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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 January 2022 |
| **Zoom details:** | <https://mohnz.zoom.us/j/96507589841> |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12.00-12.30pm | 2021 FULL 11324 | “Symptoms and Side Effects” a Modified Delphi Study | Dr Ross Drake | Dr Peter Gallagher & Dr Cordelia Thomas |
| 12.30-1.00pm | 2021 EXP 11707 | T-TRAC Study - Time to recover after concussion study | Mrs Rebekah Miller | Ms Sandy Gill & Ms Julie Jones |
| 1:00pm - 1:30pm | 2022 FULL 11171 | PPB Registry: The International Pleuropulmonary Blastoma /DICER1 Registry (for PPB, DICER1 and Associated Conditions) | Dr Karen Tsui | Ms Jessie Lenagh-Glue & Ms Albany Lucas |
|  |  | *Break (15 minutes)* |  |  |
| 1:45pm-2:15pm | 2022 FULL 11906 | MK-8591A 033-02 Doravirine/Islatravir (DOR/ISL) Rollover | Dr Alan Pithie | Dr Peter Gallagher & Dr Cordelia Thomas |
| 2:15pm - 2:45pm | 2022 FULL 11695 | Does nebulised acetylcysteine compared to saline improve oxygenation in intubated patients with thick or high-volume secretions? | Doctor Simon Gordon | Dr Patries Herst & Ms Jessie Lenagh-Glue |
| 2:45pm - 3:15pm | 2022 FULL 11800 | Evaluation of Dissociative Symptom Assessment | Dr. Martin Dorahy | Ms Albany Lucas & Ms Sandy Gill |
|  |  | *Break (15 minutes)* |  |  |
| 3:30 - 4:00pm | 2022 FULL 11285 | Getting ready for MinDArT | Ms Emma Febvre-Richards | Ms Helen Walker & Dr Patries Herst |
| 4:00pm-4:30pm | 2022 FULL 12061 | 1404-0010: A Study to Evaluate and Compare BI 456906 in Healthy Participants and in Patients with Liver Disease | Prof. Edward Gane | Dr Peter Gallagher & Ms Sandy Gill |
| 4:30pm - 5:00pm | 2022 FULL 12134 | Phase 3 Study of Pembrolizumab Versus Placebo as Adjuvant Therapy Following Surgery and Radiation in Participants with High-risk Locally Advanced Squamous Cell Carcinoma of the Skin (KEYNOTE-630) | Principal Investigator Catherine Han | Ms Julie Jones & 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 |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 22/05/2020 | 22/05/2023 | Present |
| Ms Julie Jones | Non-lay (intervention studies) | 22/05/2020 | 22/05/2022 | Present |
| Ms 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 no apologies had been received.

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 25 January 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2021 FULL 11324** |
|  | Title: | “Symptoms and Side Effects” a Modified Delphi Study |
|  | Principal Investigator: | Dr Ross Drake |
|  | Sponsor: | IMPACCT Trials Coordination Centre (ITCC) |
|  | Clock Start Date: | 11 February 2022 |

Dr Ross Drake, Vanessa Yenson and Leoni Fourie were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study aims to identify the most troubling cancer-related symptoms, to create a consensus list of research priorities and questions to directly tackle under managed cancer symptoms in children and AYA living with, and after, cancer in Australia and New Zealand.

Summary of resolved ethical issues

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

1. The Committee requested further information on the origins of the study and why it was being conducted. The Researcher explained the study will examine the developmental, social, and emotional impacts in children and young adults with cancer and compared to the impacts experienced by adults. This information would be fed back to Cancer Australia.
2. The Committee clarified the study will be conducted anonymously online. The consent form can be printed by clinicians or research staff and given to participants. Final consent (including parental consent) will be given electronically.
3. The Committee requested clarification on the surveys which would be intended for the New Zealand context. The Researcher explained that these are drafted but not yet in use in New Zealand.
4. The Committee and Researcher clarified that there is a peer review document which was not made available at the time of the meeting. This would be circulated following the meeting.

Summary of outstanding ethical issues

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

1. Please refer to alternative other than school or university to avoid excluding some potential participants.
2. Please clarify on the structure of the proposed Zoom meetings.
3. Please provide HDEC contact information.
4. Young people can consent for themselves from the age of 16. Please correct where reference is made to the age of 18-year-olds and ensure this is consistent throughout the documents.
5. Please check all documents for grammar, spelling mistakes and provide further context where necessary.
6. Please amend the adult information sheet to ensure that their children are being referred to as necessary as the adults are consenting on behalf of the children.
7. Please include information to the participant so that they are made aware their caregiver will be asked for information about them.
8. Please include the Chatham Islands as part of New Zealand.
9. Please ensure the ‘non-binary’ option is made available across the information sheets.
10. Please clarify on who is conducting the study (i.e., a partnership)

The Committee requested the following changes to the Data Management Plan (DMP):

1. Please change the section on keeping the data for 15 years following the trial (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.28).*
2. Please provide information on the participants right to access the data collected during the focus group.

**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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Peter Gallagher & Dr Cordelia Thomas.

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| **2** | **Ethics ref:** | **2021 EXP 11707** |
|  | Title: | T-TRAC Study - Time to recover after concussion study |
|  | Principal Investigator: | Mrs Rebekah Miller |
|  | Sponsor: | Brain Box Inc |
|  | Clock Start Date: | 11 February 2022 |

Mrs Rebekah Miller, Alieke Dierckx, and Martin Than were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study aims to determine if there are relationships between vestibular issues, noise sensitivity and psychological factors especially fear avoidance and anxiety among adults with mTBI. The study will also aim to determine what vestibular, audiological, and psychological symptom clusters unique to mTBI are associated with a longer time to recover.

Summary of resolved ethical issues

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

1. The Committee asked for clarification on the process to age, sex and ethnicity match the healthy volunteers. The Researcher explained that the age matched over 10-year age intervals, ethnicity would be defined as Māori and non-Māori and male/female for sex. If there are gaps in the matching, the researchers would recruit more participants to balance these gaps.

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

1. Please clarify that participants are being recruited because they are already a part of the HEADSMART study.
2. Please make it clear how participants data will be used in the T-TRAC study and ensure that there is a means to consent to this.
3. Please clarify which visits are for HEADSMART and the information from the HEADSMART visit that will be used for T-TRAC and which are specifically T-TRAC visits.
4. Please provide information about the physical tests and questionnaires that will be performed. This includes clearly differentiating between the HEADSMART and T-TRAC.
5. Please make it clearer if any visits are wholly site based or home based or could be either or part there of depending on specific circumstances.
6. Please consider including a table which shows the assessments and when they will occur and modify the table as necessary so that it is clear for the participants and/or provide explanations of the tests.
7. Please include a statement that this study will not affect the participants participation in HEADSMART.
8. Please amend the statement about no risks to the participant.
9. Please include a safety statement about the support and safety management measures in place for mental health issues if distress may be caused by the questionnaires.
10. Please include a cultural statement acknowledging the tapu of the head and how this will be managed.
11. Please amend the data section to include all the required sections, such as; identifiable data and who has access, de-identified data and who has access, data risks, rights to withdraw information and what will happen upon withdrawal, future research, data linking, data retention period.
12. Please include a statement on who is funding the study.
13. Please include a statement on Koha or reimbursements if they are given.

The Committee requested the following changes to the Part 2 Consent Form (CF):

1. Please clarify on ‘significant abnormal results’, how these will be managed and next steps that can be taken or amend to remove ‘abnormal’ if not applicable to the trial.
2. Please remove the statement about information being sent overseas if it will not be.
3. Please include statement about agreeing to allow HEADSMART data to be used for T-TRAC
4. Please remove the yes/no tick boxes from the consent if they are not optional.

Please include the statement regarding consent completion within the researcher’s declaration i.e. “I have given a verbal explanation of the research project to the participant and have answered the participant’s questions about it. “

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

1. Please ensure that information mentioned in the CF (i.e., identifiable data being sent overseas and contacting the participants GP) is mentioned in the PIS if it is applicable or remove if it is not.
2. Please include more information in the data section, such as identifiable data and who has access, de-identified data and who has access, data risks, rights to withdraw information or what will happen to data if they withdraw, and the data retention period
3. Please provide information on how to withdraw from the trial and any impacts this may have.
4. Please include a section on whether the data will be used for future research.
5. Please include information on the data linking with HEADSMART and any other data linking that may occur.
6. Please include information on how the study is funded.
7. Please include a section on koha or reimbursements.

The Committee requested the following changes to the Part 2 Consent Form (CF):

1. Please remove the Yes/no tick boxes for any point that is not optional.
2. Please include a declaration by a member of the research team confirming that they have given the participants all information requested.

The Committee requested the following changes to the Healthy Control PISCF

1. Please clarify the definition of “healthy volunteers”. If there are inclusion/exclusion criteria please put this in the relevant PIS.
2. Please include a description of what the physical tasks and questionnaires are should be included.
3. Please remove or amend "Why is information being collected about my recovery?"
4. Please include data sections, as referred to in the PIS.
5. State whether the information collected for the Koha draw will be retained as it is separate from the study.
6. Please ensure that any other points regarding the main PIS and consent documents are also applied to all PISCF as applicable

The Committee requested the following changes to the Data Management Plan (DMP):

1. Please clarify the flow of data through the study particularly regarding the relationship between HEADSMART and T-TRAC data.
2. Please ensure the DMP reflects what will happen on this specific study.
3. Please include information on where the data from each study will be stored as is relevant.
4. Please change the data storage from 5 years to a minimum of 10 years. Researchers should keep research data on child participants for at least 10 years after the child has reached the age of 16 years (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.28)*
5. Please provide further information on the safety and screening results, and their relationship between the HEADSMART and T-TRAC study.

**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).*

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

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| **3** | **Ethics ref:** | **2022 FULL 11171** |
|  | Title: | PPB Registry: The International Pleuropulmonary Blastoma  /DICER1 Registry (for PPB, DICER1 and Associated  Conditions) |
|  | Principal Investigator: | Dr Karen Tsui |
|  | Sponsor: | Children's Minnesota |
|  | Clock Start Date: | 11 February 2022 |

Dr Sarah Hunter and Dr Karen Tsui were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study aims to improve the outcomes of individuals with PPB and other DICER1-associated conditions.

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 requires scientific review to be provided as the document provided was not adequate. Please provide an independent review from someone who is expert in the field but unrelated to the study. Please refer to the [HDEC template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx)

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

1. Please include a statement regarding the incidental findings of genetic testing on biobank tissues. This may not be necessary for the younger assent forms but should be included in the older groups.
2. Please amend the statement around the incidental findings and informing of study doctors for future health and healthcare to state “If there are incidental findings that are important to your future health and healthcare, the study doctor will receive and share these findings with you.”.
3. Please include some form of Koha even including a thank you letter or card to acknowledge that there is some exchange of taonga information.
4. Please amend the wording to refer to “the Participant” in all forms for clarity.
5. Please consider using a table for mandatory or additional procedures.
6. Please remove the phrase “no one will be mad at you” from all forms. This is suggestive and potentially harmful to children in the study.
7. Please amend the ACC statement using the current HDEC template.
8. Please include information as to what specific genes will be studied. If this is only DICER1 please be specific about this.
9. Please explain what a registry is and why it may be formed. Please focus on the aspect of a “registry” in simple, lay terms.
10. Please review for clarity.
11. Please remove mention of caregivers giving consent as this is not correct. Parents/guardians give consent on behalf of incompetent children.

**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 Ms Albany Lucas and Ms Jessie Lenagh-Glue.

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| **4** | **Ethics ref:** | **2022 FULL 11906** |
|  | Title: | MK-8591A 033-02 Doravirine/Islatravir (DOR/ISL) Rollover |
|  | Principal Investigator: | Dr Alan Pithie |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited (MSD) |
|  | Clock Start Date: | 11 February 2022 |

No one form the research team was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study aims to evaluate the progress and adverse events of participants with HIV-1 who received DOR/ISL in previous DOR/ISL treatment studies and to provide continued access to treatment with investigational DOR/ISL until it becomes commercially accessible.

Summary of resolved ethical issues

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

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 clarify what is meant by “usual doctor” for the participant, if the General Practitioner (GP) is the usual doctor please say GP.

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

1. Please remove “if you withdraw it will not affect your medical care” as the participant is no longer receiving the study medication therefore affecting the participant’s medical care.
2. Please replace the birth control and discussion with the doctor section with the HDEC template version.
3. Please also add the grid of visits from the protocol into the participant information sheet to help participants track visits etc more effectively and easily.
4. Please supply participant information sheet and consent forms for children using the HDEC templates, if there are children involved in the study.
5. Please amend page 2 by changing “will be” to “may be” when referring to the study drug.
6. Please provide justification on why the trial may be stopped in the future and explain in lay language for potential participants.
7. Please explain & confirm how many participants are included in the study.

The Committee requested the following changes to the Consent Form (CF):

1. Please remove “if you are a woman who is pregnant” and replace with gender neutral terms such as “if you are pregnant” or “if you become pregnant”

The Committee requested the following changes to the Protocol:

1. Please amend page 28 by removing “consent by a legally authorized representative” as this does not apply to adults in New Zealand.
2. Please clarify if children will be enrolled in this study, as a child can still be over 35kgs, if there are children involved, they will need to reconsent at 16 years old.
3. Please make an addition to the protocol that covers whether upon completion of the 48 weeks the participants will still have access to the study drug on a compassion basis.

**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 (Primary Reviewer), Dr Peter Gallagher (Primary Reviewer).

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| **5** | **Ethics ref:** | **2022 FULL 11695** |
|  | Title: | Does nebulised acetylcysteine compared to saline improve  oxygenation in intubated patients with thick or high volume  secretions? |
|  | Principal Investigator: | Dr Simon Gordon |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 February 2022 |

Dr Simon Gordon was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study aims to delineate if there is a potential therapeutic benefit to nebulised acetylcysteine in both invasively ventilated and patients that have specific respiratory conditions, such as cystic fibrosis.

Summary of resolved ethical issues

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

1. The Committee asked about the alternative of the medicine and if the alternative is not to get anything. The Researcher explained that the standard of care the air they are breathing in on the ventilator is only humidified and does not contain any nebulized substances to thin the secretions.
2. The Committee asked about the standard of care in the intensive care units and normal procedure is to give the patient humidified air only. In New Zealand neither of the interventions in this study are given as routine.
3. The Committee asked about the data safety monitoring committee and if one is going to be used. The Researcher explained that they are not going to have an external committee but will look at it themselves.
4. The Committee asked how often potential participants will be contacted in the study. The Researcher explained that other than giving consent, patients will not be contacted further by the research team and all information required will be taken from the patient notes.
5. The Committee asked about historical controls. The Researcher explained that they would only be able to recruit enough participants in one hospital for 2 arms and not for a third control arm, so data from the two arms would be compared with historical controls.
6. The Committee asked about who is paying for the study. The Researcher explained that the hospital is sponsoring some of the equipment being used and the medication and the research nurses and the researchers would do this as part of their jobs.
7. The Committee asked about the possibility of adverse events with the equipment or if participants can get injured in any way. The Researcher explained that there is a small risk of bronchospasm, which is easily treated with other medication. They do not foresee long-term risks.
8. The Committee asked about how many people would be likely to get a bronchospasm. The Researcher explained the incidence varies but is incredibly low.
9. The Committee asked if a 24-hour window to decide to let someone into the study is feasible in terms of rostering and management. The Researcher explained that by a case-by-case basis it will not be feasible consistently and that they will look more closely into this to ensure that it is not an issue for the progress of the study.
10. The Committee asked if COVID-19 patients will be included in the trial. The Researcher explained they will be included in the trial.

Summary of outstanding ethical issues

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

1. 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 use a clinician in a different hospital.
2. Because this is unconsented research, please put in place an independent health professional (consultant, physician, other suitable person), who will verify that it is in the best interest of each participant to take part in the study. We would need to know who this person is, their relationship to the research team and the piece of paper that this person would sign.
3. The Committee advised the Researcher that relevant Māori cultural issues for this research would include blood samples as tapu, information as a taonga and the potential for whakamā in participants. The Committee requested the Researcher become familiar with these concepts and be mindful of this for future applications.

The Committee requested the following changes to the Application:

1. Please check and amend typos throughout application.
2. Please remove section C10: “Pacific people lack health literacy”
3. Please amend section E6: stating if there is a committee or not, if so, please include which committee.
4. Please amend readability of application by removing run on sentences.
5. Please describe in some detail why being in the study is in the participants best interests, as they cannot consent for themselves.

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

1. Please add a footer with page numbers, version, date, and the logo of the university at the top.
2. Please provide more information on how acetyl cysteine works.
3. Please state how many patients are on this study in New Zealand.
4. Please state how many hospitals are included/used in the study.
5. Please state how long participants are expected to be on the study for.
6. Please state what is required of the participants after they come off the ventilator.
7. Please state what type of data will be collected from these participants and where these will be collected from.
8. Please amend the use of past and present tenses used throughout the PIS.
9. In the interest of patient informed consent, is there any possibility that patients will still be on ventilators, and hence in the study, while they have capacity to consent, if not, all language must be changed to reflect the past tense.
10. Please remove the paragraph about private health or life insurance in the participant information sheet.
11. Please include a section on participant rights including access to their information, participants consent to remain in the study, and they consent to the data already collected to continue to be used, these are two different things and need to be separate points in the consent forms.
12. Please include more detail for the “What happens to my information” section, please include identifiable & coded information. Including what data will be collected and where exactly that data will be stored and for how long.
13. Please include informing the GP into the consent form.

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

1. Please include footers and page numbers.
2. Please include and highlight the paragraph of private health and life insurance into the whanau/relative section.
3. Please remove consultation as “good practice” as it is the law.
4. Please remove all sections that are not relevant to Whanau PIS.
5. Please include who has access to participants data and information.
6. Please remove last bullet point.
7. Please be explicit in what will be discussed with whanau and what is said during the consultation. Please also add this to the participant PIS.

The Committee requested the following changes to the Data Management Plan:

1. The Committee stated more information around data management is required than what is available in the study documentation satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.

**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 (Primary Reviewer), Ms Jessie Lenagh-Glue (Primary Reviewer).

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| **6** | **Ethics ref:** | **2022 FULL 11800** |
|  | Title: | Evaluation of Dissociative Symptom Assessment |
|  | Principal Investigator: | Dr. Martin Dorahy |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 February 2022 |

Dr. Martin Dorahy and James McKie were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study aims to investigate and address the dissociative symptoms detected in routine psychiatric assessment.

Summary of resolved ethical issues

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

1. The Committee asked about reimbursement for parking and travel costs. The Researcher explained that they can provide fuel vouchers for participants using the university reimbursement policy.
2. The Committee asked about the role of the case manager and why the case manager is also consenting to participate in the study. The Researcher explained they would prefer to have the participants’ case manager with them and as part of the recruitment, however, understands the coercion factor. The committee said the case manager is not providing data so is not a participant
3. The Committee asked about the strict time restraints of case managers and if the researchers are going to struggle asking the case managers for more time and assistance. The Researcher explained they have acknowledged this and if it comes down to time restraints or too many issues the researchers will take it upon themselves to work with the participant.
4. The Committee asked about the thought of using a peer support worker trained up to support the role of a case manager throughout the study. The Researcher explained they had not thought of this idea and has taken it on board as recommended by the committee.
5. The Committee asked about cultural consultation and the questionnaires used. The Researcher explained they have received cultural consultation and have sent the questionnaires used and indicated they are fine to use and further explained they are trying to get a measure of pathological disassociation, if something is typical in a participant cultural. The Researchers took on board the separation of speaking to ancestors and hearing voices and will try their hardest to make the questions and answers culturally informed.

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 further explain the role of the case manager as there may be a conflict between case manager and participants. This conflict is because case managers cannot be a participant and consent the participants, the consenting should only be done by people trained to do so from the study team.
2. Please amend the details about the Koha included and include if participants will be reimbursed for parking and travel.
3. Please amend the invitation sheet to make it more concise and please check for typos.
4. Please amend study end date to 2022.
5. Please include that potential participants can bring their own support person with them, and if the potential participant does not have a support person, the research team can provide one for the potential participant for guidance and safety.
6. Please use the word in full first for acronyms.

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

1. Please include ethics auditing in data section.
2. Please either remove “co-supervisor” or amend for potential participants to understand what a “co-supervisor” will be doing during the study.
3. Please include that this study is a masters study at the beginning of the participant information sheet and consent form.
4. The case manager should not be the person consenting the participant, they can be present at the time but the person to consent the participant needs to be a study team member who is familiar with the study and can answer all questions potentially raised by the participant, please amend.
5. Please correct data retention and storage requirements to 10 years.
6. Please include ACC information and add corresponding compensation statement to consent.
7. Please amend the following sections: certain point is reached and when statistical analysis begins its difficult to remove the data recorded sections of the participant information sheet and consent forms and change to: ‘any data collected up to the date of your withdrawal will remain with the research.’
8. Please amend for participants’ withdrawal of study to add that they can verbally withdraw from the study, this can be in person or over the telephone, or a letter.
9. Please include Maori contact details.
10. Please check for typos and general grammar throughout the participant information sheet and consent forms.

The Committee requested the following changes to the Data Management Plan (DMP):

1. The Committee stated more information around data management is required than what is available in the study documentation satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.
2. Please amend health information being stored for: from 5 years to 10 years.

**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 Ms Sandy Gill (Primary Reviewer), Ms Albany Lucas (Primary Reviewer).

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| **7** | **Ethics ref:** | **2022 FULL 11285** |
|  | Title: | Getting ready for MinDArT |
|  | Principal Investigator: | Ms Emma Febvre-Richards |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 11 February 2022 |

Ms Emma Febvre-Richards and Ms Susan Gee were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is a pilot study to assess the acceptability and feasibility of the proposed outcomes measures for a later trial of MinDArT.

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 caregiver and the support person are the same person.
2. The Committee clarified that there would be people on staff who would be there to support individuals if the person with mild dementia had ongoing support when their carer was in another room, doing the art projects themselves.
3. The Committee clarified that there would be no removal of service after the study and that a link would be provided for ongoing use of the programme.
4. The Committee clarified that the participation of the support person would be an assessment of their feelings surrounding their role as a support person.
5. The Committee clarified that the support person is also permitted their own support person for their participation.
6. The Committee clarified that there would be enough space for social distancing even with the number of participants and their support people anticipated.

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

1. Please move the statement that the study is voluntary to the first page.
2. Please describe what MinDArT is at the beginning of why the study is being conducted.
3. Please provide more detail around the interviews. Specifically, if it will be record, transcribed and if people have access to their own interviews.
4. Please specify who the deidentified data could be shared with. If this is going overseas this needs to be specified as well as where it may be sent to and accessed by whom.
5. Please include a Māori cultural support details.
6. Please include a statement that informs that multiple support people may be selected.
7. Please ensure that the data collection information in the data sheet is outlined clearly in the PIS.
8. Please include a statement on the right to access their own health data and make changes if incorrect.
9. Please note that health data must be kept for 10 years and that this must be reflected in the PIS.
10. Please amend the statement about ethical approval by HDEC to state that “The HDEC have approved the ethical aspects of the study”
11. Please include a footer with page numbers and version numbers and date.

The Committee requested the following changes to the Data Management Plan (DMP):

1. Please note that health data must be kept for 10 years.
2. Please refer to the [HDEC DMP template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) to ensure that all aspects have been considered.

**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 Helen Walker

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| **8** | **Ethics ref:** | **2022 FULL 12134** |
|  | Title: | Phase 3 Study of Pembrolizumab Versus Placebo as Adjuvant Therapy Following Surgery and Radiation in Participants with High-risk Locally Advanced Squamous Cell Carcinoma of the Skin (KEYNOTE-630) |
|  | Principal Investigator: | Catherine Han |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited (MSD) |
|  | Clock Start Date: | 11 February 2022 |

Dr Catherine Han, Dr Paul Hamilton, and Sharmin Bala were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study aims to see how well the trial drug, pembrolizumab, keeps cutaneous squamous cell carcinoma (cSSC) from coming back or spreading compared to placebo and to see if giving pembrolizumab after surgery and radiation helps patients with cSSC cancer live longer. There will additionally be concurrent assessment of the safety of the trial drug.

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 participants would be newly diagnosed and that there was a plan in place to manage feelings of being overwhelmed when explaining the study with the patient information sheet.

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

1. Please standardise the use of the term “General Practitioner” or “non-study doctor” across the study.
2. Please specify the nature of the photographs that may be taken and if these will be identifiable or of certain areas in the text of the sheet and not only in the table of procedures.
3. Please amend the typing error of “prima care” on page 22 to say “primary”.

**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).*
* 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:** | **2022 FULL 12061** |
|  | Title: | 1404-0010: A Study to Evaluate and Compare BI 456906 in  Healthy Participants and in Patients with Liver Disease |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Boehringer Ingelheim Pty Ltd. |
|  | Clock Start Date: | TIME |

Dr Edward Gane and Ms Courtney Rowse were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study aims to compare the pharmacokinetics (PK), safety, and tolerability of a single dose of BI 456906 in patients with cirrhosis and varying degrees of hepatic impairment, relative to "matched" healthy participants. The secondary aim of the study is to investigate the safety and tolerability of up to 6.0 mg weekly BI 456906 in patients who are overweight/obese with cirrhosis and varying degrees of hepatic impairment, when compared to patients who are overweight/obese without cirrhosis or hepatic impairment.

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 study participants would be matched by BMI to those who participated in the Phase 1 trial. This would include individuals who were considered obese individuals but otherwise healthy.
2. The Committee suggests the research team consider consultation with overweight individuals.
3. The Committee suggests the Researcher consider the potential mental health effects or significant distress that may result from the study.

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

1. Please simplify the explanation of the function of the study drug and review for lay terms.
2. Please review for typing errors in section 1.1.

**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).*
* 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).*

## General business

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

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| **Meeting date:** | 22 March 2022 |
| **Zoom details:** | To be determined |

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 5:00pm.