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| **Committee:** | Extra Meeting Health and Disability Ethics Committee |
| **Meeting date:** | 20 March 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11.30am-12.00pm | 2025 FULL 15353 | Treatment of early-stage vulvar cancer based on tumour features - STRIVE study | Dr Lois Eva | Kate O'Connor & Barry Taylor |
| 12.00-12.30pm | 2025 FULL 21004 | SB2640-CLIN-010: A research study to assess the safety and efficacy of Denifanstat in adult patients with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) and F2/F3 fibrosis | Dr David Orr | Maakere Marr & Patries Herst |
| 12.30-1.00pm | 2025 FULL 22380 | Phase 2 Study of V940 and Pembrolizumab in Advanced Melanoma (V940-012) | Dr Gareth Rivalland | Maree Kirk & Nicola Swain |
| 1.00-1.30pm | 2025 FULL 20608 | Optimising Prednisolone dosE in Nephrotic syndrome (OPEN) trial | Dr Chanel Prestidge | Kate O'Connor & Patries Herst |
|  | *Break (30)* |  |  |  |
| 2.00-2.30pm | 2025 FULL 22042 | MK-2400-01A Substudy of I-DXd-based Treatment Combinations or as Monotherapy in mCRPC | Dr. Peter Fong | Maakere Marr & Nicola Swain |
| 2.30-3.00pm | 2025 FULL 21456 | CP MSK Health Network | Professor Ngaire Susan Stott | Maree Kirk & Barry Taylor |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Kate O’Connor | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Ascc. Prof Nicola Swain | Non-lay Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Maakere Marr | 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 |

## Welcome

The Chair opened the meeting at 11.00am with a karakia and welcomed Committee members for this extra Committee.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

As this is an ad hoc meeting not part of the usual schedule, no previous minutes were reviewed.

## New applications

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| **1** | **Ethics ref:** | **2025 FULL 15353** |
|  | Title: | STRIVE: An international, multicentre, phase II randomised control trial based on a 2:1 randomisation for HPV- Independent (HPV-I) vulvar squamous cell carcinoma (VSCC) and a prospective trial for HPV-Associated (HPV-A) VSCC. |
|  | Principal Investigator: | Dr Lois Eva |
|  | Sponsor: | Australia New Zealand Gynaecological Oncology Group (ANZGOG) |
|  | Clock Start Date: | 07 March 2025 |

Dr Lois Eva and Anna Bendrikovskaia 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 a clear margin of less than 8mm and asked if there is a lower cut-off point, at which stage further surgery was required. The Researcher clarified that recent research suggested even a 1-2 clear margin was sufficient for HPV positive lesions. Treatment varies depending on the unit, or individual clinicians.
2. The Committee noted the questions raised in the peer review regarding the rationale, and the Researcher responded that a recent study published p53 data which answers the rationale questions directly.
3. The Committee noted the option to receive genetic results and queried that these would be provided in a way that the participant would understand. After discussion, the committee was reassured that results provided would be with consultation and potential referral to the genetics department as required.
4. The Researcher confirmed patient reported outcomes will be filled in during visits on a study tablet, and any raised flags around anxiety and depression would be noted immediately and followed up.

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 reading the participant information sheet, it is difficult to determine whether a patient would have sufficient, clearly presented information to decide whether they want to take part in the study. HPV negative cancers have a worse prognosis, needing a more aggressive approach than HPV positive cancers. Continued research shows that the size of clear margins may be important for HPV negative cancers but not HPV positive cancers. Repeat surgery has significant morbidities. Current standard of care is based on where patients seek treatment. The Committee suggested that the participant information sheet (PIS) should summarise how knowledge regarding the risks and management of the two types of cancers has evolved to give context to this research. As there will be two sites, please ensure the PIS is specific to those sites to describe what is current practice and what is different for patients who decide to participate.

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

1. Please simplify the PIS, avoid repetition, use diagrams and flow charts where possible.
2. On page 4, the explanation of genetic and genomic testing is not as well explained as it is in the protocol and can be simplified from the Canadian phrasing.
3. Confirm that the genetic section includes a genetic testing warning that it could affect other family members, a cultural statement and the implications for insurance companies.
4. Check inclusion of mobile data. This may not be needed if reported outcomes are collected at visits.
5. Currently the reimbursement paragraph states that the participant “needs to apply for food and travel assistance’ – please amend to state that usual visits and travel assistance is provided by their Te Whatu Ora district. Just remove this if it is not related to the study.
6. The PIS currently says that questionnaires are not going to be seen by anyone until the end of the study. It should include that these will be seen and followed up if there are red flags. Note that a lot of this information is collected at appointments anyway and concerns will receive the standard follow up.

**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 Kate O’Connor and Mr Barry Taylor.

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| **2** | **Ethics ref:** | **2025 FULL 21004** |
|  | Title: | A phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of denifanstat in patients with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) and F2/F3 fibrosis (FASCINATE-3) |
|  | Principal Investigator: | Dr David Orr |
|  | Sponsor: | Sagimet Biosciences |
|  | Clock Start Date: | 07 March 2025 |

Dr David Orr, Eduardo Martins, Christine Crooks, Katharine Grimmer and Marie O’Farrell 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 study design has up to 238 weeks on placebo which is a long time when the primary outcome is efficacy at 1 year. The Researcher advised that they do not expect to see results until the longer term, the 1 year is an interim analysis. Week 52 is the interim end point to be submitted first. The Committee queried whether there are any effective alternatives approved and funded for this condition in New Zealand. The Researcher advised there are not. The Committee queried at what point in 238 weeks will the researchers start to be out of equipoise and get a good signal that the people in the placebo group are doing worse than the people on the intervention. The Researcher noted the assessment would be from clinical signs and symptoms associated with the disease as well as lab results. If these are consistent with disease progression, it would be classified as a protocol outcome. The Committee requested that if there is an arm in the study that seems to be staying out of progression, that there is intention for cross over to an Open Label Extension study or to the intervention arm. The Researcher noted the company has committed to provide the drug for life for participants that join the study no matter which arm, if the drug is proven to be effective at the end of 238 weeks. The Researcher also noted that at week 52, anyone who has progressed to cirrhosis will come off the study. Progression of MASH is very slow, from mild to moderate can take 5-10 years which is why the study needs to be this long. The Medical opinion of the CI is that he is quite comfortable with this length which is consistent with previous studies.
2. The Committee questioned why in the first part of the study 100 participants have half the dose. The Researcher explained it is an exploratory arm, in the possible yet uncommon event where a participant needs a dose reduction from 50 to 25, they would like to have information of a subset of patients of how the drug performs from the first intake. This can be done without unblinding to address hair thinning concerns.

Summary of outstanding ethical issues

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

1. In the submission, Kaupapa Māori was ticked yes, bear in mind it is not and change accordingly in future.
2. Regarding ethnicity data, make sure local sites collect New Zealand data, as per Statistics NZ categories.
3. Advertising material, please correct Māori words used, missing macrons which changes understanding of the word.

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

1. Please clarify that ongoing access to the drug will be available, after the study is completed, to all participants regardless of which arm of the study they were on.
2. Remove references to teaspoons and use mls. Use of eating implements is culturally insensitive.
3. On Page 11 where the full physical exam is mentioned, state they can request a same gender health professional and can have a support person with them.
4. Review for gender neutral language, e.g. just say ‘participants of child-bearing age’
5. When writing reimbursement or payment conditions, don’t mention ‘time’ unless you are going to handle the tax implications. Be clear what they are going to receive, how soon they will receive it, why they receive it (reimbursement of expenses etc).
6. On Page 21 ‘alternative treatments’ please remove everything and just leave the last sentence on the page.
7. Currently it states Identifiable data is kept for 25 years please adjust; 15 years typical for cancer related studies.
8. Point 3, in the study design is using the international numbers for randomising and not also the New Zealand context. Describe randomisation as # out of # chances to get placebo.
9. Please change “local market” to 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).*

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

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| **3** | **Ethics ref:** | **2025 FULL 22380** |
|  | Title: | A phase 2, Randomized, Double-Blind, Placebo- and Active-Comparator-Controlled Clinical Study of V940 (mRNA-4157) Plus Pembrolizumab Versus Placebo Plus Pembrolizumab in Participants With First-Line Advanced Melanoma (INTerpath-012) |
|  | Principal Investigator: | Dr Gareth Rivalland |
|  | Sponsor: | Merck Sharp & Dohme (Australia) Pty Ltd (MSD) |
|  | Clock Start Date: | 07 March 2025 |

Dr Gareth Rivalland and Sunny Bu 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 note that Harbour cancer is a private clinic and sought assurance that there is an equality of access to this trial for patients who can’t afford private care. The Researcher advised that there are no barriers, travel and accommodation is paid for so people around the country can participate, and the researchers reach out across the country as best they can with their colleagues in public and private hospitals.
2. The Committee queried what is current Standard of Care (SOC). The Researcher advised that Pembrolizumab is current SOC, the control arm is what people would get in the public system. The extra immunotherapy is made by Moderna in the USA, a sample of tumour tissue is sent overseas where tumour-specific proteins are extracted, to produce and encapsulate the mRNA that encodes these proteins, tailored to the individual patient.
3. The Committee asked for an explanation of locality approval process as a private clinic. The Researcher advised they run an internal process looking at capacity, contractual obligations (such as sample storage), resourcing, local safety and HDEC regulation, before it goes through a governance group with oncologists with trial experience alongside business capability. Once they have all approvals, then it goes through Māori consultation which has been done.
4. The Researchers confirmed the trial is 7 years long.

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 the Researchers check all documentation and ensure acronyms explained the first time they are used.
2. The Committee noted that New Zealand data was not presented for melanoma rates in application and to bear in mind that this is how they expect parts of the submission form to be answered.
3. The Committee highlighted the Americanised language about legal representatives in protocol and in the participant information. The Committee reminded the Researcher that these don’t apply in New Zealand for clinical trials.
4. The Committee requested the following changes to the Data Management Plan (DMP) (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a):
   1. 8.1 states ‘Participants GP or appropriate specialist’. Please change to ‘and’
   2. 8.4 has incomplete listing of labs. Please expand on these.

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

1. Please clarify if samples are collected and already stored in a lab, or if they are being collected for the trial.
2. It should be stated that Pembrolizumab is funded and available in New Zealand for this type of cancer and participants would get this without being in the trial. Currently it says available in the US and provides no context for New Zealand participants.
3. On Page 19 the Section for use of new technology talks about phone and tablets which doesn’t seem like new technology. If these are for the ePRO done at site with site equipment at a visit, then this should be made clearer. This section is more for if you are using AI or machine learning, so check that is the best header for this.
4. Please clarify the study is providing a tablet at visit on site for questionnaires.
5. Include that the participant’s GP will be notified of participation for New Zealand participants.
6. Please move availability of interpreter statement to the front.

**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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| **4** | **Ethics ref:** | **2025 FULL 20608** |
|  | Title: | A multicentre, randomised, controlled trial to optimise treatment of steroid-sensitive nephrotic syndrome in children - OPtimising dosE in Nephrotic syndrome (OPEN) Trial |
|  | Principal Investigator: | Dr Chanel Prestidge |
|  | Sponsor: | Flinders University |
|  | Clock Start Date: | 07 March 2025 |

Evan Corrigan and Dr Nick Larken were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the study is International but not sponsor-initiated and is presented as investigator-initiated. The Committee also noted they are happy with the scientific peer review provided by the grant funding body.
2. The Committee noted that recruitment is going to be from local patient databases and clinic posters. The Researcher confirmed that all patients will be known to the Starship team and are likely to be recruited from that and there is no need for posters.
3. The Committee queried why New Zealand is not taking part in the health economics part. The Researcher advised this was because they couldn’t be assured that they could share and access that data securely.
4. The Committee noted that if the semi structured interviews are being done in New Zealand, an amendment with their information sheets will be needed.
5. It was confirmed there will be a koha if budget allows and it will be provided to the child as a voucher.
6. It was confirmed that an application is going to SCOTT.
7. It was clarified the 33 years retention is due to storing for fifteen years after the youngest child turning 16.

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 sought information about the participants, specifically what the average age of patients with this condition is. The Researcher advised about 8 years. It is a disease exclusively in children, more so 2-12. Some of the families have extensive experience with this condition. Families are trained to deal with relapses and can be helped over the phone. Tapering off or starting doses is where clinical involvement happens. Kids usually feel okay but if not treated well it can be a serious outcome with up to 70% mortality. The Committee noted that the participants are quite expert in their condition. Therefore, the older children’s information could be more sophisticated given that these young people are somewhat expert in managing their condition. They need to know what is different about being in the study. Parents PIS has a lengthy explanation of red and blue bottles that is the kind of information that older children should have too to give them some agency.
2. The Committee queried whether the children or parents will be completing the Quality-of-Life questionnaires. The Researcher advised it is written for the parents, but given the above, they acknowledged older children could do it themselves. Distress and mood are screened for in these participants as part of their standard of care (SoC) and there is a paediatric referral process at the hospital.

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

1. The younger child form can include some more information, for example, what form the medication will be in.
2. There is a flow chart in the protocol that shows dose groups and randomisation, that would be a useful addition to information sheets (older children and parents).
3. Please state what happens if the participant relapses during the observation period, i.e. that it gets collected as an event and they get treated as per SOC.
4. Clarify how long the study goes on for and what happens if a 15-year-old has their 16th birthday during the study. Also, it is usual practice for 16-year-olds to be reconsented as an ‘adult’.
5. Assent forms for older children should sign or write their name, younger children can tick a box or circle a smiley face.
6. For the Data section, please use the [HDEC template statement](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) wording to distinguish identifiable and coded data, lifecycle, who has access etc. which data is staying in hospital and which is being sent overseas.
7. In the Adult PIS, it allows withdraw of data early in the study. In an intervention study, it is legitimate to retain the data from participants who have withdrawn from the study. Make this clear.
8. State Parent and Guardian not caregiver for this PIS. There are uses of ‘you and your child’ which are not always sensical, such as ‘you and your child may experience side effects.’ P8 state that health data is taonga, not potential.
9. Please adjust the statement surrounding access of Māori organisations to data is to do with relevant approved projects.
10. Please check use of tense throughout the document.

**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 Kate O’Connor and Dr Patries Herst.

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| **5** | **Ethics ref:** | **2025 FULL 22042** |
|  | Title: | MK-2400-01A Substudy: A Phase 1/2, Open-label Umbrella Substudy of MK-2400-U01 Master Protocol to Evaluate the Safety and Efficacy of Ifinatamab Deruxtecan-based Treatment Combinations or Ifinatamab Deruxtecan Alone in Participants With Metastatic Castration-resistant Prostate Cancer (mCRPC) (IDeate-Prostate02) |
|  | Principal Investigator: | Dr. Peter Fong |
|  | Sponsor: | Merck Sharp & Dohme (Australia) Pty Ltd (MSD) |
|  | Clock Start Date: | 07 March 2025 |

Dr. Peter Fong and Vaidehi Chaporkar 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 stated that it makes sense that where sub-studies are submitted under a master protocol, to keep going back to the HDEC that approved the master protocol. This can be requested on the application form. Also provide the master protocol with each new sub-study to help new reviewers get a sense of the bigger picture.
2. The Committee queried how this treatment will be offered equitably. The Researcher advised once the study opens, anyone who fulfils the eligibility criteria will be spoken to about it so long as they satisfy the criteria. There are four clinics a week, all four consultants will have recruitment in their minds. These clinics cover 80% of the country. Everyone who is eligible will be offered it.
3. The Committee queried what are the comparators, is this Standard of Care (SOC), is there benefit in the non-experimental arm. The Researcher confirmed it is SOC offered in other arms and a potential benefit would be that they have more visits and CT and bone scans and more follow up of their cancer.
4. The Committee queried who would be funding the extra scans. The Researcher advised that resources used by the study is contracted out to a private company by the Sponsor and not using public resources.

Summary of outstanding ethical issues

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

1. Please remove references to ‘treatment’ and instead state study drug or similar.
2. Please include a clear statement how being in the study differs from the usual care that would be received at this hospital. So are there extra visits, tests, samples taken, etc. It is helpful to bring that upfront.
3. Include a chart which illustrates all the interventions and visits.
4. Please add a lay title.
5. Please describe what the drug is proposed to do in lay terms (like shrink the cancer, etc).
6. Please confirm the reimbursement option, also provide additional information such as when the participant will be paid. Avoid references to time, as this is taxable.
7. Ensure it is clear when stating other treatments for prostate cancer that these are for allowing the patient to know the difference between standard of care on offer, and what participation would involve.

**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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| **6** | **Ethics ref:** | **2025 FULL 21456** |
|  | Title: | The Australasian Cerebral Palsy Musculoskeletal Health Network |
|  | Principal Investigator: | Professor Ngaire Susan Stott |
|  | Sponsor: | The University of Queensland |
|  | Clock Start Date: | 07 March 2025 |

Professor Ngaire Susan Stott and Alexandar Sorhage 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 when the visits would be occurring. The Researcher noted that these participants will come to the hospital multiple times per year, so the intention is to align study visits with existing appointments.
2. The Committee noted that the peer review refers to cohort B, but this is not part of the HDEC review.

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 some of the wording in the advertisement and participant information sheet is overpromising and misleading, please reframe.
2. The Committee noted that in the protocol, the Tanner staging has the parents filling in the form. They noted an older child could do it themselves, or a research nurse rather than the parent. Please consider the way it is set up in the protocol and if there is a better way than asking the parents to do it.
3. Please contact the University research ethics office to discuss whether the University or Starship should sign off as sponsor.
4. Please provide a statement explaining the purpose of sun exposure diary.
5. Please add instructions for filling out the pain profile.

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

1. Please add on page 8 that the participants GP will be notified of their involvement in the study.
2. In New Zealand there is no requirement to fill out a form to withdraw from the study. Please ensure the requirement for writing is removed.
3. Please add a summary statement at the bottom of the assent form which describes what they are assenting to.
4. Assent forms can be older child and younger child rather than specifying ages and then just provided as appropriate for the individual child.
5. Add a statement about potential future benefit for other children.
6. Please advise that if distress was identified from the questionnaires, then a referral would be made, and their GP notified.
7. Please remove reference to the NZ Health Act.

**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. All submissions submitted to this agenda that receive approval or subsequent approval will be assigned to Northern B HDEC for post-approval monitoring.

The meeting closed at 2.55pm