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| **Committee:** | NTA Health and Disability Ethics Committee |
| **Meeting date:** | 17 June 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12.00-12.30pm |  | Committee Welcome |  |  |
| 12.30-1.00pm | 2025 FULL 22962 | Double-blind study of RG6496 in Huntington’s disease participants | Professor Tim Anderson | Dr Joy Panoho / Dr Andrea Furuya |
| 1.00-1.30pm | 2025 FULL 23083 | 1378-0041: A study to test vicadrostat (BI 690517) taken together with empagliflozin in people with type 2 diabetes, high blood pressure, and cardiovascular disease. | Professor Richard Troughton | Dr Catriona McBean / Dr Andrea Forde |
| 1.30-2.00pm | 2025 EXP 22662 | The EOCRC Network Aotearoa | Dr Tamara Glyn | Mr Jonathan Darby / Dr Andrea Furuya |
| 2.00-2.15pm |  | *Break (15 mins)* |  |  |
| 2.15-2.45pm | 2025 FULL 23080 | SWiFT Aotearoa for HDEC | Dr Richard Charlewood | Dr Joy Panoho / Dr Andrea Forde |
| 2.45-3.00pm | 2025 EXP 22583 | Biologic Options for Optimal Second-line Treatment for fistulising Crohn's Disease | Doctor Abhimati Ravikulan | Dr Catriona McBean / Dr Andrea Furuya |
| 3.00-3.15pm | 2025 EXP 19812 | MindArt for stroke survivors and supporters | Dr Susan Gee | Mr Jonathan Darby / Dr Andrea Forde |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Dr Kate Parker  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Apology  |
| Dr Andrea Forde | Non-lay (Intervention studies)  | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey  | Lay (the Law) (Chair) | 11/08/2021 | 11/08/2024 | Apology |
| Dr Malisa Mulholland | Non-lay  | 09/06/2025  |  | Apology |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Dr Katrina Gibson  | Non-lay  | 09/06/2025 |  | Apology |
| Dr Catriona McBean | Lay | 03/03/2025 | 02/03/2030 | Present |
| Dr Andrea Furuya | Non-Lay | 03/03/2025 | 02/03/2029 | Present |
| Dr Joy Panoho | Lay | 03/03/2025 | 02/02/2030 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Ms Catherine Garvey, Dr Kate Parker, Dr Malisa Mulholland, and Dr Katrina Gibson.

Dr Andrea Forde was appointed as Chair for the duration of the meeting, in the absence of Ms Catherine Garvey.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Andrea Furuya and Dr Joy Panoho confirmed their eligibility and were co-opted by the Chair as members of the Committee for the duration of the meeting.

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 20 May 2025 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2025 FULL 22962** |
|   | Title:  | A Phase I, 2-Part Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single-Ascending Doses of Intrathecally Administered RG6496 in a Randomized, Placebo-Controlled, Investigator/Participant-Blind Study with an Open-Label Extension in Huntington's Disease Gene Expansion Carriers |
|   | Principal Investigator:  | Professor Tim Anderson |
|   | Sponsor:  | F. Hoffmann-La Roche Ltd |
|   | Clock Start Date:  | 05 June 2025 |

Laura Paermentier 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 noted that the protocol could include more detail about the end points but understand that as it is an international protocol it may not be able to be amended.
2. The Committee queried where the site will be and what observation participants will be under given this is a first in human study. The Researcher advised that participants would stay at NZCRs phase I trial site where they will be under observation from doctors and nurses.
3. The Committee queried the optional data linking that will include data gathered under other studies and that will be shared with the sponsor and potentially other researchers. The Researcher advised that they have been doing Huntington’s research for fifteen years and that this data could assist researchers as a comparator. The cohort are well known to the researchers and are aware of ongoing data collection.
4. The Committee queried whether there is someone other than the clinician that can discuss the study with potential participants. The Researcher advised that there is.
5. The Committee queried the rationale for not having an Independent Data Safety Committee. The Researcher advised that there will be unblinded clinicians reviewing all data regularly.
6. The Committee queried the number of participants in New Zealand. The Researcher advised that it will be a minimum of four, but an additional site may be added in Auckland, which could mean eight participants.
7. The Committee queried whether there would be a contract in place for psychiatry services for participants if Quality of Life Questionnaires identify distress. The Researchers advised that they do have this in place as support is commonly required for Huntington patients.

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 would like clarification around the following points in the protocol from the sponsor.

The protocol states “Incidence and titer of RG6496 (RO7764733) ADAs in plasma during the study relative to prevalence of ADAs at baseline.” Please clarity if it is measured from baseline through the end of study. Please state what validated’ tests will be used.

Similarly, “PK parameters of RG6496 (RO7764733) including but not limited to AUC, Cmin, Cmax, CL, V, Tmax, and t1/2.” Please advise the timing and method. “RO7764733 did not cause reversible inhibition of CYP1A2, CYP2B6, CYP2C9, CYP2C19, CYP2D6, and CYP3A4/5 (midazolam and testosterone) at concentrations up to 200 µM”. No significant reversible inhibition was observed. This does not automatically imply irreversible inhibition. Considering these enzymes are important in metabolizing drugs, please clarify if the IP was evaluated for irreversible or time-dependent inhibition (TDI) of these enzymes. If so, please share these results.

“The Sponsor has also received a non-significant risk determination from the United States (U.S.) Food and Drug Administration (FDA) for this assay.” Please clarify if this is for Sequencing or the Investigational Product.

“In the single-dose non-GLP MTD study, concentrations were generally quantifiable in various brain tissues.” “In the spinal cord, mean concentrations were highest in the lumbar region and lowest in the cervical region” Please advise what are the actual values, sample size Standard Deviation, and statistics.

1. The Committee query whether US $50 million is sufficient insurance for an eight-year study.
2. The Committee request that the sponsor consider licencing the interventional medication in New Zealand should the trial prove successful.
3. The Committee feel that given the length of the study that a koha on top of reimbursement would be appropriate.
4. The Committee requested confirmation that the study has been registered with a clinical trial registry and that a submission has been made to SCOTT.
5. The Committee queried whether alcohol or other drugs of abuse/misuse testing will be carried out, noting that if it will be, then this should be stated in the PIS.

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

1. Please highlight that GLP agonists may reduce efficacy of some hormonal contraceptive medication. Clarify if this is the rationale for female participants needing to use effective contraception plus barrier contraception as it should not be necessary for females using highly effective contraception.
2. Please clarify how long participants must use contraception for after receiving the investigational product, and when this period is in relation to the study.
3. Please state that there may be limitations in the transferability of animal data, as mice and monkeys do not have the SNP that the investigational product is designed to act on.
4. On page 2 please simplify the language to remove jargon or provide definitions.
5. Please provide more detail about the optional data linking.
6. Please amend the Privacy Act to 2020, not 1993.
7. Please remove reference to race, use ethnicity only.
8. Please remove reference to unborn baby/child. Instead, state pregnancy or outcome of pregnancy.
9. Please remove reference to biohazard waste, state tissue instead.
10. On page 15 please change tissue destruction to tissue disposal.
11. Please update the phone number for HDEC on the FUR PIS, 0800 4 ETHIC is no longer in service. The correct phone number is 0800 400 569 (Ministry of Health general enquiries).
12. Please add to the consent form, permission for audio recording.
13. On page 8 please change the wording from “either” as there are more than two notifiable blood borne viruses in New Zealand.

**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 if possible or at least respond to the queries around the detail lacking from the 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 Joy Panoho and Dr Andrea Furuya.

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| **2**   | **Ethics ref:**   | **2025 FULL 23083** |
|   | Title:  | 1378-0041: A Phase III double-blind, randomised, parallel-group superiority trial to evaluate efficacy and safety of the combined use of oral vicadrostat (BI 690517) and empagliflozin compared with placebo and empagliflozin in participants with type 2 diabetes, hypertension and established cardiovascular disease. |
|   | Principal Investigator:  | Professor Richard Troughton |
|   | Sponsor:  | Boehringer Ingelheim Pty Ltd. |
|   | Clock Start Date:  | 05 June 2025 |

Stephanie Rose and Alieke Dierckx 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 diagram in appendix E is very useful and informative.
2. The Committee noted the thorough monitoring that will be provided by having an Independent Data Monitoring Committee and the secondary oversight of the Executive Committee.
3. The Committee queried whether there will be someone other than a clinician for potential participants to discuss the study with. The Researchers advised that there is a study co-ordinator that will do this.

Summary of outstanding ethical issues

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

1. The Committee queried the necessity for pregnancy testing at every visit and stated that this is overly invasive. If the participant has been both advised to avoid becoming pregnant and provided with advice on how to avoid pregnancy using highly effective contraceptive, simply asking the participant if they could be pregnant should be sufficient.
2. The Committee queried whether requiring hormonal and barrier contraception is overly burdensome given that animal studies and post-market surveillance do not indicate reproductive or developmental toxicity.
3. The Committee note that payment is via PayPal and queried what the alternatives are if participants do not use PayPal.
4. Please provide an insurance certificate naming New Zealand as a covered territory.
5. The Committee request the sponsor consider licencing the investigational product in New Zealand should the trial be successful.
6. The Committee queried whether participants will still have access to the investigational product at the end of the study.
7. The Committee noted that if home visits will occur then a safety plan is required for study staff.
8. The Committee noted that the positions stated for Māori consultation do not appear to be correct, and recommend contacting Lisa Crossland, Manager, Research Support and Systems Lisa.Crossland@TeWhatuOra.govt.nz or Dr Helen Wihongi, Director Māori Research Lead Helen.Wihongi@TeWhatuOra.govt.nz for advice on locality and Māori cultural review.
9. The Committee noted that the study must be registered in a Clinical trials registry.
10. In the “your journey in this study” document, please soften the language around withdrawal from the study as currently it is worded in a way which could be perceived as trying to deter individuals from making this choice.

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

1. Please customise for a New Zealand audience. Ensure a Māori cultural statement is included, and information about what happens to samples.
2. If international travel is not required, please remove reference to this.
3. Please clarify if travel reimbursement applies for New Zealand participants.
4. Currently it states Scout may be responsible for payments to participants. Please confirm who **will** be responsible for paying participants in New Zealand.
5. Koha would be more appropriate terminology than stipend for New Zealand.
6. Please state how much the koha will be.
7. Please state the New Zealand sites.
8. On page 1 please clarify if it is all three, or a combination of conditions.
9. On page 1 please replace “There is no penalty” to “You will continue to be treated for your condition as normal”.
10. Page 2 mentions unwanted effects. There could be unexpected positive effects also, so this needs to be included in the wording.
11. On page 6 please clarify the reference to screening at other sites.
12. Please clarify how long data will be stored for. Ten years is standard but currently it states thirty years, which if correct should be highlighted as a significantly long time.
13. Please remove reference to flipping a coin on page 2.
14. On pages 9 and 19 please remove reference to unborn baby. Instead, state pregnancy and outcome of pregnancy.
15. Please rephrase to say that if a participant becomes pregnant, that the outcome of the pregnancy will be followed up if they consent to the follow up.
16. Please remove reference to a cup on page 15, as New Zealand uses the metric system, and it is not culturally appropriate to use terminology which would be associated with eating or drinking in this context.
17. Please highlight that if a participant is using a GLP-1 agonist it may make some contraceptive medication less effective.
18. Please clarify whether men need to utilise contraception or not, as there are currently contradictory statements.
19. Please include reference to the Privacy Act 2020.

**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 Mr Johnathan Darby, Dr Catriona McBean and Dr Andrea Forde.

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| **3**  | **Ethics ref:**   | **2025 EXP 22662** |
|   | Title:  | Early onset colorectal cancer network Aotearoa |
|   | Principal Investigator:  | Dr Tamara Glyn |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 05 June 2025 |

Rachel Purcell 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 queried whether the PIS would be provided to potential participants prior to the consenting process, so there is sufficient time to consider the information. The Researcher stated that the PIS can be sent to potential participants prior to meeting with them.
2. The Committee queried whether the research nurse reports to the study team or the clinician. The Researcher advised that the research nurse reports to the study team.
3. The Committee queried why no koha is offered to participants. The Researchers advised that their Māori consultation recommended it was not given for this study, as there are no additional visits for the study, and everything gathered is part of normal standard of care.
4. The Committee queried whether the exclusion criteria need to be expanded. The Researcher advised that they are trying to include as wide a sample as possible to be representative of the population.

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 protocol is very general, more specific information needs to be provided. For example, what aspects of immune response, which specific cell types. Also, how the microbiome will be normalised across samples.
2. The Committee requested that it is stated where the late onset cohort data is coming from.
3. The Committee suggested that the study aims are refined and clarified to better align with an established clinical research framework. Currently, the primary objective appears programmatic, an infrastructural goal while the secondary objective involves collecting and analysing data: i.e. influence of the microbiome to treatment, extensive data phenotyping of adaptive and innate immune cell populations, growing tumours ex vivo etc. To strengthen the protocol/study, we recommend clearly distinguishing between programmatic goals and research objectives and ensuring that each aim is specific and measurable.
4. The Committee noted that information about statistical analysis should be included in the protocol.
5. The Committee stated that the Data and Tissue Management Plan should include information about what types of tests will be used and which biomarkers are being looked at. Please also strengthen the governance section.
6. The Committee noted that information needs to be included in the protocol about the use of Quality-of-Life Questionnaires and what the purpose of these are in the context of the study and when they will be used.
7. The Committee noted that the protocol should include information on the composition of the Governance Committee.

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

1. On page 1 from the fourth paragraph remove "if you do" at the end. As this is clearer for participants.
2. On page 2 please amend the inclusion date to be after HDEC approval.
3. On page 3 Under “What will happen to your tissue” insert the appropriate tissue bank site.
4. Please make it clear to participants that the data is not just being collected and stored, but that it will be used for research.
5. Please amend to reflect that there is a cohort who may not have cancer. For example, the specific use of the word tumour to describe the biopsied tissues may not always be correct.
6. There is mention of whole genomic sequencing in the consent form, but it is not mentioned in the PIS, if this is an error it should be removed.
7. Please advise participants that their medical records will be accessed and what data will be collected and when.
8. Please remove tick boxes from the consent form unless they are truly optional.
9. Please explain in lay terms what rigid sigmoidoscopy means and clarify any other complex terms or acronyms.
10. Please explain why consent is being sought to send data overseas.
11. Please include information about the method, refrigeration and collection or delivery from or by the participant about collecting stool samples at home.

**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 Mr Jonathan Darby and Dr Andrea Furuya.

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| **4**  | **Ethics ref:**   | **2025 FULL 23080** |
|   | Title:  | Study of Whole Blood in Frontline Trauma in Aotearoa New Zealand - A Randomized Controlled Double-Blinded Feasibility Trial Assessing Platelet-Rich Whole Blood versus Platelet-Poor Whole Blood In Pre-Hospital Traumatic Haemorrhage. |
|   | Principal Investigator:  | Dr Richard Charlewood |
|   | Sponsor:  | New Zealand Blood Service |
|   | Clock Start Date:  | 05 June 2025 |

Dr Richard Charlewood, Helen Knight, and Alana Harper 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 acknowledged that this is a resubmission of a previous decline and commended the excellent work that has gone into revising the protocol to address the ethical issues for this resubmission.
2. The Committee raised the issue that some individuals in the helicopter may be given the investigational product but not be eligible for the study, such as obstetric patients or other patients who require transfusion during transfer between hospitals. The Researchers stated that whilst not currently approved in New Zealand, Platelet Rich Whole Blood is approved in other countries such as the US and Canada where it is widely used. Also, in New Zealand all the individuals not eligible for the study who required urgent blood in the helicopter would likely be put on the massive haemorrhage pathway on arrival in hospital. This would involve them receiving platelets, as this is current standard of care in the hospital setting. The Researchers therefore advised the Committee that as all non-eligible participants who received the investigational product were likely to receive platelets in the receiving hospital the clinical risk related to timing.

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 recommend renaming the Data and Tissue Management Plan, to remove “tissue”, as tissue will not be collected or stored as part of this study. Please also clarify when tissue is mentioned in the document that it is not being collected or stored.
2. The Committee noted the QR code on the advertising poster does not work. The Researcher noted that it will be activated once documents are finalised.
3. Please add a statement about HDEC approval to the poster.
4. Please consider adding information at 8.2 of the Data Management Plan detailing dissemination to Māori groups, in line with discussions already had and yet to be had about this.
5. The Committee suggested wider dissemination of the ethical discussion in the protocol as an example of how to carefully and comprehensively work through a lot of challenging ethical issues and address them.

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

1. Please reword the younger child PIS as it is slightly coercive in its reference to superheroes currently.
2. Please remove reference to a coin toss in the older child PIS.
3. Please check for typos and grammar. Specifically, page 3.
4. Please include a statement that the study has NTA HDEC approval, across all forms.

**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:**   | **2025 EXP 22583** |
|   | Title:  | Biologic Options for Optimal Second-line Treatment for fistulising Crohn's Disease (BOOST-pfCD) |
|   | Principal Investigator:  | Dr Abhimati Ravikulan |
|   | Sponsor:  | Te Whatu Ora Waitaha Canterbury |
|   | Clock Start Date:  | 05 June 2025 |

As this is an expedited application, no researchers were present for the discussion, as per standard practice.

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 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 study does not follow a kaupapa Māori methodology as stated in the submission. *(National Ethical Standards for Health and Disability Research and Quality Improvement, Kaupapa Māori research, pg 43).*
2. The Committee noted that the only issue identified for Māori was data sovereignty and no consideration had been given to cultural issues, such as stigmatisation. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.3).*
3. The Committee noted that the start date was listed as March 2025 and HDEC do not provide retrospective consent. *(National Ethical Standards for Health and Disability Research and Quality Improvement, pg 32, para 2).*
4. The Committee query given the likelihood that there is a small number of participants who are most likely known to the researchers why they cannot be consented. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.47.a).*
5. Please provide a New Zealand specific appendix for the protocol, which will include information on the site, researchers, what specific information will be collected in New Zealand and where from, who will deidentify data, what will be sent overseas, where it will be sent, how many participants there will be and how any incidental findings of clinical significance would be addressed. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8)*
6. The Data Management Plan needs to be specific for this study and should include information on the justification for a waiver of consent, and what the process will be for any data breaches. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
7. The Committee suggest that this could be a prospective, randomized, biomarker (inflammation level, TNF-alpha levels, ADA, genetic polymorphism etc.) driven trial study.
8. The Committee noted that macrons are missing from Māori words.
9. The Committee recommend that this goes for full review when resubmitted.
10. The Committee noted that a waiver of consent has been sought yet in the Data Management Plan it states that participants can request a lay summary of results.
11. The Committee note that there is conflicting information about whether data will go overseas.

**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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| **6**   | **Ethics ref:**   | **2025 EXP 19812** |
|   | Title:  | MindArt: A pilot study of acceptability and feasibility of an art-based relaxation programme with stroke survivors and supporters |
|   | Principal Investigator:  | Dr Susan Gee |
|   | Sponsor:  | Burwood Academy Trust |
|   | Clock Start Date:  | 05 June 2025 |

As this is an expedited application, no researchers were present for the discussion, as per standard practice.

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 study includes home visits and that a safety plan has been provided and is very good.
2. The Committee noted that they have had good consultation.

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 in E.1 of the submission form it states that if the topic is distressing then they will move onto something else. The Committee felt that avoiding the distress raised by the matter under discussion may not be best practice. The Committee considered that it is better to address the distress.
2. The Committee noted in the booklet explaining the activities there is not any reference to the two non-group appointments.
3. The Committee noted that in the submission it states that there are no registered health professionals involved in the study, however this appears to be incorrect as there is a psychiatrist involved in the study.
4. The Committee noted that the title refers to this pilot being for stroke survivors and their supporters. The Protocol does not outline any role for supporters, although presumably they are able to be present as support for the participant, not for data collection. This should be explained in the protocol and be consistent with the PIS/CF.
5. The Committee noted that if any additional recruitment materials are required for recruitment beyond the UC Speech and Hearing Clinic, please ensure that they are uploaded for review before use.
6. The Committee noted that a subsidy will be provided to those with mobility vouchers but query what will be provided for those participants who do not have a mobility voucher.
7. Please outline in the Protocol the limitations of it being a single cohort study, particularly the increased risk of bias due to the absence of a control group. Additionally, clarify how these limitations will be addressed or mitigated in the study.
8. The Committee queried whether participants could have a support person during the MindArt sessions. If so, please include that in the PIS. At present it only indicates that support people can be present for the pre and post MindArt sessions.
9. The Committee noted that there is reference to Dementia in the Data Management Plan, which should be removed.
10. The Committee noted the protocol refers to tension rating circles. Please clarify what this is.

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

1. Please amend the HDEC phone number, as the one listed is no longer in service. The correct phone number is 0800 400 569 (Ministry of Health general enquiries).
2. The consent form should contain a yes or no option for participants to consent to the Researchers keeping the art.
3. Please clarify that the HDEC only approve the ethical aspects of the study.
4. Please outline both the tax and benefit implications of the koha.
5. Please state what happens to the tablet after the study.
6. Please explain that the koha is in two parts, for each visit.

**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:** | 15 July 2025 |
| **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. **Any other business**

The Committee discussed issues in respect of safety plans. Safety Plans focus on the safety of the Researcher, and whilst the protocol may outline processes for the home visit, the Committee asked for advice on what emphasis should be put on the safety of the participant, as opposed to a researcher, during a home visit. For example, consideration of the cultural safety of the participant, such as the removal of footwear before entering the house and the provision of kai, such as biscuits.

The Committee requested that this be raised with the Chairs and with the Ministry.

The meeting closed at 3.05pm.