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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 02 April 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11:30am - 12:00pm | 2024 FULL 19873 | ABI-5366-101: A Study to Evaluate ABI-5366 in Healthy Participants and in Participants with HSV-2 infection who have Recurrent Genital Herpes | Prof. Edward Gane | Kate / Leesa |
| 12:00 - 12:30pm | 2024 FULL 19771(Withdrawn from Agenda by Researchers) | A Phase 1 Study of BGB-B2033, Alone or in Combination With Tislelizumab, in Participants With Advanced or Metastatic Solid Tumors | Prof Ed Gane | Jonathan / Barry |
| 12:30 - 1:00pm | 2024 FULL 19715 | REFRaME-O1: A study to investigate the efficacy and safety of luveltamab tazevibulin versus IC chemotherapy in women with ovarian cancer (including fallopian tube or primary peritoneal cancers) expres | Dr Jonathan Graham | Maakere / Joan |
| 1:00 - 1:30pm | 2024 FULL 19916 | Warfarin self-testing and use of a patient portal for INR management | Dr Miriam Wheeler | Ewe Leong / Amber |
|  | **Break (30)** |  |  |  |
| 2:00 - 2:30pm | 2024 EXP 13998 | Photonic Probe for prostate cancer diagnosis | Dr Claude Aguergaray | Jonathan / Amber |
| 2:30 - 3:00pm | 2024 EXP 19491 | Early onset colorectal cancer network Aotearoa | Dr Tamara Glyn | Ewe Leong / Leesa |
| 3:00 - 3:30pm | 2024 FULL 19878 | Best ways to choose an intervention for behaviour related to gaining items | Dr Rebecca Sharp | Kate / Joan |
| 3:30 - 4:00pm | 2024 FULL 19681 | BP45369: A Study to Assess the Safety and Tolerability of RO7204239 in Participants with High Body Weight. | Dr. Leanne Barnett | Maakere / Barry |

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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 | Apology |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Mr Ewe Leong Lim | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |

## Welcome

The meeting was opened with a karakia at 11.00am and the Chair welcomed Committee members, noting that apologies had been received from Ms Alice McCarthy.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mr Jonathan Darby 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 05 March 2024 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 FULL 19873** |
|   | Title:  | A Phase 1a/1b, Blinded, Placebo-Controlled Study of the Safety, Tolerability and Pharmacokinetics of Single- and Multiple-Ascending Doses of ABI-5366 in Healthy Subjects and in Subjects who are Seropositive for Herpes Simplex Virus Type 2 with Recurrent Genital Herpes |
|   | Principal Investigator:  | Professor Edward Gane |
|   | Sponsor:  | Assembly Bioscience, Inc. |
|   | Clock Start Date:  | 21 March 2024 |

Lucy Druzianic, Julia O’Sullivan, Dr. Rohit Katial, Stanley Yune, Holly Thirlwall, and Kayla Malate 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 use of alcohol test. The Researchers responded that this is standard upon admission to clinic, and in relation to the study, higher dose animal studies found potential build-up of crystals in the kidneys so it is a safety precaution.

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 advertisements should be amended to state reimbursement as put in the participant information sheet (PIS).
2. The Committee noted the use of the word ‘treatment’ in advertisements and PIS. This should be changed as this is investigational.
3. The Committee raised the genital inspections in Part B and the potential whakamā of these and how they will be handled. After discussion, the Researchers outlined what addition to physical examination procedures are in place for sensitive examinations, but that standing orders are not formalised and documented yet. The Committee were assured that these would be done safely as the clinicians would be well-versed in conducting these examinations but suggested documenting sensitive examinations for this and future use. They also highlighted to make mandatory to have a chaperone if the physician is of the opposite sex and that they can request the gender of a clinician. The Committee further stated this should be made clear in the PIS.

**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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| **2**   | **Ethics ref:**   | **2024 FULL 19715** |
|   | Title:  | REFRaME-O1: A Phase 2/3 Open-label Study Evaluating the Efficacy and Safety of Luveltamab Tazevibulin (STRO-002) versusInvestigator’s Choice (IC) Chemotherapy in Women with Relapsed Platinum-resistant Epithelial Ovarian Cancer (Including FallopianTube or Primary Peritoneal Cancers) Expressing Folate Receptor Alpha (FOLR1) |
|   | Principal Investigator:  | Dr Jonathan Graham |
|   | Sponsor:  | Sutro Biopharma, Inc |
|   | Clock Start Date:  | 21 March 2024 |

Dr Sana Oladi and Dr Johnathan Graham 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 participants would be recruited through the clinics where there are no other options available in terms of chemotherapy for those participants.
2. The Committee clarified that the participants were not likely to self- refer based on the advertisements provided to the Committee for review.
3. The Committee clarified that there would be no remuneration aside from travel costs for participants.

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 that the sponsor authorize the research application in Ethics RM.
2. The Committee requested that the word “treatment” not be used in the advertising materials given this is an investigational trial.
3. The Committee requested clarification of the protocol where it mentions “prior to the implementation of this investigational only device” that there will be another test with a Roche system for screening the protein expression of the participants tumour. If this diagnostic tool will not be used, please remove, or amend and describe the risks of a false positive on this test to participants more clearly.
4. The Committee noted that the information presented as the prevalence in Māori and Pasifika was not very recent and that there should be some consideration of this when continuing with the study. The Committee also requested that should there be inclusion of Pasifika peoples in the study there should be a consultation process alongside Māori consultation.
5. The Committee suggested providing koha given the participants may receive no benefit from this study.
6. The Committee requested that a research nurse be the person to make approaches to participants for consenting to reduce white-coat bias where the clinician may be their treating physician for their usual oncology care.

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

1. Please clarify the procedures needed for screening that would be part of the study and not standard of care. These should be highlighted more clearly for participants as extra steps they may be asked to undertake as part of participation.
2. Please make clear that the screening test itself is investigational.
3. Please remove prompts for participants to come forward and provide information that may be relevant to the study to researchers as part of the screening process. The burden of this should not be placed on the participants and the screening should contain sufficient questions to illicit the answers required for this information to be reported and recorded.
4. Please provide a table of study tests and procedures for participants to better visualise what is required of them.
5. Please clarify for participants why the prophylactic provision of medications to stimulate the bone marrow to produce more white blood cells may be required of all participants.
6. The risks of the investigational device are different from the risks of the study drug. Please provide under “Risks” the risk that the investigational lab test may generate a false positive and if it does, a person may join the study falsely thinking that their tumor expresses the target protein. Consequently, they may be exposed to the investigational drug and all the potential negative side effects with no prospect of direct benefit.
7. Please clarify if karakia will be made available for destruction of tissue samples.
8. Please amend the statement concerning the Committee approval to state that only the ethical aspects of the study are approved by Northern B HDEC.
9. Notification to the participant’s GP should be mandatory for a clinical trial, please ensure this is not optional in the CF.

**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 update the advertisements, taking into account the feedback provided by the Committee*. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*

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

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| **3**   | **Ethics ref:**   | **2024 FULL 19916** |
|   | Title:  | Warfarin self testing and use of a patient portal for individuals living with rheumatic heart disease and mechanical valve replacement |
|   | Principal Investigator:  | Dr Miriam Wheeler |
|   | Sponsor:  | Te Whatu Ora Te Toka Tumai |
|   | Clock Start Date:  | 21 March 2024 |

Dr Miriam Wheeler 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 that the researcher was looking to access lab results from prior INR data that would have participants acting as their own controls.
2. The Committee clarified that the pharmacies would have to cover the upfront cost of the software as required. This software has been validated for pharmacy use, but the additional patient portal for self-testing is new.
3. The Committee clarified that the study was to determine the efficacy of the software used at home. This delivery of care would make the application an intervention study, not an observational one as indicated in the application.
4. The Committee clarified the cost of the testing strips and the method of testing currently employed by these participants.

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 commercial interest for the vendors/ developers of this software as a result of this intervention. The Committee requested that this be made clearer to the potential participants and that there should be sign-on of the vendor of the software as a sponsor and as a provider of insurance should study-related injury occur. *Health and Disability Ethics Committees Standard Operating Procedures* para *144* & *National Ethical Standards* para *17.1- 17.6.*
2. The Committee considered that this is a feasibility study of a patient portal and that by including people who are newly enrolled in the service there may be too many variables for the results to provide true results to the feasibility study itself. The Committee suggested restricting the eligibility criteria to people already established in the service. The researcher noted that access to care is an ongoing problem for this group but the Committee noted that this needs to be carefully considered as it could invite issues into the credibility of the data of the feasibility study. The Committee suggested that the period which participants should already have been enrolled in the service for be decided in consultation with the pharmacies providing the care. *National Ethical Standards* para *9.7a*
3. The Committee requested more detail as to the qualitative aspects of the study. This should include questions that will be asked, details of where these interviews will be held and researcher safety plans if this will be in participants homes. *National Ethical Standards* para *9.7a & 9.8.*
4. The Committee suggested that some additional thought may be required as to how the outcomes of this study will be measured and to detail this more clearly in the protocol. *National Ethical Standards* para *9.7a & 9.8.*
5. The Committee suggested further safety measures to this study to ensure that the notifications that alert the practitioners who are administering the drug or following up patients after an issue with medication will be managed. This should be detailed in the protocol, along with any other safety measures intended to minimize risk. *National Ethical Standards* para *9.7a & 9.8.*
6. The Committee requested clarification as to what access to the portal the pharmacists or general practitioners have. Please detail this in the protocol. *National Ethical Standards* para *9.7a & 9.8.*
7. The Committee requested the safety considerations for the potential for error among the three stakeholders (participant, pharmacist, GP) of the provision of this service. *National Ethical Standards* para *9.7a & 9.8.*
8. The Committee requested the following changes to the Data Management Plan *National Ethical Standards* para *12.15*:
	1. Please remove unnecessary sections that may not be relevant to this study.
	2. Please be clear as to what data may be used for future use and in what capacity this may be utilised in future studies.
	3. Please detail what will occur to qualitative data collected to deidentify and safe-keep transcripts, recordings, etc., that may be collected as part of the qualitative portion of the study.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *National Ethical Standards* para 7.15, 7.16 & 7.19:

1. Please ensure that the participants will be provided with a test kit and strips as part of participating.
2. Please clarify the process around when consenting will occur for the CPAMs specifically.
3. Please clarify the reminder process for people to ensure they are testing regularly and how this may feed back to the participants general practitioner (GP).
4. Please also clarify the exit strategy to GP care.
5. The study poses a variety of risks to participants that need to be outlined, including user error, non-compliance with prescribed testing schedule, communication problems among GP, pharmacist, and participant.
6. Please also outline how you will assess the safety/utility of relying on the patient portal as a support tool. What technical support will you provide participants?
7. Please proof-read for typos and grammar and simplify the language.
8. Please clarify how people with vision impairment will be approached and be able to contribute. Please be clear with this in conjoint with the exclusion criteria.
9. Please include a monetary value estimate for the koha and note that transport costs will be reimbursed for participants.
10. Please clarify what is meant by “vision impaired”.

**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:**   | **2024 EXP 13998** |
|   | Title:  | Photonic probe for intraoperative real-time prostate cancer diagnosis |
|   | Principal Investigator:  | Dr Claude Aguergaray |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 21 March 2024 |

Hayley Reynolds and Dr Claude Aguergaray 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 the method by which the light is utilised to determine if the cells are tumour cells or not. The researcher noted that there is a large amount of research that needs to be undertaken in this field as each type of tumour tissue requires validation to ensure that this tool is able to be rigorous enough for diagnosis.
2. The Committee clarified that the participants would be identified by the urologists pre the standard of care biopsy. Prior to the biopsy the optical probe will be inserted into the region of the biopsy to take the sample for diagnosis.
3. The Committee clarified that the consenting process would be done alongside the biopsy consenting as part of standard of care treatment. The research nurses would at this point provide options to be part of the study.
4. The Committee clarified that no clinical decisions will be made per the findings of the study procedures. There is no intersection between the study and best-clinical-care.
5. The Committee explained the principal of koha and how the participants should be able to weigh the risk-benefit of the study and if it would be beneficial to them. Koha is not enticement/ inducement to participate but something that makes the study less risk-dominant in terms of their analysis of that balance. The committee noted that the offer a voucher for coffee would have marginal impact on a participant’s assessment of risk and benefit.
6. The Committee clarified that the surgeon is blinded to the result from the probe.
7. The Committee noted that the probe comparator software was already a product used in the health system.

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 that the potential participants be given more time to consider participation. The Committee suggested providing the participant information sheet/consent form (PIS/CF) at the time the potential participants appointment being made for their clinical appointments with their urologist, and make very clear that this PIS/CF is unrelated to the consent to the standard procedure. Please detail the recruitment process in a step-wise manner in the protocol.
2. The Committee requested provision of the demographics questionnaire for review as this was not submitted with the application.
3. The Committee noted that the algorithm impact was insufficiently detailed and does not address the issues necessary for ethical consideration of an AI. The Committee suggested that this be reviewed and amended utilising a new HDEC AI guidance form currently under development that will be provided to the Researchers.
4. The Committee requested that a Data Management Plan (DMP) be provided that adequately details the governance etc., concerning the study. Please refer to the [HDEC Template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) for guidance.
5. The Committee requested clarification and some transparency with regards to the potential marketability in the product that is being tested. Specifically, from the perspective of the balance of benefit going to the manufacturer or distributor of the device, or IP-rights holder.
6. The Committee clarified that whilst there is some indication of ethnicity playing a part in the study results. The Committee noted that bias is inherent in the use of AI on small datasets and that this needs to be acknowledged and considered in the DMP.
7. The Committee queried the inclusion of Australian data in the AI training dataset and that this would be included in that part of the study alongside the Aotearoa dataset. This data and any data that may be used needs to be addressed in the AI analysis documentation.
8. The Committee requested the researcher consider providing more of a koha than a coffee voucher. The Committee does not think that this adequately shows appreciation for the participation in this study. The Committee notes that a $50 supermarket voucher would be more appropriate and that perhaps this should be covered by those groups who take the overhead costs as part of this study.
9. The Committee requested that it be clarified in the protocol that the surgeon will not have any access to the probe data and that the procedure will not be impacted by probing.

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

1. Please note there is always risk for participation in research. Please include the risk associated with the investigational device, the extra time the research will add to the procedure, etc.
2. Please clarify that this is an investigational device and explain how the laser works. Please include some manufacturing information and how the devices will be cleaned etc between use.
3. Please provide a section as to “why am I being asked to participate in the study”.
4. Please state that the biopsy results and other clinical outcomes will be given to the research team. Please also note that if there is any other information that will be given to the research team this should be included for participants.
5. Please include that images will be re-identifiable for 10 years.
6. Please include a section about the AI in the data section of the PIS/CF. Explain how the risks are being managed.
7. Please indicate that the Committee approving the study is Northern B and that they only approve of the ethical aspects of the study.
8. Please be clear that karakia may not be possible upon disposal of tissue.
9. Please remove the 0800 4 ETHIC number and replace this with the general Ministry of Health advocacy number in the [HDEC PIS/CF template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
10. Please include some explanation that there is already a comparator software in use in the industry and that this investigational product is comparable to that.

**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 update the data and tissue management plan to ensure the safety and integrity of participant data and tissue *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Jonathan Darby, Kate O’Connor and Dr Amber Parry Strong. A draft template of the AI form is to be included in the letter for this application and the Committee invite feedback.

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| **5**   | **Ethics ref:**   | **2024 EXP 19491** |
|   | Title:  | Early onset colorectal cancer network Aotearoa |
|   | Principal Investigator:  | Dr Tamara Glyn |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 21 March 2024 |

Dr Tamara Glyn, and other members of the research team 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 the recruitment process starting from the point of endoscopy or emergency obstruction. The researcher noted that this early recruitment could be invaluable in gaining a datapoint that often is not collected. This is also being done early to potentially gain healthy comparator samples and reduce the number of procedures that the participants may need to go through.
2. The Committee noted that the review of the submission would only address the nature of recruitment and consenting of participants into the tissue bank of the study. The other features of the proposed study should come after that as amended functions of the primary application. The projects concerning use of the tissue should be kept separately as each of these projects are being supplied in the form of unique studies. The Committee added that the AI work should be submitted in parallel as a separate application as this would initially utilize tissue already in the tissue banks available. This was raised as a potential issue for this work as the tissue banks would not have any AI considerations in-built into their governance. If the tissue has been consented in any of the banks this will not be consented specifically for use in AI products and therefore the HDECs would not consider that to be included in the approval of those tissue banks that already stands. The AI use-case may be low-risk but this would significantly deviate from the initial use-case defined in the governance of that tissue bank.

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 submission may include too much varied work to be considered in one application as there are many features to this planned programme. The Committee suggested applying for the AI approval under a separate application or in amendment at a later date. The Committee noted this out of concern that the AI portion deserves its own discussion and governance and that this would be easier for the researchers to work on if it was parallel rather than incorporated into this application. *National Ethical Standards* para *9.7a*
2. The Committee informed the researchers that the AI section of this study will require an AI impact assessment form that addresses the known risks for the AI product and a separate data management plan that covers each aspect of the AI lifecycle but specifically the data flow. *National Ethical Standards* para *13.1*
3. The Committee queried if the starting point of this was in fact newly consented tissue form a tissue bank. The researcher noted that the tissue bank was made up of such a homogeneous population that the project required data from further afield and this led to the formation of a community of databases that could be used to look at the condition more broadly. So far this would include tissue banks from Wellington, Dunedin and Canterbury and potentially in the future may include data from Auckland banks as well. The Committee raised concerns that this may not capture people underserved by the system and that Middlemore and Counties Manukau would be an important cornerstone of data should the researcher be able to recruit. *National Ethical Standards* para *3.1*
4. Further to the point of national connectivity, the Committee suggested that the researchers explain this system more clearly in the protocol, even potentially including a diagram, to describe more clearly how decision-making, governance and provision of samples for use will be managed. Please include also some more clear information as to how accessing tissue banks will occur and be managed and how this may differ between banks. *National Ethical Standards* para *9.7 & 9.7a*
5. The Committee queried when and how the quality-of-life (QoL) questionnaires would be administered. The researcher noted that these patient-reported outcome measures are something that the sector as a whole would benefit from as part of standard of care that currently is not funded in the health sector but would be provided by a member of the study team around the point of their diagnosis but there would be variability in this depending on the participants wellbeing given that the timing may be difficult for them (in the event of concurrent cancer diagnoses). The Committee requested that this be protocolised and provided in writing in a little more detail than has currently been included. *National Ethical Standards* para *9.7*
6. The Researcher noted that the 5-year surveillance is the standard clinical follow-up period for patients with colorectal cancers. Please detail this a little more thoroughly in the Data and Tissue Management Plan (DTMP).
7. The Committee noted that the consent forms of the different parts of the study and the tissue banks themselves appear to be at odds. The different streams of tissue and data storage may need to be consolidated through the process of outlining the different governance structures prior to writing the consent forms as there needs to be no conflict between these documents.
8. The Committee noted that it would be overly complicated and involve more risk to have leftover tissue be banked for general use. This should either be clarified to ensure that this tissue is adequately stored/kept in a manner that honours the consent and status that this tissue should have. If this is not relevant, then please clarify the potential future use.
9. The Committee queried if the dataset would be linked with other health data. The researcher noted that this would not be occurring. Please ensure this is removed where it arises in the consent forms. *National Ethical Standards* para *12.31-12.39*
10. The Committee suggested that the researchers read the NEAC guidelines for guidance on the establishment of a tissue bank as this study will be involving the creation of a “sub-bank” *National Ethical Standards* chapter *15*.
11. The Committee suggested using the resources available and find community partners such as the Cancer Society etc., to help in interacting and serving the participants in a manner that is not tokenistic. The researcher agreed on this approach and noted that they were intending on attempting this and creating a working to this effect going forward.

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

1. Please review for tone and lay language. This document is quite factual and at times confronting to the reader in the way it is worded. This could be softened to use less potentially distressing language. *National Ethical Standards* para *7.19*
2. Please clarify all of the steps raised in the content of the PISCF. If there are alternate contact people, for example, it should be clarified what they would do and when etc., and nothing mentioned in the consent form should not have a corresponding section describing it in the PISCF, protocol and DTMP. *National Ethical Standards* para *7.19*
3. Please be clear that the samples collected as part of this study are not just being sent to a tissue bank but that the samples will be shared amongst the groups highlighted in this application. *National Ethical Standards* para *15.8-15.10*
4. Please note that the consent may be too restrictive to allow for the protocol’s list of uses for tissue collected as part of the study. Consider amending this for to include these further uses of tissue. Categories of research such as AI or whole genome sequencing may be included as opt-out clauses in the consent form. *National Ethical Standards* para *7.19 & 9.8*
5. Please do not introduce any new information into the consent form that has not been first explained in the information sheet, such as contacting former participants for further use and consent.
6. Please amend measurements of blood to millilitres rather than teaspoons.
7. Please include that samples will only be collected when participants go for treatment unless there is a rigid sigmoidoscopy planned due to procedural specifics of certain sites.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

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| **6**   | **Ethics ref:**   | **2024 FULL 19878** |
|   | Title:  | Utility of an Intervention Decision-Making Tool for Challenging behaviour Maintained by the Access to Tangibles |
|   | Principal Investigator:  | Dr Rebecca Sharp |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 21 March 2024 |

Dr Rebecca Sharp and Jacob 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 disability assessment tool would ordinarily be filled in by the caregiver.
2. The Committee clarified that the children would be recruited from within Specialist schools.
3. The Committee clarified the way in which data is collected as part of behaviouralist practice.
4. The Committee noted their concern that the project and the data that would be generated as a result of the intervention would be too large for a master’s degree project. The Committee noted that the interviews alone would be sufficient scope for a master’s thesis.
5. The Committee suggested that the Researcher contact other disability researchers such as through the Donald Beasley Institute as they may be able to provide some useful contacts and perspective.
6. The Committee suggested that the AHREC may be able to review the validation of tools aspect to this study and the supervisor noted that this had been through AHREC already and that they had determined that HDEC should be the reviewing body.

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 sponsorship authorisation cannot come from the head of the department within the university but that this needs to come from the Human Research Office at the university per their requirements. *National Ethical Standards* para *11.1 & 11.1a*
2. The Committee noted that Locality Authorisation would be required as each site the researchers intend to go to conduct the study would be their own locality and require their own unique authorisation. *National Ethical Standards* para *9.7*
3. The Committee queried how the researchers would determine the impact of the intervention given there are a large number of variables in the intended patient population. The supervisor noted that homogeneous populations do not work well in behavioural studies. The Committee noted that the examples provided in the participant facing materials had been useful in providing context to this but was concerned that they were misleading in the way they indicated something that might not be true (example: young child wanting to take an iPad to a mosque). The Committee noted that the way it was worded “help you get the items you want easier” does not accurately demonstrate the principles highlighted by the supervisor around providing differing access to the same needs. *National Ethical Standards* para *9.8 & 7.16*
4. The Committee noted that as part of their role in reviewing the ethics of this application, they must consider that the population being studied is sufficient to answer the questions posed by the research in a manner that involves the smallest potential for risk to participants with the most benefit whilst also being able to determine if that population is being catered to adequately by the information that is being or will be provided to them. The Committee stated that it is impossible from what has been provided to ascertain if the content that is being reviewed will be appropriate for the potential participants who may consume that content. *National Ethical Standards* para *9.7*
5. The Committee noted that it needs to be clear what would be specifically assessed and how this may differ from standard of care and that this needs to be communicated in a way that will make sense to the participants. The Committee noted that this point ties into the idea of this study being too big for the proposed qualification it is being conducted for. The study itself could do with being narrowed into sections such as the development of an intervention, the validation of that intervention and then the comparison of that intervention. *National Ethical Standards* para *7.16*
6. The Committee queried the process of supported decision making and some of the background of these approaches and the consultation that has occurred with members of the disabilities community and asked for some clarification as to how this has impacted the methodology that is proposed in the study. The supervisor requested clarification as to what part of the study this specifically related to and the Committee noted that it was fundamental to the project as a whole. The Committee raised the concern that the information was presented in a manner that lay people who read research regularly struggled to comprehend and that it may benefit from some consultation with disabled people to make the information more relevant and more effectively communicated to this population. *National Ethical Standards* para *7.20 & 7.21*
7. The Committee queried who fills out the social validity, post-intervention questionnaire and was informed that this would be filled out by the support people. This is a technical document and needs to be reviewed for lay appropriateness. *National Ethical Standards* para *7.16*
8. The Committee requested more detail for the researcher safety plan, the lines of contact and eventualities should things occur in the visits, timing of leaving and the protocol around every potential issue that could occur. *National Ethical Standards* para *11.62*
9. The Committee noted that given there was no clear definition of what groups were being studied that it was difficult to determine the responsiveness to Māori and the way that this research may impact Māori. *National Ethical Standards* para *3.1*
10. The Committee recommended for the resubmission of this study that it may be better to address the clinicians as the subjects of the study. The supervisor noted that this may be an issue given intended recruitment in groups may not have a clinician assigned to them and this may severely limit the pool of recruitment. The Committee noted that there is little chance of the Committee approving a study with the same breadth as has been presented in this case as they, as previously noted, cannot adequately determine the risks to participants or how ethically robust this research is.
11. The Committee requested more information in the resubmission as to what data is collected during the sessions that are conducted by researchers in this field and how it is validated, stored and what risks there are to people. *National Ethical Standards* para *9.8*

**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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| --- | --- | --- |
| **7**   | **Ethics ref:**   | **2024 FULL 19681** |
|   | Title:  | A SINGLE- AND MULTIPLE DOSE, OPEN LABEL, PHASE I STUDY TO INVESTIGATE THE SAFETY, TOLERABILITY,PHARMACOKINETICS, PHARMACODYNAMICS, AND IMMUNOGENICITY OF SUBCUTANEOUSLY ADMINISTERED RO7204239 IN ADULT PARTICIPANTS WITH HIGH BODY WEIGHT |
|   | Principal Investigator:  | Dr Leanne Barnett |
|   | Sponsor:  | Roche Products (New Zealand) Ltd |
|   | Clock Start Date:  | 21 March 2024 |

Julia O’Sullivan, Kayla Malate, and Lucy Druzianic 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 and Researchers were in agreement that the term “in good health” rather than healthy would be better wording to make it more open as some people with chronic conditions would still be able to participate and not pose any risk to them or the data collected.
2. The Committee queried if the Researchers were aware of any long-term effects of the medication changing the natural process of maturation of the protein in the muscles. The Co-ordinating Investigator and Sponsor responded that the investigational medicine has a long half-life which is why participants are followed up for a long period of time. There have been no long-term effects seen in previous studies, and echocardiograms are performed as a precaution despite there being no abnormal cardiac side effects seen in non-clinical studies. These risks are detailed in the IB and in the participant information sheet.

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 use of BMI is a blunt tool to apply to people, especially when people could fall just outside BMI requirements but still be eligible if there would be flexibility at the discretion of the investigator. This current study offers no flexibility. Observing that the hard and fast cut-off may exclude persons more representative of the New Zealand population, and the Committee recommend the inclusion criteria is amended to consider the diversity of the New Zealand population.
2. The Committee stated that the radio advertisement script is missing a word, please review.
3. Please make it clear to participants that they should not have any intention to adjust their diet or current physical activity during the entire study period.
4. The Committee suggested reaching out to Māori and Pacific pathways to recruit and ensure inclusion minority groups that are disproportionately affected.
5. The Committee noted the use of the word ‘treatment’ in advertisements and PIS. This should be changed as this is investigational.

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

1. Page 16 says should not join another study. Qualitative research is research too. Please specify it shouldn’t be another clinical trial or intervention study.
2. The Committee noted both Health NZ and Te Whatu Ora should be stated.

**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).*

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 07 May 2024 |
| **Zoom details:** | To be determined |

 The following members tendered apologies for this meeting.

* Mr Ewe Leong Lim
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 4.00pm