|  |  |
| --- | --- |
| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 08 April 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 10.00-10.30am |  | Committee Welcome |  |  |
| 10.30-11.00am | 2025 FULL 21800 | Outcomes after Childhood Meningitis Study | Dr Natalie Martin | Mr Dominic Fitchett / Ms Amy Henry |
| 11.00-11.30am | 2025 FULL 21741 | A study to assess probucol (Lorelco) in Alzheimer’s disease (PIA-study) | Dr Nigel Gilchrist | Ms Dianne Glenn / Dr Andrea Forde |
| 11.30am-12.00pm |  | *Break (30 mins)* |  |  |
| 12.00-12.30pm | 2025 FULL 21995 | Disitamab Vedotin with Pembrolizumab vs Chemotherapy in Previously Untreated Urothelial Cancer Expressing HER2 | Dr Nicola Lawrence | Ms Amy Henry / Ms Neta Tomokino |
| 12.30-1.00pm | 2025 FULL 22639 | A phase 2 study of venetoclax/rituximab (VenR) re-treatment in relapsed CLL patients with disease progression following VenR as their most recent line of therapy | Dr Rory Bennett | Dr Maree Kirk / Dr Andrea Forde |
| 1.00-1.30pm | 2025 FULL 22576 | AIRTIVITY® Study: A study to assess the efficacy, safety, and tolerability of BI 1291583 2.5 mg administered once daily for up to 76 weeks in patients with Bronchiectasis | Dr Dean Quinn | Mr Dominic Fitchett / Dr Geoff Noller |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mr Dominic Fitchett  | Lay (the Law)  | 05/07/2019  | 05/07/2022  | Present  |
| Dr Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Associate Prof Nicola Swain | Non-lay Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Apologies |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Dr Geoff Noller | Non-Lay | 03/03/2025 | 02/03/2029 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 10.00am and welcomed Committee members, noting that apologies had been received from Dr Nicola Swain.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Andrea Forde confirmed their eligibility and were co-opted by the Chair as a member 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 11 March 2025 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1**   | **Ethics ref:**   | **2025 FULL 21800** |
|   | Title:  | Childhood Meningitis Quality of Life, Neurodevelopmental and Health Outcomes |
|   | Principal Investigator:  | Dr Natalie Martin |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 27 March 2025 |

A representative for the Researcher was not 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 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 evidence that the peer reviewers’ questions have been addressed.
2. The Committee queried the rationale behind getting a peer review from a paediatric gastroenterologist, rather than someone with expertise in neurology or Meningitis.
3. The Committee queried how Māori and Pacific families will be recruited and how the study will address equity for Māori and Pacific families, as stated in C15 of the submission form.
4. The Committee noted that in the Data Management Plan (DMP) the consenting paragraph on page three needs to be amended as not all participants will provide informed consent.
5. The Committee noted that in the DMP it should state that data will be kept for ten years after the youngest participant turns sixteen.
6. The Committee requested an explanation for how the study uses kaupapa Māori methodology, as this does not appear to be the case based on the information provided.
7. The Committee noted that the gift vouchers should go to the child who is the participant rather than the parent.
8. The Committee noted that there may be some participants younger than sixteen, e.g. fourteen- and fifteen-year-old participants who are able to consent for themselves under the principle of Gillick competence. Please include a plan in the protocol to determine participant capacity for these participants.
9. The Committee raised concerns around the timeliness of review for the quality-of-life surveys and the process in place should a referral be required. Noting that relying on a GP referral is not appropriate in this circumstance as the Researchers have a duty of care to their participants.
10. The Committee noted that when reporting abnormal findings of clinical significance, it may not always be appropriate to wait for parental consent, as the researchers have a duty of care or legal obligations, for example in situations of disclosure of abuse.

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

1. Please rewrite the parent PIS/CF so that it is from the perspective of the parent or guardian providing consent on behalf of their child.
2. Please provide three versions of the assent form which cater to the wide range of ages and comprehension levels of participants, i.e. one for very young children, a version for slightly older children and another version similar to the parents’ version for the oldest child participants. This could be aligned with the different stages of questionnaires.
3. Please state at the beginning of the form, whether a translator will be available.
4. Please state how the questionnaire will be completed e.g. online or in person.
5. Please provide a separate PIS/CF for participants in the subgroup.
6. Please change the wording to say we approve the ethical aspects of the 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).*
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 Dominic Fitchett and Dr Amy Henry.

|  |  |  |
| --- | --- | --- |
| **2**   | **Ethics ref:**   | **2025 FULL 21741** |
|   | Title:  | A double-blind, placebo controlled, randomised phase II trial of probucol in Alzheimer’s disease (PIA-study): The impact on cognition |
|   | Principal Investigator:  | Dr Nigel Gilchrist |
|   | Sponsor:  | Curtin University |
|   | Clock Start Date:  | 27 March 2025 |

Dr Nigel Gilchrist and Deirdre Thompson 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 requested clarity around whether the Researchers are applying to SCOTT. The Researchers confirmed that an application has been made to SCOTT.
2. The Committee queried whether individuals with disabilities will be excluded from the study based on the answer to C19 in the submission form. The Researcher advised that this is not the case, they have good accessibility, they just do not have any extra funding specifically for disability services but do not see this as a barrier to participation.
3. The Committee queried the rationale for having the peer review completed by a chemical pathologist with expertise in lipids, rather than someone with expertise in Alzheimer’s. The Researchers advised that the medicine acts on lipids.
4. The Committee queried whether public services would be used or if a contract had been engaged for ionizing radiations. The Researcher advised that a contract had been arranged.
5. The Committee noted on page 11 under ‘Non-physical risks’, the statement “Because of side effects or the time required for tests and clinic visits while you are participating in this study, you may be unable to keep up with your normal daily activities”. The Committee noted that the inability to maintain a daily routine does have significant consequences on Alzheimer’s patients, e.g. exercise or social engagements, and that this is known to be a significant risk for people with Alzheimer’s. The Researchers clarified that interruptions to the daily routine would be very infrequent, of about three hours duration.

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 are some typos in the advertising material which need to be corrected. For example, "FAre." should be "Are”, and “concered” should be "concerned".
2. The Committee sought clarity around where the sponsor was obtaining funding from and whether this was through an NHMRC grant.
3. The Committee noted that in response to D10.1 in the submission form, it was stated that the participant information sheet/consent form (PIS/CF) “is at a level that is understandable by the general public”. However, as the participants will have Alzheimer’s or early signs of dementia, it would be appropriate to seek advice from this population group, e.g. Alzheimer’s New Zealand.
4. The Committee questioned the routine advice to avoid pregnancy, given that this is a licenced medicine and post marketing information should be available on any effects on pregnancy.
5. The Committee raised concerns around timeliness and cost of referral because of quality-of-life surveys conducted and the duty of care that researchers have.
6. The Committee noted that there should be a safety plan for researcher team members conducting visits to the participant whether these are scheduled or unscheduled.
7. The Committee questioned whether twenty participants was enough for analysis of demographic distribution.
8. The Committee noted that in the submission it was stated that there is higher prevalence of Alzheimer’s from a younger age in Māori and Pacific people and therefore questioned whether they should be targeted in recruitment.
9. The Committee noted that the DMP needs some New Zealand specific information added to the Governance section.

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

1. On page 1 after ‘sponsor’ please remove “if applicable”.
2. Please state on page 2, where this medicine has been licensed and for how long, as this information is reassuring for participants.
3. The Committee noted that Māori consultation has been undertaken, however it was felt this was not adequately translated into the main PIS. Please add on page seven following the last paragraph of “what will happen to my blood” a statement about Māori consultation and clarify that whanau support is allowed and karakia is available at the time of blood collection, and about Māori data sovereignty.
4. Please change ‘side effects’ to ‘adverse events’.
5. Please revise for spelling mistakes and typos and correct as required, e.g. on Page 9 it says “riss” instead of “risk”.
6. On page 10 please make the information about reproductive risks more concise, currently it is quite repetitive.
7. On page 11 please reword the statement “and will not cause any penalty or loss of benefits to which you are otherwise entitled” as this seems to add an unintended punitive tone.
8. On page 11 regarding costs, please remove “reasonable amount” as this indicates the amount is negotiable. Please change from paying periodically, after each visit would be more appropriate in case participants cannot afford this cost.
9. On page 14 please amend to state that it is the ethical aspects of the study that have been approved.
10. Please state in the main PIS, that karakia is not available at the time of tissue destruction.
11. Please remove tick boxes from the consent form if not truly optional.

**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 appropriate, 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 Dianne Glenn and Dr Andrea Forde.

|  |  |  |
| --- | --- | --- |
| **3**   | **Ethics ref:**   | **2025 FULL 21995** |
|   | Title:  | An Open-label, Randomized, Controlled Phase 3 Study of Disitamab Vedotin in Combination with Pembrolizumab Versus Chemotherapy in Subjects with Previously Untreated Locally Advanced or Metastatic Urothelial Carcinoma that Expresses HER2 (IHC 1+ and Greater) |
|   | Principal Investigator:  | Dr Nicola Lawrence |
|   | Sponsor:  | Seagen Inc |
|   | Clock Start Date:  | 27 March 2025 |

Dr Nicola Lawrence, Mrs Ruta Padalkar, and Azmeena S. 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 queried why there are advertisements when recruitment is described as through clinical referral. The Researcher advised that they will be included as part of the pack given to participants alongside the participant information sheet (PIS).
2. The Committee sought clarity around the process for mental health support if required. The Researcher noted that this was part of standard of care for these participants and that they would still be able to access counselling services through Cancer and Blood psychological support or the Cancer society.
3. The Committee sought clarity around who would be responsible for the cost of the ongoing scans during follow up. The Researcher advised that this would be paid for by the Sponsor.
4. The Committee queried whether the response to B10 in the submission regarding the assessment of impact on public services, related to only the Auckland site or all sites, and whether this is oncology only or includes the emergency department. The Researcher confirmed that this did just relate to Auckland, however since then they have contacted Waikato. The Researcher advised there is a process for handling most situations involving the participants through oncology, utilising the study nurse, however there may be some circumstances where the emergency department is required.
5. Based on the response to C10 in the submission form, the Committee sought clarity around the consenting process for Pasifika people, noting the importance in building trust and Vā. The Researcher acknowledged this and stated that the participants usual oncologist would typically notify them of the study and give them the PIS to take away and read. Then someone else from the study team will follow up with a phone call and if the person was interested arrange an appointment to go through the consenting process. This may be with the usual oncologist but not always and can involve the Pacific navigator where appropriate and allow extra time for discussion including interpretation into the participants first language where needed.

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 what was meant by follow up until death, when the PIS/CF states that the term of the study is five years and is what the participants are consenting to. The Researcher advised that the participants all have metastatic incurable bladder cancer, and the median survival with chemotherapy is twelve months but will follow up with the sponsor to confirm what would happen should a participant survive beyond five years.
2. The Committee queried whether the contact person is the same for all the sites. The Researcher advised that the contact details would be updated once other localities were finalised.
3. The Committee noted that, as the trial is being conducted in New Zealand, that the sponsor please consider applying to licence the medicine here should the trial be successful.
4. The Committee queried the routine exclusion of pregnant and lactating people, given that this is a terminal illness, and queried whether pregnant and lactating people would have been excluded from initial treatment.
5. The Committee also considered the routine and frequent pregnancy tests on enrolled participants to be intrusive and coercive noting that participants are advised of their obligation to avoid pregnancy and of appropriate contraceptive measures when enrolled and are also requested to advise the researchers if a pregnancy occurs.
6. The Committee noted that the Data Management Plan requires some amendments. Specifically reference to participants under sixteen should be removed, and reference to a medical office of health should be removed, more detail is required in the Governance section and check for typos.

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

1. Please remove the study schema from page 5, as it took a whole page, but the Committee felt it was not helpful for understanding.
2. The Committee noted that the PIS/CF is lengthy and if there is blank space that can be removed, and tables or diagrams which do not add significantly to the participants understanding, this should be done to reduce the number of pages.
3. On page 7 where it states, “These calendars show the days when you’ll come to the clinic.”, please put the star symbol next to this statement. Please also provide an indication for how long these visits will take.
4. On page 8 where it states, “You may be required to remove part of your clothing”, please provide clarity around the purpose of this and that it does not involve examining the urethral meatus.
5. On page 11 please reword the paragraph around contacting the GP, as it is not entirely clear whether this is in reference to a positive pregnancy test or for abnormal test results.
6. On page 15 please change ‘side effects’ to ‘adverse events’. Also change ‘toxin’ to ‘nerve damage’.
7. Please provide information about where the medication is licensed overseas, and for how long.
8. Please review the pre-screening PIS as it appears to refer to things covered in the main PIS, which can be removed.
9. Please remove ‘reasonable’ with regards to reimbursement of costs.
10. Please use ‘medicine’ rather than ‘drug’.
11. Please clarify the process for mental health support required because of quality-of-life surveys, as currently the PIS states that these would not be reviewed until the end of the study, which is not acceptable for duty of care.
12. Please change ‘poop’ to ‘poo’ to reflect New Zealand vernacular.
13. Please change ‘unborn baby’ to outcome of pregnancy

**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 Amy Henry and Ms Neta Tomokino.

|  |  |  |
| --- | --- | --- |
| **4**  | **Ethics ref:**   | **2025 FULL 22639** |
|   | Title:  | A phase 2 study of venetoclax/rituximab (VenR) re-treatment in relapsed CLL patients with disease progression following VenR as their most recent line of therapy |
|   | Principal Investigator:  | Dr Rory Bennett |
|   | Sponsor:  | Australasian Leukaemia & Lymphoma Group |
|   | Clock Start Date:  | 27 March 2025 |

Dr Francisca Reed 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 sought clarity around whether the bone marrow biopsy is for the benefit of the participant or the sponsor. The Researcher advised that it is for the benefit of the participant as they need to determine why they have stopped responding to treatment and whether there is benefit for the individual being in the trial.
2. The Committee questioned why IUCD was not listed as a contraceptive measure, but double barrier contraception was. The Researcher advised that IUCD use was associated with an increased risk of infection.

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 is some inconsistency throughout the protocol around the number of participants, please clarify.
2. The Committee noted the protocol mentions the collection of ethnicity data, please ensure the data gathered in New Zealand is consistent with New Zealand requirements, not just Australian guidelines.
3. The Committee noted that the process for reporting adverse events was not as clear for New Zealand, as for Australia.
4. The Committee noted that in answer to whether the study uses kaupapa Māori methodology the answer given is that it does, however this appears to be a mistake as this is a clinical drug trial being led from Australia.
5. The Committee noted that the answer to C19 of the submission form, “Study team will only provide reasonable reimbursement of travel costs (such as meals, accommodation) as described in the consent form and subject to the sponsor's approval” is inconsistent with the PIS which states that “travel expenses cannot be reimbursed by the study organizers.”
6. The Committee noted that the governance section of the Data Management Plan needs to be expanded for New Zealand. Also remove reference to under sixteen-year-olds.
7. The Committee questioned the routine exclusion of pregnant and lactating people, as well as those with HIV, Hepatitis B or C, given that they would not have been excluded from initial treatment with this medicine as it is standard of care, and that this is a licenced medicine.
8. The Committee questioned whether a potential participant who was found to be viremic for Hepatitis C, would firstly be informed of their viremic status, and whether they could undergo treatment and then be included in the study. The Researcher confirmed that they would be informed and that provided the viral load was at an acceptable level, they would be able to be included, especially as they anticipate that recruitment will be challenging for this trial.

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

1. Please use ‘adverse events’ rather than ‘side effects’.
2. In the contraceptive section, please provide clarification as to why IUCD is not an appropriate method for this study. Please remove double barrier contraception as this also increases risks for vaginal damage and subsequent infection. Lubricant use should be recommended with condoms for the same reason.
3. Please remove reference to ‘unborn child’ and replace with ‘outcome of pregnancy’.
4. Please review for technical language and replace with lay language where possible or provide definition. e.g. Instead of ECOG performance status – state a questionnaire to measure.
5. On page 8 please provide information about storage and destruction of test samples. Also state that karakia is not available at the time of tissue destruction.
6. On page 14 please amend the statement around reimbursement of costs, in line with what was stated in C19 of the submission form.

**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).*

|  |  |  |
| --- | --- | --- |
| **5**   | **Ethics ref:**   | **2025 FULL 22576** |
|   | Title:  | A Phase III, randomised, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of BI 1291583 2.5 mg administered once daily for up to 76 weeks in patients with bronchiectasis (The AIRTIVITY® Study) |
|   | Principal Investigator:  | Dr Dean Quinn |
|   | Sponsor:  | Boehringer Ingelheim Pty Ltd |
|   | Clock Start Date:  | 27 March 2025 |

Dr Dean Quinn and Katie Kennett 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 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 the submission “no” was ticked in response to the question whether ACC equivalent insurance will be provided, however this is a requirement, so presumably this was an error.
2. The Committee requested an insurance certificate that names New Zealand as the territory be provided.
3. The Committee requested further information about data privacy and security regarding the smartphone app.
4. The Committee noted the overrepresentation of Māori and Pacific people with bronchiectasis and queried whether they would be targeted in recruitment.
5. The Committee suggested that it would be appropriate to offer karakia at the time of tissue collection, as this would not be possible at the time of disposal, due to going overseas.
6. The Committee noted that there is an expectation that participants use highly effective contraception for five months post study, however, follow up is only for four weeks. The rationale for this discrepancy was unclear to the Committee. The Committee recommended some further follow up that aligns with the requirement to avoid pregnancy would be appropriate.
7. The Committee noted that mandatory regular pregnancy testing is overly intrusive and coercive, noting that participants are advised of their obligation to avoid pregnancy, and of appropriate contraceptive measures when enrolled and are also requested to advise the researchers if a pregnancy occurs.
8. The Committee queried the rationale for regular pregnancy testing. The Committee noted that young people with (consent form (CF) are being recruited and that there was no process in place should an unexpected positive result be found in mandatory testing. The Committee considered that mandatory testing resulted in a duty of care to provide support and protect privacy.
9. The Committee questioned the need for highly effective contraception, plus barrier contraception. The Committee noted that this investigational product is not in seminal fluid.
10. The Committee requested that the sponsor consider licensing the product in New Zealand as they are testing it here.
11. The Committee noted that the Data Management Plan refers to participants under sixteen, and a medical office of health. The Governance section requires more detail. Please amend.

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

1. Please add at the beginning that an interpreter will be available.
2. The Committee noted that the PIS is quite long, where possible please remove repetitive information.
3. Please state where overseas, including city and country, tissue samples will be sent or stored.
4. Please include data management information regarding the smartphone app.
5. Please remove reference to teaspoons of blood, as this is culturally inappropriate. Use ml’s instead.
6. Please change personal doctor to general practitioner (G.P.), as this is standard New Zealand terminology.
7. Please review for technical language and substitute lay terms where possible and/or provide definitions, for example ‘placebo’.
8. Please remove reference to ‘baby’ as a live birth cannot be assumed. Outcome of pregnancy would be more appropriate.
9. Please state the amount of the stipend and advise on tax obligations and effect on benefits.
10. Please simplify the section about withdrawal from the study, currently it is overly complicated.

**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 Mr Dominic Fitchett and Dr Geoff Noller.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 13 May 2025 |
| **Zoom details:** | 96507589841 |

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. **Other business**

The Committee noted that multiple studies today contained mandatory regular pregnancy tests throughout the duration of the study.

This is intrusive and overbearing and raises a duty of care.

It should be raised as an issue at the next chairs meeting.

The meeting closed at 1.30pm.