whānau are being asked to provide information on their behalf, which will include some information about the participant’s health.
9. The Committee noted that an alternative option for obtaining information from caregivers is to use secondary data e.g. request information from the occupational therapist. This could be helpful for obtaining information about deceased participants.

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

1. Please use the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) for the Participant Information Sheet and Consent Form.
2. At page 2, please add the word ‘bin’ after ‘recycle’.
3. Please include a statement to make it clear that the information from this study will be linked to the information collected from the prior study.
4. Please review the document and remove any formatting or tracked changes, including comment balloons.
5. Please use larger font in the document to make it accessible for people with limited visibility or difficulty understanding.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made 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 Ms Susan Sherrard and Mrs Leesa Russell.

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| **6** | **Ethics ref:** | **21/NTB/129** |  |
|  | Title: | The AVIatioN Study |  |
|  | Principal Investigator: | Dr Barbara Cormack |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 20 May 2021 |  |

Dr Barbara Cormack was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. A prospective cohort study looking at low birth weight babies in the Neonatal Intensive Care Unit (NICU), and their vitamin intake. Approximately 100 babies will be included from Auckland City Hospital and Waikato Hospital who are under 1,000g, and live to day seven and require intravenous (IV) nutrition.
2. Levels of vitamins will be measured to understand whether very preterm babies are given enough important nutrients, and to assess whether low levels are associated with health complications.
3. The study will involve taking a few drops of blood on or around day seven after birth, at a time when the baby is having a routine blood test for clinical reasons. The blood collected will be analysed to determine the levels of vitamins in the baby’s blood.
4. Basic health information will be collected from the medical records of babies and their mothers. The information collected will include medical history, medications and treatments and the results of hospital laboratory tests.

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 if the researcher could ask mothers directly about their socioeconomic status and ethnicity. The researcher stated this information could be obtained from the mother in the first five days after the baby’s birth. The Committee noted that the mother would need to consent for this information to be collected about herself. The Participant Information Sheet and Consent Form needs to be amended as it currently does not cover this.
2. The Committee queried who will consent for the baby’s tissue to be taken and analysed. The Committee noted that the Consent Form is broadly addressed to whānau/friends. However, the Committee considered that it is the parent/legal guardian who will provide consent to the medical intervention for the baby. Accordingly, the mother is the most appropriate person to provide consent for herself and the baby rather than whānau/friends. Please use the words ‘parent/legal guardian’ on the Consent Form instead of ‘Relative/Whānau’. Please also make it clear in the Participant Information Sheet and Consent Form that the mother is also a participant as she will provide data as well.
3. The Committee noted that from reading the Protocol, there is suspicion that some babies will be slightly over nourished in some vitamins. The Committee asked what the researcher will do if the study shows harmful levels of vitamins. The researcher stated, in reference to vitamin E, that vitamin doses in IV nutrition are currently appropriate but when combined with the IV lipid (which is also high in vitamin E) it might mean there is too much. However, the researcher stated they they cannot do anything for individual participants because they would have the results too late. The researcher also noted that too much vitamin E can increase risk of sepsis. The Committee asked if the researcher has a plan for monitoring adverse events such as sepsis. The researcher stated that sepsis is not necessarily an adverse event, given it is a normal outcome of neonatal care. Further, monitoring for sepsis is already routine in neonatal units, and a certain percentage of babies do get sepsis. Further, there is a data monitoring committee for this study and the researcher confirmed that there is a data monitoring plan as part of the protocol. The researcher also confirmed there is ongoing review of vitamin levels and noted that if there is no association with clinical outcome, then there may be no problem. Please include information about this and note sepsis as a possible risk in Participant Information Sheet.
4. The Committee noted that the Data Management Plan appeared to be generic and did not mention tissue. Please make sure the Data Management Plan reflects the extra blood being taken.
5. The Committee also noted that the Data Management Plan includes a lengthy section around use of data for future research; however, this is not mentioned in the Participant Information Sheet. The researcher stated that there is currently no plan to use the data for future research. Please review and amend the Data Management Plan to include tissue and reconcile and reflect what will actually be done in the study.
6. The Committee queried how data will be stored because the information on this in the Data Management Plan is inconsistent with that in other documents. The researcher stated that data will be held inputted on a spreadsheet, which will then be stored into secure electronic data capture software held by the University of Auckland. Please amend the Data Management Plan to explain this means of storage.
7. The Committee queried whether tikanga, Māori review, Māori data sovereignty were considered as part of this study. Similarly, tikanga around taking blood, and tikanga regarding talking to whānau postpartum. The researcher stated that Thomas Wright, a member of the research team, is Māori. He is very involved in this study and wrote the Protocol. Further, since the application was submitted, the research team have had Māori review of the Protocol. Please incorporate and show this more in the documents, with consideration given to Māori participants particularly as this study will be during a time of vulnerability.
8. The Committee asked how long the researcher will follow the babies for the study. The researcher stated that they would not follow the babies beyond 36 weeks or after discharge from the NICU. Data will be collected up until discharge. Please include this information in the Participant Information Sheet as it is important for family/whānau to know how long they will be involved.

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

1. Please remove ‘blood transfusion’ as a possible risk of the study. The Committee discussed and confirmed with the researcher that risk of blood transfusion for this study is not a realistic risk. Please consider the real risks and only include those.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made 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 Mr John Hancock and Mrs Stephanie Pollard.

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| **7** | **Ethics ref:** | **21/NTB/131** |  |
|  | Title: | D9072C00001: A Study of Subcutaneous Durvalumab in Patients with Non-Small Cell and Small Cell Lung Cancer |  |
|  | Principal Investigator: | Dr Rajiv Kumar |  |
|  | Sponsor: | AstraZeneca |  |
|  | Clock Start Date: | 20 May 2021 |  |

Dr Rajiv Kumar and Courtney Rowse were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Durvalumab is a human monoclonal antibody (mAb) of the immunoglobulin G (IgG) 1 kappa subclass that blocks the interaction of programmed death-ligand 1 (PD-L1) with programmed cell death 1 (PD-1) on T cells and CD80 (B7.1) on immune cells and is being developed by AstraZeneca for the treatment of cancer. As of November 2020, durvalumab is approved in various countries for non-small cell lung cancer and extensive-stage small cell lung cancer under the brand name IMFINZI Injection as an intravenous (IV) infusion over 60 minutes.
2. The purpose of this study is to establish the subcutaneous dose level of durvalumab that is comparable to the currently approved IV administration and will provide equivalent target saturation of PD-L1 receptors

Summary of resolved ethical issues

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

1. The Committee thanked the researchers for submitting a good application and asked the them to explain the medication, noting that it is also going to the Standing Committee on Therapeutic Trials for approval. The researchers stated that the medication is recognised internationally as standard of care for patients with stage 3 lung cancer. However, it is currently not recognised in New Zealand. The researchers added that the rationale of this study is that initially the medication was administered every 2 weeks, which can be crippling for a patient group that is physically quite well. The next step is to administer it every 4 weeks, then subcutaneously so that it can be given to people in the community.
2. The Committee asked if any of the survey documents were missing or if it was just the one that was submitted. The researchers clarified that the surveys have the same acronym but are on the same document.
3. The Committee asked how many sites are involved in the study. The researchers stated there are eight countries involved but for New Zealand, it will just be New Zealand Clinical Research, and patients will be referred from hospitals.
4. The Committee noted there are three levels in this protocol, level 3 being the actual standard of care treatment. The Committee asked whether participants would not receive the actual standard of care treatment until quite far down the dosing schedule. The researchers confirmed this. The Committee asked if there are any risks around this regarding disease progression and was reassured by the researchers’ explanation, noting that participants would have already completed definitive chemoradiotherapy. Participants will not be under-treated, instead they will have the opportunity to have treatment they otherwise would not have been able to in New Zealand.
5. The Committee noted that the Data and Tissue Management Plan and Participant Information Sheet and Consent Form for Future Unspecified Research are good.

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 researchers clearly state which vaccines are considered ‘live vaccines’. The Committee suggested that all live vaccines do not need to be named, but some could be given as main examples.
2. The Committee referred to the risks section of the Participant Information Sheet. Please be clearer and separate out the risks specifically associated with the medication, administration, and study procedures. Please also note and make clear that risks may be different at the different phases of the study.
3. The Committee noted that the researchers will take bloods and check for immune related diseases such as HIV. The Committee requested that the researchers update the documentation accordingly around notifiable diseases such as active acute Hepatitis B and C. These are both notifiable as per the Schedule of Notifiable Diseases in the Health Act 1956 if it is new information about a patient’s health.

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

1. Under the ‘What is included in my participation?’ section, please be clear about the technology that participants will be required to use.
2. Please remove the statement, ‘I have read this in my first language’ from the consent form. If translated consent forms are not being used, please do not use this statement because it implies that the study will exclude participants who do not have English as their first language. The Committee suggested the following wording instead, ‘I have read and understood this Consent Form’.
3. Please include information about the questions involved for the genetic sub-study. This information can be broad and the researchers could state, ‘the optional genetic sub-study is looking at the relationship of genetic factors which influence the success of this medication’.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made 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 Mrs Kate O’Connor and Mrs Leesa Russell.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 06 July 2021, 12:00 PM |
| **Meeting venue:** | ONLINE - Zoom Meeting |

1. **Review of Last Minutes**

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

The meeting closed at 3:40pm.