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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27 October 2020 |
| **Meeting venue:** | Zoom Video Conference Meeting ID: 832 8269 4300 |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
|  | Confirmation of minutes of meeting of 22 September 2020 |
|  | New applications (see over for details) |
| 12:30-12:55pm  12:55-1:20pm  1:20-1:45pm  1:45-2:10pm  2:10-2:35pm  2:35-3:00pm  3:00-3:10pm  3:10-3:35pm  3:35-4:00pm  4:00-4:25pm  4:25-4:50pm  4:50-5:15pm | 1. 20/CEN/219 (Helen W / Devonie) 2. 20/CEN/223 (Helen D / Devonie) 3. 20/CEN/221 (Cordelia / Devonie) 4. 20/CEN/222 (Sandy / Julie) 5. 20/CEN/225 (Helen D / Peter 6. 20/CEN/226 (Cordelia / Julie)   (Quick break)   1. 20/CEN/228 (Sandy/ Peter) Peter 2. 20/CEN/229(Helen W/ Julie) 3. 20/CEN/230 (Cordelia / Peter) 4. 20/CEN/232 (Sandy / Peter) 5. 20/CEN/233 (Helen W / Julie) |
|  | Substantial amendments (see over for details) |
| 5:15-5:30pm  5:30-5:45pm | 1. MEC/10/10/103/AM22 2. Whataboutme HRC appeal result |
| 5:45pm | General business:  Noting section  Meeting start times  Electronic distribution of minutes |
| 5:50pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 22/05/2020 | 22/05/2023 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 22/05/2020 | 22/05/2023 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 22/05/2020 | 22/05/2023 | Apologies |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 22/05/2020 | 22/05/2023 | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | 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 | Apologies |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Dr Patries Herst and Dr Jill Wilkinson

The Chair noted that it would be desirable to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Devonie Waaka confirmed her eligibility and was co-opted by the Chair as a member of the Committee to assist with the first three applications.

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 22 September 2020 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **20/CEN/219** |
|  | Title: | A Study of Nivolumab or Placebo in Combination with Docetaxel in Men with Metastatic Castration-resistant Prostate Cancer (mCRPC). |
|  | Principal Investigator: | Dr. Navin Wewala |
|  | Sponsor: | Bristol-Myers Squibb |
|  | Clock Start Date: | 15 October 2020 |

Dr Navin Wewala was present 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 CA2097DX study aims to demonstrate that treatment with docetaxel in combination with nivolumab will be efficacious in participants with metastatic castration-resistant prostate cancer (mCRPC).

Summary of outstanding ethical issues

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

1. Please revise the protocol to add a prompt if a participant withdraws to request permission to continue to use any sample provided.

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

1. Please insert a statement into the PIS advising participants what the study team will do if they score low on the quality of life questionnaires.
2. Please revise the section on participant to withdrawal to state if a participant withdraws they will be invited for a final assessment.
3. A discrepancy between ‘local doctor’ and ‘GP’ between the PIS and consent form could be potentially confusing, please stick to one term.
4. Please insert a statement advising that a positive result for hepatitis, HIV etc will be notified to the medical officer of health.

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).*
* 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).*

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| **2** | **Ethics ref:** | **20/CEN/223** |
|  | Title: | TWIST3: Validation of the Time to Walking Independently after Stroke Tool |
|  | Principal Investigator: | Professor Cathy Stinear |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 15 October 2020 |

Professor Cathy Stinear was present 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 observational study will test a prediction tool called TWIST, which predicts whether and when a person with recent stroke will walk safely on their own again.

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 a potential legal issue where the study may not comply with [Right 7(4) of the Code of Health and Disability Services Consumers’ Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/). The Researcher clarified they were not intending to recruit incompetent participants but wanted to allow family members to support participants who may struggle with communication. The Committee advised the support person could sign on behalf of the participant at their direction and assist the participant with interpretation but the consent must be obtained from the participant.
2. The Researcher confirmed any family members participating in interviews would provide their own separate consent.

Summary of outstanding ethical issues

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

1. Please update the protocol to include that the assessment of the clinical team (e.g. neurologist, speech language therapist) that the participant is competent to provide consent is to be recorded in the study notes.
2. Please consider how to communicate individual results in a way so participants understand it is just a prediction and may differ from their outcome.
3. The Committee requested the Researcher supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health). The Committee recommended the Researcher adapt [the data management template](https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx) available on the HDEC website.
4. Please revise the recruitment approach so the clinical team first introduces the study then if the participant is interested the research team may approach to explain the study.

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

1. Please add ACC information to the family PIS.
2. Please insert a statement to the main PIS advising participants of the right to access and correct information held about them .
3. Please revise the sheet to make it clear that family will only be contacted for the interview if permission from the participant is granted.
4. Please ensure anything in the consent form has been adequately explained in the PIS.
5. Please include more information on the use and limits of participant data in all information sheets. Participants should understand where their data will be stored, what it may be used for, who will have access to it, when it will be destroyed etc.
6. Please insert information explaining that anonymous information provided to other researchers will have participants’ study codes removed but de-identified data can be linked and re-identified.

Decision

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

* 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 supply a data governance plan to ensure the safety and integrity of participant data

*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

* 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 Ms Helen Davidson and Dr Devonie Waaka.

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| **3** | **Ethics ref:** | **20/CEN/221** |
|  | Title: | Vitamin D Level in Children with Cancer |
|  | Principal Investigator: | Dr Leonie Naeije |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 October 2020 |

Dr Leonie Naejie was present 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. Multiple risk factors for low vitamin D levels are identified in paediatric oncology/haematology. Vitamin D insufficiency can have negative effects on bone health and subsequently result in low bone density, osteoporosis or osteonecrosis. These complications can have a negative impact on quality of life, as well as on the quality of cancer treatment.
2. In this clinical, prospective observational study the researchers hypothesise that vitamin D insufficiency or deficiency is common in this population and that supplementation according to standard practice will be effective in normalising these levels.

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 everyone under the age of 16 would be asked to assent but acknowledged that some young people under 16 may have capacity to consent for themselves. If they are competent they are able to consent to participation. The Researcher stated what they usually do in this situation is have the full form for both the young person and parent. Their usual practice is to split the assent form into ‘older child’ and ‘younger child’ rather than a number value for age range.
2. The Committee queried what was standard of care and what was research. The Researcher explained the supplementation itself was part of standard of care and the data collection and analysis was the study.

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 supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health). The Committee recommended the Researcher adapt [the data management template](https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx) available on the HDEC website.
2. Please include an analysis plan in the protocol.

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

1. Please simplify any technical language (e.g. ‘pigmented skin’, ‘oral supplementation’) for a lay audience.
2. Please include a statement advising participants of the right to access and correct any information held about them.
3. Please include contact details for HDEC ([HDECS@health.govt.nz](mailto:HDECS@health.govt.nz), 0800 4 ETHIC).
4. Please update the advocacy email to [advocacy@advocacy.org.nz](mailto:advocacy@advocacy.org.nz).
5. Please remove the tickboxes for requesting an interpreter and insert a statement saying to ask for one if needed.
6. Please add an option on the consent form to receive a lay summary of the study results.
7. Please remove the sore finger reference as this applies to standard care.
8. Please insert a cultural tissue statement as even though the blood taken is for standard care it is still being used for a research test.

Decision

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

* 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).*
* Please supply a data governance plan to ensure the safety and integrity of participant data

*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **4** | **Ethics ref:** | **20/CEN/222** |
|  | Title: | Parent coaching in the Early Start Denver Model for parents of young children with Autism Spectrum Disorder. |
|  | Principal Investigator: | Ms Lauren van Noorden |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 October 2020 |

Ms Lauren van Noorden was present or 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 Early Start Denver Model (ESDM) is a promising intervention approach for improving the outcomes of young children with Autism Spectrum Disorder (Autism). There is also some evidence that parents can be taught to use the ESDM procedures with their own children. However, the existing ESDM parent coaching literature has evaluated 1:1 parent coaching, which is a resource intensive service delivery model. Furthermore, existing ESDM parent coaching literature has shown that not all parents who receive this intervention learn to use the strategies with a high level of accuracy (fidelity).
2. This study proposes to use a three-tiered intervention design, where parents will be taught to use the ESDM strategies in three additive phases, or until they reach fidelity. The first tier will be a group parent coaching programme, which could provide an efficient service delivery model if effective. For parents who do not reach fidelity during this first (group-coaching) tier, a second tier of 1:1 parent coaching will be offered. This stepped approach to parent coaching may ensure that parents can access the support they need to learn to use the ESDM strategies with their own children. However, for parents who do not reach fidelity during this second (1:1 coaching) tier, a third tier of individualised parent coaching will be offered and in-depth information will be collected from these parents about the challenges they faced in learning the ESDM strategies in the previous tiers, and what solutions they believe will help them to be successful in learning to use the strategies with their own children.
3. At all stages of the study, data will be collected about parent use of the ESDM strategies, and any changes in child engagement, communication, and imitation skills.

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 quality of life questionnaires assessing mental health would be used and the PIS did not explain how quickly the information would be collated or how the researchers would respond to a low score. The Researcher stated it was not intended to be diagnostic, but they would talk with participants and empower them to make their own decision if they need further help. The Committee stated if a study is collecting mental health data it has an obligation to act on it immediately if it receives information of concern. The Committee requested a clause in the consent form agreeing that the researcher may contact the participant’s GP and information in the PIS explaining what the Researcher will do if a participant scores low.
2. The Committee advised that Māori consultation is required and could be done through the University. Please supply evidence of Māori consultation with the resubmission.
3. The Committee requested an independent peer review and recommended the Researcher use the [scientific peer review template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/HDEC-Peer-Review-Template.docx)
4. The Committee welcomes the attendance of the supervisor of any student who applies to HDEC and strongly encourages the Researcher’s supervisor to attend the next meeting.

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

1. Please adapt the data section from the [HDEC template.](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc)
2. Please remove 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).
3. Update the consent form so that parents/guardians consent for their own participation and also consent on behalf of child
4. Please include more information about the Broad Autism Phenotype Questionnaire (e.g. what it is for and why parents are being asked to complete it) as it is not currently clear in the main PIS. Please include all patient facing questionnaires and interview questionnaires.
5. Please revise the statement about Lauren getting money to state the researcher is receiving a stipend or equivalent.
6. Please revise the statement about costs to simply state participants do not need to pay to participate.
7. Please replace any use of ‘I’ with ‘the researcher’.
8. Please update the PIS to reflect the correct document retention period for children (i.e. 10 retained for years after the child turns 16).
9. Please clarify the statement regarding use of data following withdrawal to advise participants that if they withdraw any data collected up until that point will continue to be used.
10. Please revise the PIS to use the third-person throughout (e.g. page 5 uses ‘me’).
11. Please reconsider use of the term ‘primary caregiver’ as this could potentially be a point of contention between parents.
12. Please insert the ACC statement available on the HDEC template.
13. Please revise the statement on the consent form assuring that participation is confidential as this cannot be guaranteed in a group activity.
14. Please check the reference to health information in the consent form as this will not be used in the study.
15. Please revise the HDEC has given approval statement to clarify that HDEC has given *ethical* approval.

Decision

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

* 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 supply an independent peer review for the current version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
* Please supply evidence of Māori consultation to ensure the study is appropriate for a New Zealand context *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7).*

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| **5** | **Ethics ref:** | **20/CEN/225** |
|  | Title: | Follow up study of children conceived following a Lipiodol HSG |
|  | Principal Investigator: | Prof Paul Hofman |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 15 October 2020 |

Professor Paul Hofman was present 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. As more children are born following assisted reproduction, the long-term health of these children needs confirming especially with respect to growth, puberty, neurocognition, bone health and metabolic syndromes. Unlike childhood outcomes form other assisted reproductive techniques, there are no studies so far to assess the long-term outcome of offspring born following Lipiodol HSG. To the researchers’ knowledge this will be the first study to assess growth, body composition and development of children born following Lipiodol HSG.
2. The study aims to recruit 50 children between 6-14 years old and compare the growth, body composition (using DEXA scan) and development (using standardised developmental assessment tools) and compare these with siblings or friends as control.

Summary of outstanding ethical issues

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

1. The Committee queried whether the children would be photographed for the pubertal staging. The Researcher explained they would not and would not be examined, instead they would be shown photographs and point to a stage they believe they are at. Please include information about this in the PIS so children are aware of what is involved.
2. The Committee queried whether people on the database had consented to be contacted for research. The Researcher stated they had not and so the keeper of the database would send information on their behalf, then if anyone expresses interest the Researcher will contact them. The Committee requested a copy of the letter to be sent.
3. Please revise the protocol to limit the control group to siblings. If the study is unable to recruit enough participants then an amendment for friends can be submitted via the HDEC amendment pathway.
4. The Committee advised that if siblings will be recruited as controls then there will need to be two separate parental consents for this. Please revise the sheet to accommodate this.
5. Please revise the protocol to ensure all information is kept for at least ten years after the youngest participant turns 16.
6. The Committee advised that knowledge is a taonga and whakamā is likely to be present in Māori participants and the Researcher should be mindful of this.
7. Please adapt and incorporate the data management section from the [HDEC template.](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc)

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

1. Please include details of the koha voucher in the PIS.
2. Please revise the statement about HDEC approval to specify that HDEC has given *ethical* approval.
3. Please undertake a general revision to correct any typos, spelling errors, grammar etc.
4. Please amend the statement on page 5 about participants’ right to access information to explain they also have the right to correct any information about themselves.
5. Please ensure the ACC statement is the one from the [latest HDEC template](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc). Please move the statement to the body of the PIS as it is currently in the contact details section.
6. Please revise the information about the research team having access after the study as it currently implies Researchers may access information after the study has been completed.
7. Please simplify the information about pregnancy in the older children’s PIS.
8. Please include a Māori health contact in the older children’s PIS.
9. Please revise the statement on page 3 about participants changing their mind if uncomfortable as they can change their mind for any reason.

Decision

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

* 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).*
* Please supply a copy of the letter to be sent to potential participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*

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

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| **6** | **Ethics ref:** | **20/CEN/226** |
|  | Title: | VIS649-102: A study assessing single doses of VIS649, in healthy adults. |
|  | Principal Investigator: | Dr Paul Hamilton |
|  | Sponsor: | IQVIA RDS Pty Limited |
|  | Clock Start Date: | 15 October 2020 |

Dr Paul Hamilton and Dr Chris Wynne and were present for discussion of this application.

Potential conflicts of interest

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

Dr Devonie Waaka had declared a potential conflict of interest but had departed the meeting before the application was heard so did not participate in the discussion.

Summary of Study

1. VIS649 is being developed for the treatment of a kidney disorder called IgA nephropathy.
2. This is the third study of VIS649 in humans. In the first two studies of VIS649 in humans, the study drug was given to participants into a vein (IV). In this study, VIS649 will be given as an injection under the skin in the abdomen (subcutaneous or SC).
3. The study has two main aims:

* To see how safe and well-tolerated single SC doses of VIS649 are, in healthy adults.
* To measure levels of VIS649 in the blood over time, following single SC doses of VIS649.

The study will also look at:

* Whether VIS649 is processed and cleared differently in people of Japanese ethnicity.
* Whether the body produces antibodies against VIS649.

1. Up to approximately 36 healthy adults will be enrolled into a maximum of 3 planned dose groups. The study will aim to recruit 3 participants of Japanese descent into each group.

Summary of resolved ethical issues

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

1. The Researcher queried if the new wording around how participants would be compensated was acceptable. The Committee confirmed it was.

Summary of outstanding ethical issues

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

1. Please include the number of how many humans have received the drug to the PIS.
2. Please clarify the future use of information on page 12 of the PIS and whether it is related to the study drug only or wider FUR.

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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| **7** | **Ethics ref:** | **20/CEN/228** |
|  | Title: | BO41932: Tumour-agnostic Precision Immuno-oncology Phase II Platform Trial (TAPISTRY) |
|  | Principal Investigator: | Dr Michelle Wilson |
|  | Sponsor: | Roche Products (New Zealand) Limited |
|  | Clock Start Date: | 15 October 2020 |

Dr Michelle Wilson was present 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, multi-cohort phase II study designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents (or in specified combinations) in patients with unresectable, locally advanced or metastatic solid tumours determined to harbour specific oncogenic genomic alterations.

Summary of resolved ethical issues

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

1. The Committee queried the likelihood of a pregnancy during the study. The Researcher stated it would be extremely low but not impossible. The Committee advised that in the event of a participant becoming pregnant the Researcher can submit an amendment with a pregnant participant PIS.

Summary of outstanding ethical issues

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

1. Please insert a statement into the PIS advising participants what the study team will do if they score low on the quality of life questionnaires.

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/229** |
|  | Title: | DNLI-F-0002: A study assessing different formulations of DNL343, in healthy adults. |
|  | Principal Investigator: | Dr Christian Schwabe |
|  | Sponsor: | Denali Therapeutics |
|  | Clock Start Date: | 15 October 2020 |

Dr Christian Schwabe was present for discussion of this application.

Potential conflicts of interest

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

Dr Devonie Waaka had declared a potential conflict of interest but had departed the meeting before the application was heard so did not participate in the discussion.

Summary of Study

1. DNLI-F-002 is being developed for the treatment of amyotrophic lateral sclerosis (ALS).
2. This study will test different formulations of DNL343: a capsule used in the first study of DNL343 in humans (original formulation); granules mixed with water (new formulation); and a liquid suspension (new formulation).

Summary of outstanding ethical issues

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

1. Please revise the protocol to specify that pregnancy follow-up data needs to be stored for 10 years after the child turns 16.

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

1. Please include the following statement in 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.”
2. Please include any information on any potential risks of an allergic reaction to the drug.
3. Please correct the typo on page 5 that is missing the word ‘you’ (“make sure are still eligible for”) and the typo on page 8 (‘do’ should be ‘to’).

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).*
* 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).*

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| **9** | **Ethics ref:** | **20/CEN/230** |
|  | Title: | MK3475-U03 |
|  | Principal Investigator: | Dr Nicola Lawrence |
|  | Sponsor: youre | MSD |
|  | Clock Start Date: | 15 October 2020 |

Dr Nicola Lawrence, Ms Sophie Goodger, Mr Valmir Silva and Ms Toni Hopkins were present 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 umbrella study, with a Master protocol U03 and two substudy protocols 03A and 03B. The study will evaluate multiple treatment arms across different patient populations. In the Master Protocol, a substudy refers to a specific participant population & is described in a separate substudy protocol. The substudies are composed of a specific set of study treatment arms. A study treatment arm refers to a combination of investigational agent(s). In general, investigational agents will be added to a substudy after an initial evaluation of safety and tolerability has been completed in a separate Phase 1 study.

Summary of resolved ethical issues

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

1. Please remove all options for consent by legally authorised representatives as this is not applicable to adults in New Zealand.
2. Please revise the statement about notifying positive HIV and Hepatitis results to the DHB to state the Medical Officer of Health will be notified.
3. Please correct the typo on page 6, number 11 where the fifth bullet point repeats BP twice.
4. Please revise the information on contraception in the PIS so potential participants know whether or not they will need to use contraception as this may affect their wish to participate.
5. Please clarify what samples are being sent where and for what purpose on page 24.
6. Please clarify what samples may be stored for up to 15 years following the end of the study (e.g. biomarkers or genetic samples).
7. Please clarify the reimbursement on page 26 as this could affect whether someone in financially difficult circumstances is able to participate.
8. Please revise the statement on participants requesting information to remove the ‘if important’ as participants do not need to justify their request.
9. Please create a short lay friendly study title.

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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| **10** | **Ethics ref:** | **20/CEN/232** |
|  | Title: | MK-3655-001: Assessment of the safety and effectiveness of MK-3655, in adults with non-alcoholic steatohepatitis (NASH). |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Merck Sharp and Dohme |
|  | Clock Start Date: | 15 October 2020 |

Professor Edward Gane was present for discussion of this application.

Potential conflicts of interest

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

Dr Devonie Waaka had declared a potential conflict of interest but had departed the meeting before the application was heard so did not participate in the discussion.

Summary of Study

1. MK-3655 is being developed for the treatment of non-alcoholic steatohepatitis (NASH).
2. The study will be conducted in approximately 328 adults with pre-cirrhotic NASH. The trial aims to:
   * Assess how safe and well-tolerated MK-3655 is.
   * See how well MK-3655 works compared to placebo.
   * See whether MK-3655 improves participants' quality of life.

Summary of outstanding ethical issues

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

1. Please remove the female contraception information as post-menopausal women cannot get pregnant and it is not needed.
2. Please insert a statement into the PIS advising what the study team will do should a participant score low on quality of life scales.
3. Please insert the cultural paragraph and a Māori contact number into the FUR PIS.
4. Please remove the statement about additional side effects on page 11.
5. Please include any information on male contraception and if there is any teratogenic risk for males as it currently talks about pregnancy and breastfeeding.
6. Please insert a statement advising participants of their right to access and correct information held about themselves.

Decision

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

* 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 Mrs Sandy Gill and Dr Peter Gallagher.

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| **11** | **Ethics ref:** | **20/CEN/233** |
|  | Title: | 73763989HPB2003 Combination of siRNA and Nucleoside analogue with or without Core Inhibitor for chronic hepatitis B |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Janssen-Cilag Pty Ltd |
|  | Clock Start Date: | 15 October 2020 |

Professor Edward Gane was present 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 liver biopsy study is primarily performed to assess changes in intrahepatic viral and host immune markers in response to JNJ-3989-based combination treatment.
2. 24 chronic HBV-infected participants will be enrolled in 2 panels, approximately 12 participants in each panel. Panel 1 will consist of participants who are HBeAg positive and not currently treated and Panel 2 will consist of participants who are HBeAg negative and virologically suppressed.
3. Participants will be randomized in a 1:1 ratio within each panel to receive either Intervention arm 1 (combination regimen JNJ-3989+JNJ-6379+NA) or Intervention arm 2 (combination regimen JNJ-3989+NA) for 48 weeks.

Summary of outstanding ethical issues

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

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

1. Please clarify that interpreters are available for each study visit if needed.
2. Please remove the statement about gathering information on participants’ religious and philosophical beliefs if this is not necessary for the study.

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).*

## Substantial amendments

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| --- | --- | --- |
| **1** | **Ethics ref:** | **MEC/10/10/103/AM22** |
|  | Title: | New Zealand Health Survey (or NZHS) |
|  | Principal Investigator: | Mr Grant Pittams |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 October 2020 |

Mr Grant Pittams was present for discussion of this amendment.

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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee noted this amendment appeared to fundamentally change the nature of the research but as the study was so old and original documentation unavailable it was difficult to assess.
2. The Committee noted the submission stated a full legal opinion was attached but this has not been included.
3. The Committee noted the HDC Code may not apply as no health service is being provided but the health information privacy code and NEAC standards would still be applicable.
4. The Committee noted that any child participants who have since turned 16 would most likely not have provided consent.
5. The Committee queried the number of participants as the amendment incorrectly states there are over one billion.
6. The Committee queried if written consent was obtained or if consent was implied by completing the interview.
7. The Committee noted it does not have enough information to approve or decline the amendment. The Committee agreed to defer to the HDEC Secretariat to investigate how to proceed.

## Review of approved studies

19/CEN/68

The Committee thanked the HRC for acknowledging its safety concerns and for including a safety plan.

## General business

1. The Committee noted the content of the “ noting section” of the agenda.
2. The Committee agreed to schedule future zoom meetings to begin half an hour earlier at 11:30am.
3. The Committee requested the previous meeting’s minutes be sent electronically with the agenda.
4. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 24 November 2020, 12:00 PM |
| **Meeting venue:** | Zoom TBC |

The following members tendered apologies for this meeting.

* Dr Jill Wilkinson

1. **Review of Last Minutes**

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

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 4:30pm.