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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 March 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11.00-11.30am |  | Committee Welcome |  |  |
| 11.30am-12.00pm | 2025 FULL 21571 | Exploring therapy treatment experiences of adolescent girls and adult women who have undergone a treatment programme for harmful sexual behaviour. | Dr Tess Patterson | Alice / Leesa |
| 12.00-12.30pm | 2025 EXP 22258 | Popliteal and saphenous nerve block versus a modified ankle block for acute post-operative pain following ankle fracture fixation (APPLE): a single blinded randomised controlled trial | Dr Wayne Hoskins | Catherine / Patries |
| 12.30-1.00pm | 2025 FULL 22270 | Efficiency of wound closure on split-thickness skin graft (STSG) donation sites using TRTx wound support gel. | Dr Terry Creagh | Kate / Amber |
| 1.00-1.30pm |  | Break (30 mins) |  |  |
| 1.30-2.00pm | 2025 FULL 22197 | The Brain Injury Screening Tool in children (BIST-child) | Dr Jimmy Chong | Alice / Barry |
| 2.00-2.30pm | 2025 FULL 21951 | Ready to Eat: Intervention for Tamariki to move from tube feeding to eating | Dr.  Sarah Leadley | Catherine / Amber |
| 2.30-3.00pm | 2025 FULL 22124 | Enhancing Therapies for People with Dementia | Dr Rebecca Sharp | Kate / Leesa |
| 3.00-3.30pm | 2025 FULL 22110 | Enhancing Rehabilitation Participation for People with Brain Injuries | Dr Rebecca Sharp | Kate / Leesa |
| 3.30-3.45pm |  | Break (15 mins) |  |  |
| 3.45-4.15pm | 2025 FULL 22144 | A Study of Safety, Efficacy and Tolerability of BGB-45035 in participants with moderate to severe Eczema and Prurigo Nodularis | Dr Arna Letica | Alice / Amber |
| 4.15-4.45pm | 2025 FULL 22205 | HS-20118-101: A Study to Evaluate Single and Multiple Doses of HS-20118 in Adult Subjects | Dr Paul Hamilton | Catherine / Barry |
| 4.45-5.15pm | 2025 FULL 21415 | Hapai: immunotherapy closer to home | Dr Helen Wihongi | Kate / Patries |

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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 |
| Mrs Leesa Russell | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Alice McCarthy | Lay (the Law) | 22/12/2021 | 22/12/2024 | Present |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Apologies |
| Ms Catherine Garvey | Lay (the Law) | 19/03/2019 | 19/03/2022 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |

## Welcome

The Chair opened the meeting at 11.00am and welcomed Committee members, noting that apologies had been received from Ms Maakere Marr.  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Catherine Garvey and Dr Patries Herst 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 04 February 2025 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2025 FULL 21571** |
|  | Title: | Understanding the treatment experiences and needs of females who have engaged in harmful sexual behaviour. |
|  | Principal Investigator: | Dr Tess Patterson |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 20 February 2025 |

Dr Tess Patterson and Linda Hobbs 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 HDEC only have jurisdiction for New Zealand participants, so if the Australian arm wants to use the HDEC approval, that should be subject to their own requirements and consideration.
2. The Committee clarified the referral of these patients for treatment and how long treatment is with the Researcher.

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 they want to limit inclusion criteria to young people aged 16 and over because they can consent for themselves. The Committee stated it was fearful that if the research involves a girl younger than 16, that the additional involvement of the parents to consent paired with their assent employs some power dynamics that may be quite harmful. There is provision for young people to consent for themselves in NEAC National Ethical Standards if they are competent to understand the risks, but it does rely on a professional to assess this. This could be explored later as an amendment if the Researchers agree to make the cut off as age 16 and over. The Researcher noted their agreement with this. From here on, the review will assess this as for people 16 and over, removing the younger participants from the submission.
2. Māori and Pacific are overrepresented in research population, but there is no indication of how this study will cater to these specific needs. Please ensure the study is getting a representative sample of these populations, and outline more specifics surrounding responsiveness, how whakamā will be handled, inter-generational trauma, etc.
3. Please document and provide a safety protocol to ensure the Researcher is safe for the interaction in person. This should include things like someone else knowing where they are and can be called if there is a problem. The Committee needs to see this stepped out.
4. The Committee discussed the recruitment strategy with the Researchers, highlighting that the standard university approach may be inappropriate for research involving very sensitive topics. The recruitment process needs to be more supported given the subject of the research, and the Committee requested it is clarified and more detailed in the documentation how this could be more tailored, such as a face-to-face approach and how this process can be engaging and responsive.
5. The Committee requested that the documentation be more descriptive about where in person interviews will take place, and document how the Researchers will maintain confidentiality for attending in person. Please describe how the person is led through by someone and is discrete if it’s onsite to ensure participants feel safe.
6. The responses in the application state that participation is unlikely to be distressing, but the topic of the research does not seem like this would be the case. The Committee queried what evidence there is it would not be. The Researcher responded that after the period in which these participants are approached, distress is unlikely for their participation. The Committee acknowledged this but requested some plan in place for what will happen if someone is distressed, especially if they will not be in person.
7. The Committee noted that removing names from transcripts of who it belongs to is not de-identifying the data fully. Content of the transcripts could be potentially identifiable, such as names supplies or even specific events that could be associated with someone. The data management plan and protocol need more detail around how this will be fully de-identified, or, if this is not possible, adjust all documentation to reflect what steps are taken to reduce identification but fully de-identifying information is not possible.
8. The Committee queried if the transcription service being used is safe and confidential. The Researcher confirmed that the IT security team at the University has signed off this service as safe. The Committee however requested clarity around whether the transcription is done by AI or whether this is done by a person. If by an AI, please provide assurance that it is not retaining information for learning-purposes. If this is a person/people, please provide assurance that they are well-versed in emotional consequences of transcribing these conversations and what protections are in place for them.
9. Protocol currently only states confidentiality and storage of data aligning with HDEC requirements and institutional/organisational policies. This also needs to align with and refer to New Zealand law. In addition, there is a difference between New Zealand and Australian privacy laws. When transferring New Zealand data to Australia, assurance must be provided that New Zealand data will be protected in Australia with the same level of assurance as it would here as per an agreement with the Australian site(s). If this can or cannot be done, this must be made clear to participants.
10. The Committee noted that the Researcher should consult with participants on what is considered identifiable in their transcript to ensure protection of vulnerable people. Please also consider how summary of results will be sent out in a way that doesn’t disclose participation – inclusion of the study title for example will be considered sensitive.
11. The Committee noted the intellectual disability exclusion and that does not always mean that they cannot provide their own informed consent, especially with supported decision making. Given that a portion of potential participants may have these, these could be excluded far too broadly if they are an important group to include. Similar to the consent for under 16, this could be done through a later amendment if the Researchers feel the research is missing an important voice.

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

1. Withdrawal statement needs to discuss that there are options around whether their data stays or is destroyed. This is currently only presented as YES/NO options in CF and not explained further.

**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).*
4. Please provide more detail in study documentation to ensure participant safety if there are potential concerns with their well-being raised as part of this study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4-8.6, 8.9)*
5. Please provide a researcher safety plan addressing the concerns raised by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).*
6. Please update the data management plan, taking into account the feedback provided by the Committee*.* *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Alice McCarthy and Mrs Leesa Russell.

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| **2** | **Ethics ref:** | **2025 EXP 22258** |
|  | Title: | A Prospective, Randomised Trial Evaluating popliteal and saphenous nerve block versus a modified ankle block for Pain Control of Operatively Treated Ankle Fractures |
|  | Principal Investigator: | Dr Wayne Hoskins |
|  | Sponsor: | Te Whatu Ora Te Tai Tokerau |
|  | Clock Start Date: | 20 February 2025 |

Dr Wayne Hoskins and Adam Payne 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 recruitment will be done by a member of the research team not involved in the direct care and procedure of the participants.
2. The Committee noted for future that the requirements around evidence of independent scientific peer review is that they must provide comments discussing the scientific merits of the study to assure the Committee it is scientifically valid.

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 Researcher clarified current practice is not standardised, so pain management will be at discretion of surgeon and anaesthetist if they do not participate, otherwise they are randomised as part of the study. It was clarified further that the inclusion/exclusion criteria will ensure no one will be randomised into something not appropriate. The Committee requested there is a clear explanation in participant information sheet (PIS) that some doctors don’t use regional at all, so in study you definitely will in one of these two ways, but if not, it may not be this.
2. The Committee clarified with the Researcher that the extra phone call at 3 days post discharge is additional to standard of care. Please include in the PIS who will give them the call and what they will be asked.
3. The data management plan (DMP) under 8.2 states ‘The CRO and Sponsor, for study conduct, data analysis and pharmacovigilance purposes, product registration and marketing, or as otherwise permitted by applicable local and international laws and regulations.’ If this is not pertinent to the study, please remove.
4. The Committee noted to add Te Whatu Ora as Sponsor to PIS and DMP (currently states “N/A”).

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

1. Please review for consistency when referring to the participant – please ensure it says ‘you’ as this is directed to them.
2. On page 3, under the explanation of why you are doing the study, is not entirely clear and says the same thing twice. A picture or diagram would help explain the rationale for the study.
3. Page 5 lists rare side effects. Please quantify that in some way or explain these have never encountered it in the clinic but is possible.
4. Add who else other than researchers have access to information as said in the CF and DMP.
5. Please review for repetition of statements and words.

**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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| **3** | **Ethics ref:** | **2025 FULL 22270** |
|  | Title: | A pilot study to assess the efficiency of wound closure on split-thickness skin graft (STSG) donation sites using TRTx wound support gel. |
|  | Principal Investigator: | Dr Terry Creagh |
|  | Sponsor: | Te Whatu Ora Waitaha Canterbury |
|  | Clock Start Date: | 20 February 2025 |

Professor Rudi Marquez-Mazlin and Elle Coberger 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 raised that this is stated investigator initiated, however the Committee noted that balance of benefit goes towards the company who make the gel. The Committee require evidence of ACC-equivalent insurance. Participants also need to be informed that this has commercial benefit. Language contained in the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates) can be used. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1, 17.3-17.6)*
2. The Committee requested the Investigator’s Brochure (IB) for the gel in order to cover how this interacts with the body and clarify any interactions with the blood stream if any. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4-8.6)*
3. The Committee stated the protocol needs to outline how randomisation occurs. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8)*
4. There is a lack of information in protocol and participant information sheet (PIS) about what the gel does. Website information publicly available indicates the mechanism in more detail, which implies that it being just a topical cream isn’t entirely accurate. While observations have been made in a small dose, it is not currently clear that it won’t get into the blood if a large amount of surface will increase the dose and therefore increase the risk. This needs to be stepped out, and the provision of IB may help answer this *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17, 8.4-8.6, 9.8)*.
5. The data management plan (DMP) needs reviewing as the template has not been customised to project with irrelevant statements kept in.
6. The Committee reminded the Researcher that the study needs to be registered with a WHO clinical trials register.
7. After discussion, it was clarified that the company making the gel will be the sponsor and hospital the locality, and the university needs to be determined their role. The study’s DMP is the place to clarify these roles.
8. The Committee requested assurance about a safety committee and stopping rules. Please provide a formal process and documentation in place around that. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25)*
9. The Committee requested peer review from a wound healing expert or similar as this is first in human. The committee considers that as a therapeutic product that ‘meets the criteria for SCOTT review as this gel is a therapeutic product that influences, inhibits, or modifies a physiological process – angiogenesis – review from the Standing Committee on Therapeutic Trials (SCOTT) may be required. . *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.28)*
10. Please ensure the study protocol is clear about the study design i.e. how randomisation occurs, or not, and whether assignment to a study arm can be blinded.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. The information sheet is missing information about the control arm and what their participation involves.
2. As this is a commercial trial, please remove the ACC statement and replace with a commercial statement. The [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates) wording can be used.
3. A more neutral stance is required for the PIS. Written currently like its world-changing and can be coercive. Currently don’t know the benefits in humans.
4. State that the participant’s General Practitioner (GP) will be informed in event of clinically significant abnormal findings/concerns. Delete optional tick-box in relevant CF clause as this should be mandatory.
5. If this is randomised, then the study should not allow withdraw of data to preserve study quality. If a certain subset all withdraws and they take data with them, then information will be missing in analysis.

**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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| **4** | **Ethics ref:** | **2025 FULL 22197** |
|  | Title: | The predictive validity of the Brain Injury Screening Tool (BIST) for 8–16-year-olds who have a mild traumatic brain injury in an inpatient setting |
|  | Principal Investigator: | Dr Jimmy Chong |
|  | Sponsor: | Te Whatu Ora Te Toka Tumai Auckland |
|  | Clock Start Date: | 20 February 2025 |

Dr Jimmy Chong 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 Researcher confirmed the screening tool is standard of care (SOC) in adult populations. Predictive validity for this age group is currently unknown.
2. The Committee queried consultation, and after discussion were satisfied that as part of locality authorisation, that appropriate Māori consultation will be undertaken before its signed off.

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 if the digital tool had received sign off from Te Whatu Ora. After discussion, it was confirmed that the tool has not yet received sign off but would not be used until it does.
2. The Committee clarified long term follow up is extra to standard of care done by research officers hired by hospital research office. A home visit safety protocol is required to be provided to HDEC for how they will be kept safe.
3. The CI has signed off as local Sponsor on the submission form which isn’t appropriate but confirmed that the hospitals will each sign off as Locality. Sponsor sign off of hospital can be amended as part of response to provisional approval.
4. The Committee noted that questionnaires and assessment tools are not provided for the Committee to review. Please provide them.

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

1. The Assent form for 8–11-year-olds is too wordy. It would benefit from having pictures or diagrams.
2. The Adult PIS talked as if they are only participating but they are also consenting for their child, so just clarify that they are consenting for their participation AND their child to also participate.
3. ACC statement from relevant sheets can be removed, as an observation study there is no risk of treatment injury.
4. Identify sites as Locality, not just broadly ‘New Zealand.’
5. Include obtaining consent to notify GP if there are abnormal results in relevant sheets.
6. Mention the koha offered under ‘will the study cost anything’.
7. Page 3 of the Main PIS states ‘We will only be holding anonymous (de-identified) information ...’ . There is a difference between anonymous and coded or de-identified data: anonymous cannot be re-identified. Be specific here as to whether it is de-identified (coded) or anonymous. Also be clear if it will be coded or de-identifies it could still potentially be linked.

**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 provide a researcher safety plan addressing the concerns raised by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Alice McCarthy and Mr Barry Taylor.

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| **5** | **Ethics ref:** | **2025 FULL 21951** |
|  | Title: | Ready to Eat: Intervention for tamariki to move from tube feeding to eating |
|  | Principal Investigator: | Dr Sarah Leadley |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 20 February 2025 |

Dr Sarah Leadley and Mikyla Welsh 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 the recruitment process and involvement of the students. The Researcher clarified that all students involved in the study will meet the families ahead of time unless the timing means they have already started with the CI. If families were uncomfortable with meeting with students, there is option to express that. In terms of training, they will shadow the CI and observe during the first phase and gets hands on supervision and training. CI is still seeing families often. This is a model that has been used before successfully.
2. The Committee queried if the 6-month waitlist will prevent them from getting other help or chances to re-assess them and is there an opportunity at certain time points to assess whether they’re participants. The Researcher responded that usually they will visit every 2 months for check-ins. Clinical need will be prioritised.

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 for 1–4-year-olds there is an assent form, and queried whether this is meaningful with respect for the child. With 3- and 4-year-olds, more verbal description and sometimes with pictures will be employed. The Committee stated to ensure that so long as their assent is in some way noted and their obvious unwillingness to participate is honoured, this can be recorded in a manner appropriate.
2. The advertising should include the HDEC ethics reference.

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

1. Participation involves significant engagement so please increase the koha value.
2. Be clear that clinical needs take priority when it comes to the wait list and that they should talk to their health professionals if they want to know what to do while they wait.

**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 22124** |
|  | Title: | Enhancing Therapies for People with Dementia |
|  | Principal Investigator: | Dr Rebecca Sharp |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 20 February 2025 |

Dr Rebecca Sharp was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified involvement of Masters students with the Researcher, clarifying that it still remains under the CI’s responsibility, and the Masters students would work with the participants.
2. The Researcher clarified who the providers were and the established relationships.

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 following changes to the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8):*
   1. Please clarify how the change or tweak to a person’s rehabilitation is chosen for specific patient/participant and how will researchers know that it is safe and will not cause harm.
   2. Some places in documentation talks about behaviours that may impede engagement with rehab. Clarify who decides what these are. One would want to be mindful of discrimination in this space e.g. good patient vs bad patient. The wording can be reframed as ‘patients who are not engaging in rehab to get the best out of it’ with less focus on the behaviour of the patient.
   3. Please include mitigations for risk of fatigue and those who feel surveilled and observed.
   4. The consenting process seems to outline that the researchers will consent the person first and then approach their whānau/support. If the latter doesn’t consent, this will affect the person already consented. Clarify whether someone can participate without the participation of their whānau/support person.
   5. Adverse events are not risks to participants. Plan for risks for researchers and a plan for risks to researchers and a plan for what goes wrong in study.
   6. Provide further detail surrounding what would result in exclusion, such as if there is a condition of a participant that would result in the determination that they cannot provide fully informed consent, etc.
   7. Clarification is required on what is happening for the study and what residents are responding to. Please clarify for consistency across all documentation that only those who can provide consent, either on their own or supported will be included and you will be excluding people who lack capacity to consent. Whānau are consenting only for their own participation and are not providing a proxy consent. Across documentation, please provide concrete examples of what these changes may involve, and assure that the individualised changes to therapy will not affect anyone else.

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

1. The easy read version talks about making everyday activities more engaging and exciting, but the full version states " finding out the effectiveness of common therapies carried out in dementia care homes." These are different objectives, although the full PIS drifts into observing 'activities'. Please be clear that not all activities are therapy.
2. The organisational PIS is vague about distinguishing therapy and activities but adds ‘environmental enrichment' into the mix as well. If factors in the broader environment are changed, then non-consenting participants will be subject to the these. Please clarify what is intended here.
3. The whānau PIS needs to tightly distinguish what the involvement of whānau is i.e. their thoughts about the therapy in relation to their family member. It drifts into being akin to a proxy consent and discusses ‘your client’ which should be amended.
4. Give examples of what could be included as an intervention or change for participants.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Mrs Leesa Russell.

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| **7** | **Ethics ref:** | **2025 FULL 22110** |
|  | Title: | Enhancing Rehabilitation Participation for People with Brain Injuries |
|  | Principal Investigator: | Dr Rebecca Sharp |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 20 February 2025 |

Dr Rebecca Sharp was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified involvement of Masters students with the Researcher, clarifying that it still remains under the CI’s responsibility, and the Masters students would work with the participants.
2. The Researcher clarified who the providers were and the established relationships.

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 following changes to the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8):*
   1. Please clarify what changes could be considered as a change to standard practices, such as change to physical environment or the change in delivery/ equipment that’s used, or a change in the way the people delivering the activity approach that activity. These examples would be useful in the information sheet as well.
   2. Please clarify how the change or tweak to a person’s rehab is chosen for specific patient/participant and how will researchers know that it is safe and will not cause harm.
   3. Some places in documentation talks about behaviours that may impede engagement with rehab. Clarify who decides what these are. One would want to be mindful of discrimination in this space ‘good patient vs bad patient exclusion. The wording can be reframed as ‘patients who are not engaging in rehab to get the best out of it’ with less focus on the behaviour of the patient.
   4. Please include mitigations for risk of fatigue and those who feel surveilled and observed.
   5. The consenting process seems to outline that the researchers will consent the person first and then approach their whānau/support. If the latter doesn’t consent, this will affect the person already consented. Clarify whether someone can participate without the participation of their whānau/support person.
   6. Adverse events are not risks to participants. Plan for risks for researchers and a plan for risks to researchers and a plan for what goes wrong in study.
   7. Provide further detail surrounding what would result in exclusion, such as if there is a condition of a participant that would result in you determining they cannot provide fully informed consent, etc.

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

1. The ‘Agree to continue even if ability to consent worsens’ is a good feature, but please ensure that this option is being offered consistently across all consent forms.
2. Please include risk of fatigue and highlight that they will be observed.
3. Page 3 is too dense, please consider using bullet points.
4. ACC clause should be included as is intervention.
5. ‘Measure your behaviour’ needs to be better explained, and what constitutes a ‘behaviour’ behaviour. Supported consent explains this better than easy read PIS/CF, so include for consistency for both.
6. 15-20 sessions per client seems to only be explained in the support staff consent. This is a lot and needs to be really clear to participants as it appears they are only doing 4 20-minute sessions the way it is currently written.
7. HDEC doesn't require organisational consents unless the Researchers want to obtain it, the Committee just need to know their agreement. This is achieved mostly as part of Locality Authorisation with the providers.
8. Whānau PIS should state 'your family member' rather than the client due to the personal relationship.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Mrs Leesa Russell.

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| **8** | **Ethics ref:** | **2025 FULL 22144** |
|  | Title: | Phase 1a/1b, Randomized Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single- and Multiple-Ascending Doses and Food Effect of BGB-45035 in Healthy Participants and its Safety and Tolerability in Patients With Autoimmune Dermatological Diseases |
|  | Principal Investigator: | Dr Arna Letica |
|  | Sponsor: | BeiGene NZ Unlimited |
|  | Clock Start Date: | 20 February 2025 |

Dr Arna Letica, Jayde Sefton, Marius Zhou, Joline Ong, Linzie Lim, Kshemina Mhaskar, and Cheryl Glover 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 raised the use of questionnaires to determine quality of life, and queried how soon it could be identified that someone is having a tough time. After discussion, the Committee was assured of adequate response and support. The Committee noted to ensure the central study plan for responsiveness to suicidality questions are consistent across all sites.

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 advertising talks about untreated conditions, but it is unclear if these people are being treated at all or if it is that the treatment isn’t working. Please refine ads and participant information to be very clear as to who is allowed in the study and who is not.

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

1. Please complete the dollar amount reimbursement, and make sure that it is the same or equitable across sites.
2. The information sheets need to be clear on what form of relief participants could take and what they can do to manage their symptoms while still being part of the study.
3. Restrictions on participants ingesting herbal supplements and other things mentioned in protocol not included in PIS, please amend.
4. If Sponsor is committed to Medicines NZ guidelines, please state this definitively.
5. Please clarify extent of physical exam, sensitive areas-choice of examiner and if they are allowed a support person.

**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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| **9** | **Ethics ref:** | **2025 FULL 22205** |
|  | Title: | A Phase I Clinical Study to Evaluate the Safety, Tolerability, Immunogenicity, Pharmacokinetics, and Pharmacodynamics of Single and Multiple Ascending Oral Doses of HS-20118 in Adult Participants |
|  | Principal Investigator: | Dr Paul Hamilton |
|  | Sponsor: | Jiangsu Hansoh Pharmaceutical Group Co., Ltd. |
|  | Clock Start Date: | 20 February 2025 |

Dr Paul Hamilton and Charlene Botha 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 the reimbursement amount is blank. Please provide this and ensure usual tax-implications outlined for participants.
2. Amend advertising to remove word treatment, reframe as investigational product.

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

1. SAD and MAD PISs needs to include the risks that were identified in the protocol.
2. Please include what reimbursement will be and confirm that will be in line with normal reimbursement expectations.
3. Please ensure measurements for fluids are written in millilitres, not teaspoons.
4. If Sponsor is committed to Medicines NZ guidelines, please state this definitively.
5. Change from Southern to Northern B HDEC.
6. State that the participant’s General Practitioner (GP) will be informed in event of clinically significant abnormal findings/concerns. Delete optional tick-box in relevant CF clause as this should be mandatory.
7. SAD mentions multiple doses. Please amend for accuracy.

**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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| **10** | **Ethics ref:** | **2025 FULL 21415** |
|  | Title: | Hāpai te Haumanu Awhiriki: kia haumaru ai, kia tat mai. Immunotherapy closer to home |
|  | Principal Investigator: | Dr Helen Wihongi |
|  | Sponsor: | Ira Tātai Whakaheke |
|  | Clock Start Date: | 20 February 2025 |

Dr Helen Wihongi and Dr Laird Cameron 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 discussed with the Researchers that currently there are initial engagements undertaken with stakeholders to identify the providers for the study. As the interaction with participants is not yet formed, the Committee and Researchers agreed that the application in its current form was submitted too early. The Committee requested this is submitted to the HDECs once the work around this initial engagement is done and the component with participants is stepped out and finalised. Further comments below made by the Committee are recommendations for when the application is made to ensure that the study documentation meets the National Ethical Standards when it comes back to the Committee for review at the appropriate time.

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 current data management plan (DMP) provided is very detailed, especially around data sovereignty, however some specifics are missing which are currently required as per National Ethical Standard 12.15a. Please ensure information surrounding who has access to information and what information is collected is identified within the DMP or is highlighted in the protocol or other supplementary document.

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

1. Currently, the supplied participant information sheets imply that only verbal consenting will occur. The Committee noted that verbal consent and engagement alongside written information is excellent for obtaining informed consent, however participants should be provided with written information to keep to refer back should they need to recall what their participation involves or have any further considerations to ensure informed consent is an ongoing process.
2. Participants will need to be provided with information about data access such as who has access to their information and what form this information will take.

**Decision**

This application was *withdrawn* after discussion with the Committee and will see the application at a later time.

## General business

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

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| **Meeting date:** | 01 April 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. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 5.15pm.