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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 26 July 2022 |
| **Zoom details:** | <https://mohnz.zoom.us/j/96507589841> |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12:00pm-12:30pm | 2022 FULL 12841 | COG APAL2020SC: Paediatric Acute Leukaemia Screening Trial - Developing New Therapies for Relapsed Leukaemia | Dr Andrew Wood | Ms Julie Jones & Ms Sandy Gill |
| 12:30pm-1:00pm |  | Break 30 minutes |  |  |
| 1:00pm-1:30pm | 2022 FULL 13115 | Examining Food Insecurity in a Regional New Zealand Emergency Department | Dr Stephanie Richling | Mx Albany Lucas & Ms Sandy Gill |
| 1:30pm-1:45pm |  | Break 15 minutes |  |  |
| 1:45pm-2:15pm | 2022 FULL 13155 | The WRAP Registry | Dr Rahul Bera | Ms Jessie Lenagh- Glue & Dr Patries Herst |
| 2:15pm-2:45pm | 2022 FULL 12982 | EMP-01-101: A Study to Assess EMP-01 in Healthy Participants. | Dr. Mark Marshall | Dr Patries Herst & Ms Helen Walker |
| 2:45pm-3:15pm | 2022 FULL 12790 | CSL300\_3001: IMAGINE (Interleukin 6 Blockade Modifying Antibody-Mediated Graft INjury and eGFR Decline) | Dr Ian Dittmer | Ms Julie Jones &  Dr Cordelia  Thomas |
| 3:15pm-3:25pm |  | Break 10 minutes |  |  |
| 3:25pm-3:55pm | 2022 FULL 11727 | NHFO2: ED | Dr Louis Kirton | Dr Patries Herst  & Dr Cordelia  Thomas |
| 3:55pm-4:25pm | 2022 FULL 12636 | Clinical trial of BI 425809 effect on cognition and functional capacity in schizophrenia. | Associate  Professor  Sylvester Wayne  Miles | Ms Julie Jones &  Ms Jessie Lenagh-  Glue |
| 4:25pm-4:55pm | 2022 FULL 13023 | VIR-CHDV-V201: A Study to Evaluate VIR-2218 and VIR-3434 in Participants with Chronic Hepatitis D Virus Infection | Professor Ed Gane | Mx Albany Lucas  & Ms Jessie  Lenagh-Glue |

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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) | 22/05/2020 | 22/05/2023 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Mrs Patricia Mitchell | Non-lay (health/disability service provision) | 10/07/2020 | 22/05/2023 | Apologies |
| Ms Julie Jones | Non-lay (intervention studies) | 22/05/2020 | 22/05/2022 | Present |
| Mx Albany Lucas | Non-lay (observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (ethical/moral reasoning) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that apologies had been received from Mrs Patricia Mitchell.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 28 June 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 12841** |
|  | Title: | COG APAL2020SC: Paediatric Acute Leukaemia Screening Trial - Developing New Therapies for Relapsed Leukaemia |
|  | Principal Investigator: | Dr Andrew Wood |
|  | Sponsor: | Children’s Oncology Group |
|  | Clock Start Date: | 14 July 2022 |

Dr Sarah Hunter and Dr Mark Winstanley was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that testing would be for the purpose of identifying targets for therapies not currently available in New Zealand. This would allow for the clinicians to forward the participants to new trials for drugs that would potentially be brought to New Zealand.
2. The Committee noted that there were no statistics for Māori incidence in the submission, this should be included in the future.
3. The Committee clarified the New Consent form and it’s use.

Summary of outstanding ethical issues

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

1. The Committee requested that there be some rewording in the Paediatric Assent documents under the section ‘Why is this study being done”, around the screening and availability of alternative therapeutic treatments. As it is currently written there is some potential for heartbreak if parents or participants are led to believe a better treatment has been identified for them, but may not be available to them.
2. Please remove mention of notifiable diseases in the Data Management Plan as it is not relevant to the study.

The Committee requested the following changes to the Main Participant Information Sheets and Consent Forms (PIS/CF):

1. Please remove the 'as required by US Law' text related to the clintrials.gov as this is not relevant to the New Zealand study. This text was seen in multiple documents.
2. Please include a section on withdrawal. Withdrawal is only introduced in the consent but not covered in the body of the information sheet. Including what will happen to data if a participant withdraws.
3. Please provide clarity on the access to identifiable and non-identifiable information. The Committee noted that this appears to be combined but should be split into the two different types of data, with access and governance explained clearly.
4. Please amend the wording ‘you will not be penalized’ as this is aggressive and threatening. Please consider changing this to: “It is your choice …and if you choose not to, that is completely fine”.
5. Please amend page 6 where it states the “age of majority” is 16. This is incorrect and the Age of Majority Act states it is 20 years of age. The Care of Children Act allows young people to make decisions at 16 years of age. Please remove the section of the statement in brackets to correct this.

The Committee requested the following changes to the Paediatric Participant Information Sheets and Consent/Assent Forms (PIS/CF):

1. Please include the risk of bone marrow collection.

The Committee requested the following changes to the Future Unspecified Research Participant Information Sheets and Consent Forms (PIS/CF):

1. Please review the sentence "They may wish that they had never found out." to clarify meaning.

The Committee requested the following changes to the Reconsent Participant Information Sheets and Consent Forms (PIS/CF):

1. Please amend the sentence "If your cancer went away during treatment but comes back in the future, you may need to have some tissue taken (tumour tissue, bone marrow or blood). If this happens, we would like to send another sample of this tissue to the storage bank. We will only do this if your parent/guardian agreed to this when they gave their consent and if you agree now on this form. You can say no if you do not want us to send any further samples." Currently this is not necessary as the participant is able to make this decision and the parent or guardian phrasing is irrelevant.
2. Please remove the parent/guardian from the reconsent as the participant can consent for themselves once they are 16 years old.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| **2** | **Ethics ref:** | **2022 FULL 13115** |
|  | Title: | Examining Food Insecurity in a Regional New Zealand Emergency Department |
|  | Principal Investigator: | Dr Stephanie Richling |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 July 2022 |

Dr Stephanie Richling was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the support that would be provided to the participants, that it would not be conditional support, and that the list of contacts was up to date and accurate.
2. The Committee clarified that the study was to screen and forward to services for follow up.
3. The Committee clarified the cultural competency of the social worker that would be required as part of the study.
4. The Committee queried the choice for the single survey per household given the multi-generational household likelihood in the study population. The researcher clarified this is due to the survey being targeted to the ED presentation not the household.
5. The Committee clarified that there would be cultural consultation.
6. The Committee queried the questions around the health issues or injury that the researcher explained was due to secondary aims of the study to attempt to link the conditions they are presenting to ED with to incidence of food insecurity.

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 the term “Food insecurity” may not be understood by the participants. This, including where it occurs in the title, should be changed to something more lay friendly. *National Ethical Standards* para *7.16*
2. The Committee queried if the questions specific to food insecurity in the questionnaires would focus on budgeting to buy food or whether there was no/limited access to healthy food. The Committee noted that the questions seemed unrelated to the possibility of food insecurity and more around who was preparing food etc. The Committee queried if these questions would have any sensitivity towards the study aims. *National Ethical Standards* para *9.7*
3. The Committee noted that the research could cause stigmatisation towards Māori and Pasifika people. The Committee suggests consulting with Māori and Pasifika, or Māori/Pasifika supporting organisations, and re-construct this study to prevent potential stigmatisation. *National Ethical Standards* para *3.1 & 3.3*
4. The Committee noted that there would be significant Whakamā inherent in this topic and that this needs to be addressed in the submission. The Committee suggested that the research team consider this cultural aspect in the development of the study. *National Ethical Standards* para *3.3*
5. The Committee noted that the questionnaire requests information about age, gender, and ethnicity be provided even if potential participants refuse to participate. This should be removed.
6. The Committee noted inconsistencies in the application as it states “participants must be over 18” prior to then stating, “if participants are under 18 years parents or guardians can complete the questionnaire on behalf of the child”. This should be amended to be consistent and acknowledge that the child would still be a participant in this case. *National Ethical Standards* para *7.16 & 7.18*
7. The Committee noted that if an adult is giving consent on behalf of a minor there would still need to be assent given by the child as they would be a participant. *National Ethical Standards* para *6.25 & 7.16-7.18*
8. The Committee noted that there was no child assent form, this needs to be provided and should be a simplified version of the adult consent. *National Ethical Standards* para *6.25- 6.27*
9. The Committee noted that in the event an adult could not consent, a caregiver cannot legally consent for them. An EPOA or Welfare Guardian may be able to do so otherwise Right 7(4) of the Code of Rights would apply and the research would have to be in the best interests of the participant. Legal advice is suggested to re-write this statement, as currently it would require separate consideration by HDEC, to review if the participation was in the best interests of the participant who was unable to consent. *National Ethical Standards* para 7.18 & *7.20- 7.21*
10. The Committee noted that the treating clinician will not be consulted prior to approach of the participants and that this may be impractical as the researcher would then need to clinically assess the participant before the approach for participation. This needs to be a clearly defined process, wherein the researcher is not making a decision to approach for research purposes when entering a room in a clinical capacity. This needs to be specified more clearly in the protocol and other study documentation to ensure the interests of the participants are being met and protected. *National Ethical Standards* para *9.7-9.8*
11. The Committee noted that Right 7 (6) of the Code of Rights requires written consent to research participation. This could be an electronic signature, but the law requires written informed consent for research. *National Ethical Standards* para *7.15*
12. The Committee queried what the process would be if there was abuse or neglect identified during the completion of the questionnaire. This process should be outlined in the Participant Information Sheet and protocol. *National Ethical Standards* para *9.8, 8.3, 8.4 & 7.15*
13. The Committee noted that approach to potential participants should be done by someone not currently treating the person to prevent feelings of coercion. *National Ethical Standards* para *7.18*
14. The verbal consent currently says that the survey will be anonymous, but the survey asks for the participants address which would mean that the survey would not be anonymous. The language in the verbal consent is not clear in parts. Participants are not told that the social worker will be collecting information about them and what type of information is collected. Please ensure that consent language is correct.
15. The Committee suggests that the study be broken up into 2 parts. An initial approach with the validated food insecurity questions on an anonymised survey, which could utilise implied consent. Within this survey, people could be asked if they would like in the ED to participate in part 2 and could provide contact details ask whether the person is willing to the research team. Part 2 would require full consent to collect personal and health information and can be conducted at a later time. A 2-part study would reduce the potential burden on the Emergency Department.

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

1. Please amend to be less brief and include more granular detail as to what will be required of participants and how the participants will be protected. *National Ethical Standards* para *7.15*
2. Please refer to the [HDEC PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) to help in responding to the need for further information. *National Ethical Standards* para *7.15*

**Decision**

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

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| **3** | **Ethics ref:** | **2022 FULL 13155** |
|  | Title: | The WRAP Registry |
|  | Principal Investigator: | Dr Rahul Bera |
|  | Sponsor: | Merit Medical Systems Inc. |
|  | Clock Start Date: | 14 July 2022 |

Dr Rahul Bera and Mr Hector Gonzales was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that only coded information would be sent to the sponsor.
2. The Researcher clarified that there would be no additional pressure for stents to be used in clinical care due to the research.
3. The Committee requested that the researcher in future submissions to only supply necessary documentation.

Summary of outstanding ethical issues

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

1. The Committee noted that there were no New Zealand relevant data as to recruitment and that this should be included in the Protocol, Data Management Plan and Participant Information Sheet.
2. The Committee requested that a koha, such as a letter of thanks, be provided to participants.
3. The Committee noted that there was mention of questionnaires in several documents. These references should be removed if these do not exist. Should they exist, please submit to HDEC for review.
4. The Committee requested the following changes to the Data Management Plan:
   1. Please refer to the [HDEC Data Management Template](https://ethics.health.govt.nz/assets/HDEC-data-only-management-template-Oct-2021.docx) to better clarify the details of data management for this study.
   2. Please address the significance of health data as taonga.

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

1. Please include more detail in the section “What will happen to my information”, specifically around the difference between the different forms of identification attached to the data, where it will be stored, who will have access and for what purpose. For more specific detail please see the [HDEC PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
2. Please specify what data will be sent to the sponsor and the identifiers if any that would be attached.
3. Please remove references to non-New Zealand pertaining information.
4. Please include Whānau in the list of people who may be consulted when considering participation.
5. Please amend ‘subject’ to ‘participant’ in all cases.
6. Please make consistent the term used to refer to the study doctor or research doctor in the incidental findings.
7. Please remove mention of social security numbers.
8. Please include Māori cultural considerations. Please see the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for this.
9. Please note that there needs to be a plan in place, detailed in the PIS as to what would be done in the event of identification of significant mental distress in the event a questionnaire asks questions surrounding the topic of depression or anxiety. Any risk response needs to be included.
10. Please note that reference to “Māori health support” should be amended to “Māori cultural support”.
11. Please note that New Zealand law requires the participants to have the right to access correct and withdraw their information. This is not a limited right and should be specified as such.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Patries Herst and Ms Jessie Lenagh-Glue.

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| **4** | **Ethics ref:** | **2022 FULL 12982** |
|  | Title: | EMP-01-101: A Study to Assess EMP-01 in Healthy Participants |
|  | Principal Investigator: | Dr Mark Marshall |
|  | Sponsor: | Novotech Limited |
|  | Clock Start Date: | 14 July 2022 |

Miss Courtney Rowse, Dr. Marshall (PI), Suresh Muthukamaraswamy and Holly Thirlwall was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the data platforms in use would be 3rd party vendor platforms on tablets for the study that would be provided to participants for questionnaires and participant journey preparedness. This was for ease of participant access and all data would be coded only.
2. The Committee noted that there were safety and medical measures in place to monitor and deal with any “bad trips”. This is documented in the protocol. There were also steps in the creation of the drug to aid in the prevention of this.

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

1. Please include ‘anxiety’ and ‘teeth grinding/jaw clenching’ in the list of risks. Risks in the investigator brochure and Protocol should be the same as the PIS and vice versa.
2. Please list “Acute Hepatitis C and B” as notifiable diseases as per the current Schedules.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the 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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| **5** | **Ethics ref:** | **2022 FULL 12790** |
|  | Title: | CSL300\_3001: IMAGINE (Interleukin 6 Blockade Modifying Antibody-Mediated Graft INjury and eGFR Decline) |
|  | Principal Investigator: | Dr Ian Dittmer |
|  | Sponsor: | Novotech Limited |
|  | Clock Start Date: | 14 July 2022 |

Dr Ian Dittmer and Andrew Pilmore were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that there is no current standard of care treatment for rejections and as such there would be no obvious detriment to those individuals receiving the placebo for 5 years. Should the trial prove to be very successful and statistically beneficial the study may be cut short to give those participants the study drug.
2. The Committee clarified that a non-clinician would be doing the initial contact to prevent coercion.

Summary of outstanding ethical issues

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

1. The Committee noted that the advertisement states that “there may be reimbursement for time and travel” but there is no reference for this in the PIS, please amend this to remove the term “time” as this has tax ramifications.
2. The Committee queried if there would be any issues with withdrawal after the study.
3. The Committee queried why the applicant stated there would be no benefit to participants. In this event it would not be ethical for a 5-year trial with no potential benefit to participants. Please amend this as a potential benefit across all relevant documents.

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

1. The Committee noted that the reference to ‘IRB’ should be clarified to be the internal review process.
2. The Committee noted that there should be softening of statements around withdrawal from the study, so participants do not to feel forced to remain in the study.
3. Please remove reference to a “dummy” drug. Reword this to refer to a non-active drug or similar.
4. Please review for repetition, blanks, and typos. Please note that the information about the device is repeated at least three times and this needs only to be stated once.
5. Please remove “Future research is important to advance science” as this reads as coercive.
6. Please remove reference to the legally accepted representative in the pregnant partner PIS (which is not subject to review at the time of initial HDEC review).
7. Please include statements around what is likely to happen after the study concludes with respect to the study drug, placebo participants and what would happen should the drug be successful or not.
8. Please state how many participants will be from New Zealand.
9. Please consider amending the 'what will my participation involve' section, potentially using a table to summarise this. The section is very long, is repetitive in parts and hard to read for participants. Please highlight the important parts from this section.
10. Please amend the notifiable disease statement by including what diseases will be notifiable and who would be notified.
11. Please consider reducing the amount of information in the home care section. The information could be provided much more concisely.
12. Please consider reducing the information about the PK Samples as this should be in the optional PIS. Recommend just mentioning how many participants will be in the PK sample group and that a separate consent will be provided.
13. Please remove the sample storage location of optional samples as this is in the optional PIS.
14. Please make it clear whether the 20% of participants who experience ‘infections’ have serious infections as the current wording implies this.
15. Please remove reference to spermicide as this is not available in New Zealand.
16. Please amend the reimbursement statement to state they “will” be reimbursed for travel.
17. Please ensure there is a clear section specifying what will happen to identifiable information. Please refer to the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for this.
18. Please include a statement for the karakia of samples as this is mentioned as being available in the submission document.
19. Please remove “as required by U.S. Law” page 20. US law is not applicable in New Zealand.
20. Please remove the repeats of the contraception for males clause and the auditing and records access clause in the consent form.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

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

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| **6** | **Ethics ref:** | **2022 FULL 11727** |
|  | Title: | NHFO2: ED |
|  | Principal Investigator: | Dr Louis Kirton |
|  | Sponsor: | Fisher and Paykel Healthcare Limited |
|  | Clock Start Date: | 14 July 2022 |

Dr Louis Kirton, Professor Richard Beasley, Dr Stacey Kung and Mrs Jenny Spark were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified there would not be enrolment of individuals unable to consent, even to the short form. This would be assessed upon screening.
2. The Committee clarified that it was intended that both forms of consenting both short and long would occur. Those deemed able to give full consent up front due to a non-critical condition would be fully consented up front. This was later concluded that
3. The Committee clarified that ineligibility based on the 10-minute wait period during consent was in fact an appropriate waiting period and response time to assess this.
4. The Committee clarified that in the event the person could not provide full consent after treatment this would result in removal of data from the trial. The only caveat to this would be if the safety of individuals was at risk and that data would be deidentified and reported as an adverse event and would be followed up via an appropriate avenue.
5. The Committee clarified that the statement concerning withdrawal of data that has been deidentified and distributed was in fact correct as there would be no way to re-identify data at that point.

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 suggested having 2 participant information sheets for each participant, a short consent prior to treatment and full consent post-treatment for continued use of data. This may be better in terms of ease of process in an emergency department setting.

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

1. Please refer to the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for a “What will happen of something goes wrong” set of statements.
2. Please amend the statement concerning the distribution of data worldwide.
3. Please consider removing the statement concerning the collection of ethnicities.
4. Please place a full stop after the statement concerning bloating and discomfort rather than a colon.
5. Please include a cultural statement involving the head being tapu.
6. Please clarify the role of the general practitioner (GP) in the study. Please consider including a statement noting that the GP will be informed of participation.

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

1. Please include headers, footers and numbering on the pages of this form.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

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

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| **7** | **Ethics ref:** | **2022 FULL 12636** |
|  | Title: | Clinical trial of BI 425809 effect on cognition and functional capacity in schizophrenia. |
|  | Principal Investigator: | Dr Deborah Campbell |
|  | Sponsor: | Boehringer Ingelheim Pty Limited |
|  | Clock Start Date: | 14 July 2022 |

Dr Deborah Campbell and Dr Wayne Miles were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that the advertising was quite unclear and overcrowded and should be redesigned so that it is easier to read.
2. The Committee clarified how the study doctor would identify those inclusion criteria which would then be used to screen the potential group subject to pre-screening via the “break glass” technique.
3. The Committee clarified that there would not be exclusion based on a compulsory treatment order.

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 clarification as to the screening process in a response to HDEC.
2. The Committee requested that correspondence be provided to HDEC from the researchers between the research team and the Privacy Commissioner as assurance as to the validity and legality of the screening processes to be employed in the study.

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

1. Please amend the statement “too much alcohol’ to be more specific as the amount of alcohol that is acceptable.
2. Please correct all reference to Northern A Ethics Committee to Central, under 'what if something goes wrong'. And ensure that this specifically notes that only the “ethical aspects of the study have been approved by Central Heath and Disability Ethics Committee”.
3. Please remove the section concerning contacting the privacy commission to exercise their rights regarding privacy.
4. Please detail the steps that will be taken and the review process for questionnaires in the event that suicidal ideation and depression are identified.
5. Please include the ability to have a chaperone and acknowledge that for some people, a physical exam can be distressing due to past events.
6. Please remove that it is ‘impossible’ to trace information back to people as this is not strictly correct.
7. Please remove duplications of the rights under data protection law.
8. Please fix the error on page 21 where there is a repetition of the word treatment.
9. Please ensure that there is a request for sharing of information between the study partner about the participant to the research team.

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

1. Please include the location of storage facilities.

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

1. Please include all information from the Main PIS as is relevant here. Please include all relevant information for the study partner in their PIS, and not refer to the other persons PIS.
2. Please note that the data section needs more information regarding identifiable and non-identifiable information. and who has access etc.
3. Please correct the reference to Northern A Ethics Committee to Central, under 'what if something goes wrong'. And ensure that this specifically notes that the “ethical aspects of the study have been approved by Central Ethics Committee”.
4. Please ensure that there is a request for sharing of information between the study partner about the participant to the research team.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by the full Committee.

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| **8** | **Ethics ref:** | **2022 FULL 13023** |
|  | Title: | VIR-CHDV-V201: A Study to Evaluate VIR-2218 and VIR-3434 in Participants with Chronic Hepatitis D Virus Infection |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | PPD Global Limited |
|  | Clock Start Date: | 14 July 2022 |

Courtney Rowse, Professor Ed Gane, Chin Kuh and Holly Thirlwall was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the use of an additional clause for the destruction of tissue.
2. The Committee clarified that even though there is no Māori incidence of Hepatitis D, Māori consultation was sought, and approval given. Pasifika consultation is underway.
3. The Committee clarified that there would be 5 cohorts and how they were assigned.

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

1. Please specify that PPD is not purely off-shore and that there is an onshore presence from the sponsor.
2. Please amend the last sentence of the first paragraph where HBV is referenced but HDV is meant.
3. Please expand upon the induction and maintenance period appointments to provide detail to the participants.
4. Please describe how assignment to cohorts will happen. This should be worded carefully to prevent some feeling of disappointment if participants do not progress.
5. Please include a statement noting that cultural consultation has occurred.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

## General business

1. The Chair reminded the Committee of the date and time of its next scheduled meeting:

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| --- | --- |
| **Meeting date:** | 23rd August 2022 |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting.

* Ms Jessie Lenagh-Glue

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**

A query as to the status of Hepatitis B and C as notifiable diseases was raised and will be carried to the next Chair’s meeting.

1. **Other business**
2. **Other business for information**
3. **Any other business**

The meeting closed at 5:30pm.