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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 28 July 2020 |
| **Meeting venue:** | Zoom 367 426 700 <https://mohnz.zoom.us/j/367426700> |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
|  | Confirmation of minutes of meeting of 23 June 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  5:15-5:40pm | 1. 20/CEN/151 (Helen W / Patries) 2. 20/CEN/147 (Helen D / Peter) 3. 20/CEN/146 (Cordelia / Jillian) 4. 20/CEN/148 (Sandy / Julie) 5. 20/CEN/149 (Helen D / Peter) 6. 20/CEN/150 (Cordelia / Julie)   (Quick break)   1. 20/CEN/152 (Sandy/ Patries) 2. 20/CEN/153 (Helen W/ Jillian) 3. 20/CEN/154 (Cordelia / Peter) [COI: Julie] 4. 20/CEN/156 (Sandy / Jillian) 5. 20/CEN/157 (Helen W / Julie) 6. 20/CEN/158 ( Helen D/ Patries) |
| 5:40pm | General business:  Noting section |
| 5:45pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 22/05/2018 | 22/05/2020 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 22/05/2015 | 22/05/2020 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 22/05/2015 | 22/05/2020 | Present |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 22/05/2015 | 22/05/2020 | Present |
| Ms Helen Davidson | Lay (ethical/moral reasoning) | 06/12/2018 | 06/12/2021 | Present |
| Ms Julie Jones | Non-lay (intervention studies) | 22/05/2020 | 22/05/2022 | Present |
| Dr Jillian Wilkinson | Non-lay (observational studies) | 22/05/2020 | 22/05/2023 | Present |

## Welcome

The Chair opened the meeting at 12:30pm 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 23 June 2020 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **20/CEN/147** |
|  | Title: | CIBMTR Registries |
|  | Principal Investigator: | Dr Andrew Butler |
|  | Sponsor: | National Marrow Donor Program |
|  | Clock Start Date: | 23 June 2020 |

Dr Andrew Butler was not 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 ethical issues

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

1. The Committee noted the CIBMTR already had approval under an old submission number (NTX/11/EXP/139) that was still active, submitted by researchers with ADHB. The Committee queried why a new application was submitted instead of an amendment and whether the Researcher was in contact with the Auckland researchers. The Committee queried whether there was a coordinated ‘national registry’ in New Zealand or whether separate DHBs submit to different registries through different processes. The Committee strongly recommends there be one application to encompass all of New Zealand, with DHBs opting in or not as localities.
2. The Committee noted the application was unclear and requested an overview of the ‘registry structure’ in New Zealand. The Committee requested information explaining what registries are involved (e.g. the application references an Australasian registry as well as a New Zealand one) and the difference between them.
3. The Committee queried why a submission was being made now as the registry appears to have been active since the 1970s. The Committee queried whether participants had been providing consent up until now.
4. The Committee noted the Participant Information Sheet was relatively brief and did not contain adequate information in order to obtain full consent from participants. The Committee requested additional information to explain the registry structure so participants are aware of what they will be consenting to.
5. The Committee requested the inclusion of a comprehensive explanation of what will happen to participants’ data on the registry (e.g. who has access to it, any potential future uses, linkages, whether this would be a public or commercial database, if there are limitations, safeguards and security, would the data be identified or anonymised / aggregated etc).
6. The Committee queried what happens if a participant changes their mind and decides to withdraw or if a participant who turns 16 decides they do not wish to continue. The Committee requested information explaining what happens to their data if they withdraw along with any caveats (e.g. if this is not possible if it has already been linked).
7. The Committee noted the application intended to recruit participants under 16 years old. The Committee advised this would require parental consent and an assent form for the children. The Committee recommended adapting the [HDEC assent template.](https://ethics.health.govt.nz/system/files/documents/pages/main-assent-7-11-years-clinical-trial.doc)
8. 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)
9. The Committee requested the Researcher adapt the [PIS template available on the HDEC website](https://ethics.health.govt.nz/system/files/documents/pages/participant_information_sheet_consent_form_template_july_2020.doc) to incorporate any missing information (e.g. advocacy contact details).
10. The Committee noted the tone of the information sheet seems to imply it is expected to sign on rather than an invitation to participate. The Committee requested a revision to address this.

Decision

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

* In order to obtain informed consent from participants please update the participant information sheet and consent form with the information requested 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 note the application form can be duplicated, and the original answers edited when preparing the re-submission to save having to fill it out again from scratch. [Page 33 of the online forms user manual has instructions on how to do this.](https://ethics.health.govt.nz/system/files/documents/pages/online_forms_user_manual_1.1_0.pdf)

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| **2** | **Ethics ref:** | **20/CEN/146** |
|  | Title: | ReRAD:Re-Irradiation of Progressive or Recurrent DIPG |
|  | Principal Investigator: | Dr Karen Tsui |
|  | Sponsor: | Australia and New Zealand Children's Haematology/O |
|  | Clock Start Date: | 16 July 2020 |

Dr Karen Tsui 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 ethical issues

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

1. The Committee queried whether increased radiation to the brainstem could cause cognitive impairment. The Researcher stated this was a risk but the treatment of brain tumours involves a careful balancing of potential risk vs potential benefit.
2. The Committee noted an inconsistency in the assent forms. The 7-10-year-old sheet contains a statement under ‘What will happen to my information?’ advising that no one will know the information came from the child and the Starship doctor would only tell if someone harmed the child or they wanted to harm themselves. The Committee noted an equivalent statement was not on the 11-15-year-old sheet and requested one be added.
3. The Committee requested the inclusion of a Māori health contact in the 11-15-year-old assent sheet.
4. The Committee requested an overall proof-read of the sheet to correct any typos.
5. The Committee queried what the statement ‘on the other hand could ask for more days’ referred to. The Researcher agreed to clarify the statement.
6. The Committee requested the reference to a participant’s ‘local doctor’ be replaced with ‘GP’ (or GP added in brackets afterward).
7. The Committee requested the phrase ‘figure out’ on page 7 be replaced by ‘find out’ or ‘discover’.
8. The Committee advised that advocacy services are separate to the HDC and similarly the sheet does not include information on the right to complain to the HDC. The Committee requested the Researcher adapt the [PIS template available on the HDEC website](https://ethics.health.govt.nz/system/files/documents/pages/participant_information_sheet_consent_form_template_july_2020.doc) to incorporate any missing information (e.g. advocacy contact details).
9. The Committee noted the statement on page 11 that all research involving humans is reviewed by HDEC is incorrect and requested a revision to simply state this study received HDEC approval.
10. The Committee noted the reconsent PIS does not contain the full information in the main PIS. The Committee requested the insertion of a statement advising that the full PIS is available to them if they wish to read it.
11. The Committee noted the final bullet point under in the section describing the study purpose is potentially insensitive (“How long are you able to live with recurrent DIPG?”). The Committee requested a revision to make this sentence less blunt. The Researcher stated they believed it was there to emphasise that the treatment is not a cure but agreed it could be toned down.
12. The Committee noted a statement regarding unborn children and harm from radiation to the brain of the participant. The Committee queried if the sheet is implying that participation in the study could affect the development of a future foetus. The Researcher stated they will consult a radiation oncologist and update the sheet if necessary. The Researcher stated as the study is Canadian this could be a legal requirement in Canada.
13. The Committee requested the inclusion of the cultural statement in all information sheets.
14. The Committee advised that for future applications it is helpful to provide any relevant statistics for Māori when answering question P.4.1 (how the study may benefit Māori) in the application form.

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 Dr Cordelia Thomas and Dr Jill Wilkinson

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| **3** | **Ethics ref:** | **20/CEN/148** |
|  | Title: | AtTend |
|  | Principal Investigator: | Dr Kathryn Chrystal |
|  | Sponsor: | NHMRC |
|  | Clock Start Date: | 16 July 2020 |

Dr Kathryn Chrystal 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 ethical issues

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

1. 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)
2. The Committee noted the coordinating investigator’s CV was dated September 2017 and requested an updated version.
3. The Committee noted the participant numbers on page 3 seemed to indicate there were 550 participants overseas and an additional 80 in Australia-New Zealand. The Committee requested a revision to make the total number of participants clear.
4. The Committee noted page 4 stated treatment would be offered to the participant until it no longer controlled their cancer. The Committee queried if the study would offer indefinite treatment. The Researcher stated they would be offered treatment until the cancer progresses or the side effects are too bad. The Committee queried if a participant responded indefinitely would they continue to receive the treatment indefinitely. The Researcher confirmed they would but this would have a small chance of occurring.
5. The Committee suggested an example of traditional herbal medicines when these are discussed on page 5 (e.g. St John’s Wort).
6. The Committee noted a typo in the first bullet point and surplus empty bullet point on page 7.
7. The Committee requested the data destruction information on page 10 be revised to simply state it will be securely destroyed.
8. The Committee noted the contact email addresses (e.g. for advocacy) are outdated and requested these be updated with the latest which can be found on the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/participant_information_sheet_consent_form_template_july_2020.doc)
9. The Committee requested the consent form use, or have equivalent meaning for the clauses listed on the HDEC template (e.g. around data use, add a clause that participants understand their responsibilities, an option for a copy of the study results, a clause about sending information overseas etc).
10. The Committee requested the PIS use the commercial ACC statement available on the HDEC PIS template. The Researcher stated it was not a commercial study as it was a collaborative research group and although Roche were supplying the drug this was an investigator-initiated trial. The Committee stated they would need evidence of this as the application implied Roche would have the power to place restrictions on publication. The Researcher agreed to provide clarification. The Committee advised that if the trial is to be conducted for the benefit of the manufacturer then ACC-equivalent commercial insurance would be required.
11. The Committee noted the PIS switches between stating ‘you’ and ‘participant’ and requested a revision to simply use ‘you’.
12. The Committee noted the statement that all research involving humans is reviewed by HDEC is incorrect and requested a revision to simply state ethical aspects this study received HDEC approval.
13. The Committee queried whether the only options available for participants are sterility or abstinence and if no birth control is permitted. The Researcher agreed to provide clarification.

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 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 an updated CV for the Coordinating Investigator.

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Sandy Gill and Ms Julie Jones.

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| **4** | **Ethics ref:** | **20/CEN/149** |
|  | Title: | BIOPRO Study |
|  | Principal Investigator: | Doctor Meghan Hill |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 July 2020 |

Dr Meghan Hill 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 ethical issues

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

1. The Committee queried whether the intention of the research is to obtain medical information and link it to the sample. The Researcher confirmed it is. The Committee queried how recruitment would work. The Researcher stated they would review patients on the delivery unit and they or a research specialist hired for the study (e.g. a research midwife) could approach eligible patients. The Committee queried under what authority the Researcher would review medical information. The Researcher stated in the United States they have been getting a waiver of consent and were unsure of the legal framework here. The Committee stated in New Zealand it is usually not permissible for someone not on a patient’s clinical team to review their records without consent. The Committee advised it would be better for the information to come from a patient’s clinical team as patient autonomy is paramount. The Committee suggested the LMC can speak with eligible patients and if they express interest then the Researcher can approach them to consent them to the study.
2. The Committee expressed concern around whether patients would have sufficient time to read the information sheet and go through the consent process. The Committee recommended the Researcher consider how to get the PIS to participants in advance (e.g. sent by the midwife or clinical team before their appointment).
3. The Committee advised that a tissue bank application is not necessary and instead participants can sign a consent for Future Unspecified Use (FUR). The Committee recommended adapting the [FUR template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/fur_piscf_template_0.doc)
4. The Committee noted page 6 of the PIS references questionnaires and queried which will be used.
5. The Committee recommended the Researcher adapt the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/participant_information_sheet_consent_form_template_july_2020.doc)
6. The Committee requested the Researcher include the new ACC statement available from the template on the HDEC website

“If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.  
  
If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”

1. The Committee requested the inclusion of a cultural tissue statement to the PIS. The Committee recommended the following statement:

“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate.

There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”

1. The Committee advised that in New Zealand participants have the right to withdraw consent for the use of their sample for FUR.
2. The Committee recommended the Researcher consider how to manage the risk of stigmatisation in the re-submission.

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 update the study protocol and revise the recruitment process, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

Please note the application form can be duplicated, and the original answers edited when preparing the re-submission to save having to fill it out again from scratch. [Page 33 of the online forms user manual has instructions on how to do this.](https://ethics.health.govt.nz/system/files/documents/pages/online_forms_user_manual_1.1_0.pdf)

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| **5** | **Ethics ref:** | **20/CEN/150** |
|  | Title: | A Phase 2, multicenter, single-arm, open-label study to evaluate the efficacy and safety of AK104 in subjects with recurrent or metastatic cervical cancer |
|  | Principal Investigator: | Dr Michelle Wilson |
|  | Sponsor: | Akesobio Australia Pty Ltd |
|  | Clock Start Date: | 16 July 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 ethical issues

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

1. The Committee noted the statement that all research involving humans is reviewed by HDEC is incorrect and requested a revision to simply state this study received HDEC approval.
2. The Committee queried whether the information in the PIS about shaving chest hair was relevant. The Researcher agreed to remove it.
3. The Committee requested removal of the sentence stating race and ethnicity are considered sensitive under data protection law as the Privacy Act 1993 does not state this.
4. The Committee requested the inclusion of the full HDEC cultural tissue statement:

“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate.

There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”

1. The Committee noted information on the use of data is repeated in the information sheet twice. The Committee requested the surplus information be removed.
2. The Committee requested the statement on page 3 describing the study doctor deciding the study is right for participants be reworded to prioritise patient autonomy. The Committee suggested revising it to “If the study doctor thinks you are suitable, and you decide to participate…” or something similar.
3. The Committee requested the information describing the time required to remain after treatment be clarified further. Is there a minimum wait period for the first treatment where it states patients must remain for up to three hours? Also correct the statement that patients remain for ‘up to a minimum of 1 hour’ for subsequent infusions.
4. The Committee noted the requirements for the 24-hour urine sample could be clearer and requested the reason for a 24-hour urine sample collection be included.
5. The Committee requested the statement about cancer worsening be revised to state ‘appears’ to worsen (Post-progression PISCF Point 2.)
6. The Committee requested the HDEC email be updated to [HDECS@health.govt.nz](mailto:HDECS@health.govt.nz).
7. The Committee noted a minor typo on page 9 (side effects talks of ‘1 of 10’ when it should read ‘1 out of 10’).
8. The Committee requested the inclusion of a lay title.
9. The Committee requested a statement advising participants of their right to access and correct information held about themselves.
10. The Committee requested the consent form clause that participants ‘understand they can’ receive a copy of results be simplified to ask if they wish to with a ‘yes / no’ tick box.

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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| **6** | **Ethics ref:** | **20/CEN/151** |
|  | Title: | The REEF-D study to investigate the Efficacy, Safety and Pharmacokinetics of JNJ-73763989 for the treatment of Hepatitis B and Hepatitis D co-infection |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Janssen-Cilag Pty Ltd |
|  | Clock Start Date: | 16 July 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 ethical issues

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

1. The Committee queried whether the study would make use of questionnaires. The Researcher stated it would not and agreed to remove the reference to questionnaires on page 7.
2. The Committee requested the side effects on page 13 use whole numbers instead of or in addition to percentages.
3. The Committee asked that the percentages under “side effect of drugs” would be changed to **“**how many participants out of 100” (e.g. 10 patients out of 100 rather than 10%) and to remove the individual percentages after each of the side effects listed in the tables. The Researcher stated they do for this for many cancer studies and confirmed they would for this study also.
4. The Committee noted the statement that all research involving humans is reviewed by HDEC is incorrect and requested a revision to simply state that ethical aspects of the study were approved by HDEC.
5. The Committee requested the statement that HDEC checks the project is ‘running smoothly’ be revised as this is technically incorrect.

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/152** |
|  | Title: | Isatuximab in combination with lenalidomide and dexamethasone in high-risk smouldering multiple myeloma (ITHACA) |
|  | Principal Investigator: | Dr Andrew Butler |
|  | Sponsor: | Sanofi Australia |
|  | Clock Start Date: | 16 July 2020 |

Dr Andrew Butler was not 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 ethical issues

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

1. The Committee noted the study involved quality of life questionnaires and there was no safety plan for managing participants experiencing distress. The Committee requested the Researcher update the protocol with a safety plan on how to manage any participants displaying signs of distress or suicidal ideation.
2. The Committee noted it was unclear what standard of care treatment would be and what the study treatment is. The Committee requested a clarification to clearly differentiate the two.
3. The Committee queried whether the bone marrow aspiration is necessary and what would happen in the scenario of a participant not wanting another aspiration after the first one. The Committee queried whether this participant would be eligible to continue or whether they would be forced to withdraw.
4. The Committee queried whether there is a risk value for cytokine release syndrome and tumour lysis syndrome or whether this is a potential risk at this stage. The Committee requested clarification to the information sheet if necessary.
5. The Committee advised that in New Zealand verbal withdrawal is permitted and the participant is not required to fill out a form or sign anything. The researcher may fill out the form on their behalf.

The Committee requested the following changes to the participant information sheet and consent form:

1. Please make it clear that New Zealand is only participating in part two of the study.
2. The Committee requested a simplification of the dosing schedule. The Committee requested an explanation that part 1 has occurred overseas and information about it removed.
3. The Committee requested the commercial insurance statement available on the [HDEC PIS template](https://ethics.health.govt.nz/system/files/documents/pages/participant_information_sheet_consent_form_template_july_2020.doc) be inserted into all information sheets.
4. The Committee requested that on page 11 the percentages for side effects are replaced with the number of patients out of 100 (e.g. 10 patients out of 100 rather than 10%) and remove the individual percentages after each side effect in the tables.

1. The Committee requested the insertion of a statement on page 18 advising that the study cannot be halted for commercial reasons.
2. The Committee requested the cultural statement on the FUR PIS be included in all other sheets.
3. The Committee requested a statement advising that health data will be sent to Paris.
4. The Committee requested a clause on the pregnant partner consent form for them to agree to their health information going overseas.

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 provide clarity around the risks of cytokine release syndrome and tumour lysis syndrome.
* Please confirm whether participants may refuse bone marrow aspiration or is this is mandatory.
* Please provide a safety plan addressing the concerns raised by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*

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

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| **8** | **Ethics ref:** | **20/CEN/153** |
|  | Title: | Seroepidemiological investigation for coronavirus (COVID-19)infection testing DSL's COVID-19 IVD device |
|  | Principal Investigator: | A/Prof Ashton Partridge |
|  | Sponsor: | Manufacturing Systems Limited |
|  | Clock Start Date: | 16 July 2020 |

A/Prof Ashton Partridge 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 ethical issues

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

1. The Committee queried why participants would not be informed of their antibody results. The Researcher stated the data is inconclusive and they would not want any participants to misinterpret a positive result and believe they have immunity as it is not known whether having antibodies protects against infection or not. The Committee agreed this was sensible and requested a statement advising that neither test is 100% certain and is not a completely reliable indicator of having had the infection at some stage in the past.
2. 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)
3. The Committee requested the research use the [ethnicity categories from the New Zealand census.](https://www.stats.govt.nz/topics/ethnicity)
4. The Committee expressed concern at the potential for coercion or perceived coercion and suggested allowing potential participants to contact the researchers separately and privately. Similarly, it is advised to conduct the blood draw off-site to protect anonymity and confidentiality.
5. The Committee requested ‘trained medical professional’ be replaced with ‘phlebotomist’.
6. The Committee requested the addition of a header/footer to the donor data collection forms.
7. The Committee advised that in New Zealand verbal withdrawal is permitted and the participant is not required to fill out a form or sign anything.
8. The Committee requested the Researcher supply any advertisement posters as these require approval before they may be used.

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 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 any advertisements or recruitment posters. *(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 Dr Cordelia Thomas and Dr Peter Gallagher.

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| **9** | **Ethics ref:** | **20/CEN/154** |
|  | Title: | AIR Algorithm Study |
|  | Principal Investigator: | Professor Richard Beasley |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 17 July 2020 |

Research staff from the Medical Research Institute of New Zealand were 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.

Ms Julie Jones declared a potential conflict of interest, and the Committee agreed she would not participate in the discussion or contribute to the decision.

Summary of ethical issues

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

1. The Committee complimented the researcher on a comprehensive and easy to follow PIS.
2. The Committee advised that reimbursement is not subject to tax and requested this be corrected in the PIS.
3. The Committee suggested the inclusion of a table of visits would be helpful.
4. The Committee requested the final two bullet points under ‘What will my participation involve?’ be clarified as they appear to contradict each other.

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/156** |
|  | Title: | Rights of children in health data |
|  | Principal Investigator: | Dr Yvonne Anderson |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 16 July 2020 |

Dr Yvonne Anderson and Ms Cervantée Wild 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 ethical issues

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

1. The Committee noted the answer to P.4.1. and suggested another possible benefit to the research may be that Māori may feel more empowered when giving their views about what happens to their data.
2. The Committee noted the answer for P.4.2. and advised that information is a taonga and suggested this would be useful to include in future applications.
3. The Committee requested the Researchers update the protocol to include a safety plan on how to manage a participant displaying signs of aggression, distress etc.
4. 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)
5. The Committee requested the Researcher add caveats to the PIS advising that confidentiality at the focus group cannot be guaranteed as other participants will be there and that as data will be aggregated together a participant will not be able to withdraw their contribution.
6. The Committee noted one information sheet and assent form for children 5 – 15 is not suitable as there are large cognitive differences between a 5-year-old and a 15-year-old. The Committee requested the researcher split the assent form into one for 5 – 11-year olds and one for 12 – 15-year olds.
7. The Committee queried if the proposed koha would be for each individual or the family as a whole. The Researcher stated it was budgeted per participant. The Committee queried if a $20 petrol voucher is appropriate for a five-year old. The Researcher stated they would offer something suitable for children such as a bag of fruit.
8. The Committee requested a general revision to the PIS to simplify it.
9. The Committee advised the PIS requires a data management section. The Committee noted the protocol contains details on who will have access to data and what it will be used for and suggested this be transferred to the PIS.

Decision

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

* Please provide a safety plan addressing the concerns raised by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
* 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 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 the full Committee on the portal as an online review.

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| **11** | **Ethics ref:** | **20/CEN/157** |
|  | Title: | Effectiveness of Multistrain Probiotics as an adjuvant treatment in Major depressive disorder |
|  | Principal Investigator: | Dr. Venkat Naga |
|  | Sponsor: | Oakley Mental Health Research Foundation |
|  | Clock Start Date: | 16 July 2020 |

Dr. Venkat Naga 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 ethical issues

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

1. The Committee requested the Researcher get in contact with their local research office for assistance with the resubmission.
2. The Committee requested the Researcher adapt the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/participant_information_sheet_consent_form_template_july_2020.doc) The Committee advised that the information sheet and consent form can be part of the same document.
3. The Committee requested the inclusion of document headers and footers in the questionnaires.
4. The Committee requested the Researcher supply a copy of any advertisements or pamphlets intended to be used.
5. The Committee advised that participants are free to withdraw at any point of the study if they wish to and to withdraw their data up until the point it has been used for analysis/publication at which point it is no longer feasible.
6. The Committee advised that health information is required to be kept for a minimum of 10 years. The information sheet currently says it will be kept for 6 years which is insufficient.
7. The Committee advised against stating ‘no risk’ and requested ‘minimal risk’ be used instead.
8. The Committee queried whether information on probiotic storage would or should be provided to participants. A copy should be provided to the committee if it is (e.g. whether to keep at room temperature or refrigerated).
9. The Committee requested the inclusion of a Māori health contact number in the PIS.
10. The Committee requested the inclusion of advocacy contact details (see the HDEC template).
11. The Committee requested an update to the sheet mentioning a blood test upon completion of the study to clarify that it will happen after 8 weeks of taking the probiotic.
12. The Committee requested the insertion of the following cultural tissue statement:

“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate.

There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”

1. The Committee stated it was impressed by the extensive Māori consultation undertaken. The Committee advised the only thing missing was the inclusion of mental health statistics in Māori when answering P.4.1. in the application form which would have been useful.
2. The Committee requested a revision to the protocol and PIS to ensure participants do not buy or use their own probiotics over the counter while on the trial as this will bias the study results.

Decision

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

* In order to obtain informed consent from participants please update the participant information sheet and consent form with the information requested 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 note the application form can be duplicated, and the original answers edited when preparing the re-submission to save having to fill it out again from scratch. [Page 33 of the online forms user manual has instructions on how to do this.](https://ethics.health.govt.nz/system/files/documents/pages/online_forms_user_manual_1.1_0.pdf)

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| **12** | **Ethics ref:** | **20/CEN/158** |
|  | Title: | The impact of deprivation in palliative care |
|  | Principal Investigator: | Mrs Jackie Robinson |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 16 July 2020 |

Mrs Jackie Robinson 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 ethical issues

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

1. The Committee noted the title used for the hui sheet (e.g. bold font in the centre) was better than the main PIS and suggested it be coped to the main sheet.
2. The Committee requested the addition of a footer containing the title, page numbers etc to the main PIS.
3. The Committee queried the koha offered as the application mentioned $100 and the PIS mentions a supermarket voucher. The Researcher confirmed it would be a supermarket voucher worth $100.
4. The Committee requested the addition of information in the PIS advising that participants have the right to access and correct their information and that auditors may also access it.
5. The Committee requested the addition of a Māori health contact number for the interview and hui sheets.
6. The Committee queried what koha would be available for attending the hui. The Researcher stated it would depend on the marae and would they revise this at a later date.
7. The Committee requested a revision to the information about withdrawal to simply state that withdrawal is possible up until the point data has been used.
8. The Committee queried a statement that the focus group could take place where the individual wants and requested a revision to specify what options there may be.
9. The Committee requested the Researcher include the [new ACC statement available from the HDEC template](https://ethics.health.govt.nz/system/files/documents/pages/participant_information_sheet_consent_form_template_july_2020.doc) into all information sheets:

“If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.  
  
If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”

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 Helen Davidson & Patries Herst.

## 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:** | 25 August 2020, 12:00 PM |
| **Meeting venue:** | Zoom Meeting ID: 367 426 700 , https://mohnz.zoom.us/j/367426700, 6011 |

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 5:45pm.