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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 20 March 2018 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.05pm | Confirmation of minutes of meeting of 20 February 2018 |
| 1.30pm | New applications (see over for details) |
| 1.30-1.55  1.55-2.20  2.20-2.45  2.45-3.10  3.10-3.35  3.35-4.00  4.00-4.25 | i 18/NTA/32  ii 18/NTA/33  iii 18/NTA/34  iv 18/NTA/35  v 18/NTA/38  vi 18/NTA/41  vii 18/NTA/43 |
| 4.25-4.50pm | Substantial amendments (see over for details) |
|  | i NTX/10/03/018/AM09 |
| 5.00pm | General business:   * Noting section of agenda |
| 5.15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 11/11/2015 | 11/11/2018 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 | Present |
| Dr Christine Crooks | Non-lay (intervention studies) | 11/11/2015 | 11/11/2018 | Present |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 12/08/2015 | 12/08/2018 | Present |
| Dr Kate Parker | Non-lay (observational studies) | 11/11/2015 | 11/11/2018 | Present |
| Dr Catherine Jackson | Non-lay (health/disability service provision) | 11/11/2016 | 11/11/2019 | Present |
| Ms Toni Millar | Lay (consumer/community perspectives) | 11/11/2016 | 11/11/2019 | Present |
| Ms Rochelle Style | Lay (ethical/moral reasoning) | 14/06/2017 | 14/06/2020 | Apologies |

## Welcome

The Chair opened the meeting at 1:00pm and welcomed Committee members, noting that apologies had been received from Ms Rochelle Styles.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Dr Maliaga Erick confirmed her eligibility, and was co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 20 February 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/NTA/32** |
|  | Title: | An observational study for the optimisation of the Cxbladder SCT test for the detection of urothelial carcinoma |
|  | Principal Investigator: | Prof Parry Guilford |
|  | Sponsor: | Dunedin School of Medicine and Southern District H |
|  | Clock Start Date: | 08 March 2018 |

Dr Tony Locke and Mr Lux Selvanesan were present by teleconference 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 Study

1. An observational study to collect high quality voided clinical urine samples to be used to optimise the Cxbladder Single Cell Technology (SCT) test for the detection of early stage urothelial carcinoma for patients presenting with haematuria.
2. All patients presenting for imaging or to the urology clinic for evaluation for possible urothelial carcinoma will be considered for recruitment.
3. Non-invasive, voided urine samples will be used to develop the Cxbladder SCT assay. In addition, Cxbladder Triage, Cxbladder Detect, and Cxbladder Resolve scores will be calculated and compared to Cxbladder SCT results.
4. Participants will undergo all routine standard of care clinical investigations required for diagnosis of urothelial carcinoma.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee were as follows.

1. The Researcher confirmed that this is the optimisation part of the study. A proof of concept has been tested and applied for an academic patent. The proof of concept needs to be converted into a commercial test / assay. Samples are required to test assay and optimise if necessary. Once tested and locked down the next phase would be a clinical trial. The Researchers confirmed that this is purely observational research and participants would receive standard of care as usual.
2. The Committee queried why the questionnaires collected lots of clinical information. The Researcher explained that bladder cancer is multifactorial disease and collecting this additional information will help understand if alternative diagnosis / diseases could affect the diagnosis. As this is an optimisation test it’s the first time using cancer patients and therefore need to be thorough that the results are not a false positive or false negative. Collecting clinical data helps clarify the disease status of the individual when developing a diagnostic test.
3. The committee queried why the study needs to collect information about participant occupation. The Researcher noted that there are certain properties about an individual which can make then at risk impact, such as occupation, for example exposure to chemicals or phenols.
4. The Committee expressed concern that the courier company transporting the urine could identify the individual and therefore this would be a confidentiality issue. The Researcher agreed to develop a labelling system which would de-identify the sender. Please provide the Committee with assurance that participant information will not be identifiable.
5. The committee noted that the responses to the Maori questions in the application were not adequate. Please ensure these questioned provide better quality answers in future applications.
6. The Committee noted that the peer review was provided internally from the Sponsor. The Research agreed to arrange an independent peer review.
7. Please ensure information (end date) is included on how long the study team will access participant follow up information is added to the Participant Information Sheet

Summary of ethical issues (outstanding)

1. The Committee queried why urine samples were being collected from participant’s homes. The Researcher advised that the tests would cover several components and repeat testing would be necessary to assess repeatability/ reliability of the tests. Please make clearer in the Participant Information Sheet that part 2 of the study is optional. Please include a second consent form for part 2.
2. The Committee noted that the researchers are collecting information on ethnicity. Please use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan) please state.
3. The Committee queried whether all participants in this observational cohort will get all of the comparator Cxbladder tests in addition to the Cxbladder SCT test. The researcher confirmed that this the case. Please ensure this is made clear to participants in the Participant Information Sheet.
4. The Committee queried if hoping to store for future use related to this biomarker. The Researcher confirmed that the samples used for future use would be related to the same test to help discover new technologies or novel bio-markers.
5. The Researcher advised the intention was to store samples at Pacific Edge freezers. The Committee noted that any human tissue stored in New Zealand beyond a specified research project must be stored in a registered tissue bank. Please provide assurance to the committee that if the samples are stored beyond the life of the project that they will be stored at a registered tissue bank.
6. The Committee noted that Professor Parry Guildford as the Principal Investigator, Chief Scientific Advisor and Peer Reviewer was a conflict of interest and would like to see a degree of separation between these roles. If Professor Guildford continues in his role as C.I. then an independent Peer Review is required. The Researcher agreed to consider this arrangement and provide assurance to the Committee that this conflict is removed from the study.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please make if clearer in the Participant Information Sheet that part 2 of the study is optional. Please include a second consent form for part 2 of the study.
2. The Committee noted that it was good to have a separate future unspecified use of human tissue Participant Information Sheet. The Committee suggested using the standard HDEC template (available at: <https://ethics.health.govt.nz/system/files/documents/pages/fur_piscf_template.doc>. This will ensure statements on intellectual property rights, where samples are stored, for how long, incidental findings and whether results are given back to the participant and how that will be done, etc. will be included.
3. Please include Māori health support contact details in the Participant Information Sheet.
4. Please ensure that it is clear under the benefits / risks section of the Participant Information Sheet that participants are unlikely to benefit from taking part in the study.
5. Change the approving ethics committee to the Northern A HDEC
6. Please be clear in the Participant Information Sheet what clinical information will be sent off with the future use samples.
7. The Committee would like the researchers to include more detail to the Participant Information Sheet on the current test procedure to make it clearer that the study compares the Cxbladder SCT to other Cxbladder tests.
8. The Committee queried if results from the diagnostic test will be fed back to the participant’s urologist. There is conflicting information in the application form. Please make it clear in the Participant Information Sheet that their information will go back to the urologist at some point. Please clarify whether these results will be made available in a timely way for the urologist to use in their care of the patient.
9. Please be clear in the Participant Information Sheet that one of the study procedures is accessing participant’s medical records and image results. Please ensure this is added as an item to the consent form.
10. Please ensure typos in the Participant Information Sheet are corrected.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please provide a further scientific peer review of the study protocol from an expert who is independent of the study.
* Please provide assurance to the committee that sample will be stored at a registered tissue bank.
* Please respond to the outstanding ethical concerns detailed above.

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| **2** | **Ethics ref:** | **18/NTA/33** |
|  | Title: | MDV3100-13: Effectiveness and Safety study of enzalutamide in Men with High Risk Prostate Cancer |
|  | Principal Investigator: | Dr Claire Hardie |
|  | Sponsor: | Pfizer Limited |
|  | Clock Start Date: | 08 March 2018 |

No investigators were present 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 Study

1. This study will test whether enzalutamide plus leuprolide OR enzalutamide alone can prolong metastasis-free survival (MFS), compared with placebo plus leuprolide.
2. Prolongation of MFS may delay or prevent prostate cancer symptoms and delay the need for subsequent therapies (eg cytotoxic chemotherapy).
3. Approx. 1860 men with high-risk non-metastatic prostate cancer progressing after radical prostatectomy or radiotherapy or both) will be randomized (1:1:1) to receive either:
   1. Enzalutamide (once daily) plus leuprolide (injection every 12 weeks)
   2. Enzalutamide monotherapy
   3. Placebo plus leuprolide.
4. Treatment is given for 36 weeks, then suspended if PSA is undetectable (< 0.2 ng/mL). This potentially averts adverse effects associated with long-term continuous androgen deprivation therapy. Study drug treatment may be reinitiated if PSA rises above 2.0 ng/mL (if prior prostatectomy) or 5.0 ng/mL (without prostatectomy). Participants with detectable PSA at 36 weeks, will continue study treatment until permanent treatment discontinuation criteria are met.
5. Prostate cancer assessments include: CT/MRI scans, bone scans, survival status, PSA values, testosterone, resumption of hormonal therapy, symptomatic skeletal events and pain (via Brief Pain Inventory) and 3 quality of life questionnaires.
6. Safety assessments include: adverse events, laboratory tests, physical examinations, and vital signs. An independent data monitoring committee will periodically monitor safety data.
7. Patients who permanently discontinue study treatment will remain in the study, for safety follow-up, 30 days after the last dose of study drug or before initiation of a new treatment, whichever occurs first. Long-term follow-up will occur every 12 weeks thereafter.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee were as follows.

1. The committee would like clarification around the duration / end date of the study. One part of the application states the study will be finished in 2024 but another section implies it will be longer.
2. Please state who will be keeping the data for future use. The application sates that the data is partially identifiable. The committee expressed concern is this data is been given to people outside the research group. Please provide clarity as to whom will be accessing the health information and in what form.
3. Please provide more information to the Committee on data management throughout the study, i.e. how it will be stored and for how long.
4. Please provide clarity how the researcher/clinician relationship will be managed.
5. The Committee noted that answers to the Māori questions lack detail. Please provide more health related information specific to Maori and this condition, e.g., incident rates in Maori and their response to treatment.
6. The Committee noted that there is no information in the protocol to outline how a positive response to anxiety and depression questions in the study questionnaires would be managed. Please provide more detail in the protocol.
7. Please provide an emergency contact card for participants enrolled in the study.
8. Please remove the space to collect the participant name on all questionnaires as these will go to the Sponsor.
9. The Committee noted that this research is being done by Medivation Inc. USA, a wholly owned subsidiary of Pfizer Inc (in partnership with Astellas Pharma Global Development Inc.). In reference to Pfizer in the participant information sheet please also mention Astellas Pharma Global Development Inc.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please add more detail to the Participant Information Sheet around the level of risk, estimated exposure and the effects (material or not material) for the participant undergoing radiology tests and CT scanning in addition to standard of care.
2. Section 10 of the Participant Information Sheet should specify how long the samples will be stored for and be explicit about the blood samples tests are for.
3. Please ensure it is clear in the Participant Information Sheet that there is a risk the cancer may return.
4. Please be clear in the Participant Information Sheet what personal information you are collecting.
5. Section 18 of the Participant Information Sheet implies the study is collecting tissue. Please clarify this.
6. Section 2 of the Participant Information Sheet states “*This research is being conducted by Medivation, Inc. USA, a wholly owned subsidiary of Pfizer Inc (in partnership with Astellas Pharma Global Development, Inc) and sponsored in New Zealand by Novotech (New Zealand) Limited”*. The Committee noted that Novotech is the Clinical research Organisation running the study and not the Sponsor. Please ensure the correct Sponsor is detailed in the Participant Information Sheet.
7. Section 17 of the Participant Information Sheet states; “*If you were injured as a result of treatment given as part of this study, which is unlikely, you won’t be eligible for compensation from ACC. However, compensation would be available from the study’s sponsor, Medivation, Inc.”* The Committee would like to know what the relationship is between Medivation and Pfizer Inc. We recommend the use of the word Pfizer as this is the name on the insurance certificate
8. The Participant Information Sheet states that study will collect information about a pregnancy if it occurs during the study. The Committee requested that a separate Participant Information Sheet and consent form is required for this.
9. Section 15 of the Participant Information Sheet states results of the study will be shared 6 months after the study finishes. Please ensure it is clear to the participant that this could be a long time away if the study is due to conclude in 2024.
10. Please provide more detail in the Participant Information Sheet on regular monitoring of blood tests throughout the study.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph *6.22*).
* Please respond to the outstanding ethical concerns detailed above.

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| **3** | **Ethics ref:** | **18/NTA/34** |
|  | Title: | PIF: Cultural Resiliency and Vulnerability |
|  | Principal Investigator: | Dr El-Shadan Tautolo |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 08 March 2018 |

Dr El-Shadan Tautolo and Leon Lustini were present in person for discussion of this application.

Potential conflicts of interest

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

Mrs Mali Erick declared a potential conflict of interest, and the Committee decided that Dr Erick would leave the room and not take part in discussion or vote on the decision.

Summary of Study

1. The aims of this study are to identify the specific cultural and acculturative factors that make some Pacific people vulnerable to mental illness and others resilient to mental illness.
2. The researchers will identify these factors and use them to help identify specific ways in which mental health services can be modified to better meet the cultural needs of Pacific consumers.
3. The study will utilise a three-stage mixed methods design:
4. Stage 1 is a quantitative survey of approximately 500 Pacific women and 500 Pacific men; Stage 2 uses individual in-depth interviews with a sub-sample of these women and men to explore in detail some of the broader patterns and associations identified in Stage 1, and; Stage 3 is a implementation phase in which we will translate findings into practical changes to mental health service delivery.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee were as follows.

1. The Committee queried if the survey can be done in a different language. The researcher advised that this is not possible. The researcher noted that interviewers and participants are matched based on ethnicity and to overcome any translation issues.
2. The answer to question b.4.4.1 states that data generated by the study might be made available to other researchers may be potentially identifiable. The Researcher explained that because this is a longitudinal study it is likely that new researchers would join the team and would have access to the data. The Researcher confirmed that the data would not be shared with researchers outside this study.
3. The Committee queried who will have access to health information used in the study. The Researcher advised that the lead investigators and biostatistician involved in the study will have access to participants' self-reported health information only.
4. The Committee queried the use of a diagnostic algorithms to diagnose a range of mental disorders and why the researcher thought it was not safe to report back to participant or their doctor. The Researcher advised that the diagnosis are for research purposes only and a real diagnosis should be made by a qualified psychologist. The Committee queried the safety of the participant if red flags were identified. The Researcher advise that the purpose of the interview is to address any concerns at that point, not at the data analysis stage. Participants would be directed to professional help at the interview point.
5. The Committee asked for clarity around the process if a red flag was identified in an interview. The research advised that there are appropriate measures in place to address this and would assess on a cases by case basis. The Research noted that there had not been any crisis’s reported in previous studies.

Summary of ethical issues (outstanding)

1. The Committee noted that that protocol is missing a safety plan. Please ensure this is provided to the Committee.
2. The Committee queried if there was a debrief process for the interviewers who may feel traumatised. Please consider a process to ensure there is an opportunity for the interviewers to debrief, if required.
3. The Committee noted that one of the co-investigators is also the psychiatrist who may receive referrals. Please use a different referral to add some separation between the researcher / clinician role.
4. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. The current Participant Information Sheet says data will be kept for 6 years. Please ensure this is amended to say data will be kept for 10 years.
2. The section” What will happen during the Culture and Mental Health Study?” of the Participant Information Sheet says “In 2018 or early 2019, a researcher from the PIF Study will contact you about visiting you at home (or other location convenient to you).” Please consider giving a timeframe such as within two months of consenting, to avoid a potentially long gap in contact.
3. Please ensure it is clear in the Participant Information Sheet what participants are consenting to i.e. part 1 and part 2 of the of the study which involves completing a face-to-face interview in two parts).
4. In the section “Part 1: An interview about mental disorder” in the Participant Information Sheet please make it clear it is about ‘their’ experiences of mental health issues and not in a broader context.
5. Please ensure the Participant Information Sheet and consent form seeks permission to use participants data previously collected.
6. Please ensure it is clear in the Participant Information Sheet that the interviews will visit the participant home and complete the questionnaires on a computer whilst at the participant’s home.
7. Please review the wording / language in the Participant Information Sheet around mental health disorders and mental health diagnosis, in particular be clear that the study is not doing the diagnosis.
8. Please make it clear in the Participant Information Sheet that it is one interview, not two separate interviews.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please respond to the outstanding ethical concerns detailed above

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| **4** | **Ethics ref:** | **18/NTA/35** |
|  | Title: | Early Start Denver Model “Play Date” for Young Children with Autism Spectrum Disorder and their Peers |
|  | Principal Investigator: | Dr Larah van der Meer |
|  | Sponsor: |  |
|  | Clock Start Date: | 08 March 2018 |

Dr Larah van der Meer was present by teleconference 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 Study

1. The study aims to evaluate whether the Early Start Denver Model (ESDM) of early intervention for children with autism spectrum disorder (ASD) is effective when implemented during play dates between children with ASD and their typically developing peers.
2. A single-case research design to evaluate whether the intervention is effective for up to six children with ASD and twelve typically developing peers.
3. Consist of three main phases.
   1. First, will observe play dates between children with ASD and typically developing peers to see how they currently interact and play.
   2. Second, will implement the ESDM intervention to teach social interaction and play skills between the children. Specifically, we will assess whether the intervention is effective in improving engagement, social interactions, and play behaviours.
4. Third, will evaluate whether these skills maintain after the intervention is withdrawn and whether parents perceive the intervention to be socially relevant and acceptable.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee were as follows.

1. The Committee queried if videos from the study will be kept for future use. The Researcher confirmed that only the data, not videos, would be kept for future use. The researcher confirmed that the videos would be destroyed as soon as the data analysis is complete.
2. The committee queried what happens if someone withdraws from the study once the dyads are working together on the intervention. If one or both of them withdraw would that make all the study information for that pair unusable? The Researcher advised that this would depend on when in the study a participant withdrew, for example, if it was towards the end of the study the data could be used if the participants agreed, however if it was nearer to the start then the recruitment process would start again. The Committee suggested not destroying or withdrawing data until the study concludes and it may be useful.
3. The Committee expressed concern that there may be a situation where an autistic child is lashing out and how this situation would be managed. The Researcher noted that this is outlined in the Participant Information Sheet and is an associated the risk and benefits with the study.

Summary of ethical issues (outstanding)

1. The Committee requested more information in the study protocol to explain more clearly how the intervention and different groups work. The Committee suggested a timeline graphic to show the series of interventions and what part of the study applies to the different groups.
2. The Committee requested to see a copy of the letter the research team will use to approach ECEs when recruiting potential participants. The letter should outline the study and specifically state what the researcher is seeking permission for.
3. The Committee would like more information on how the study plan to recruit from ECEs, e.g. flyers etc.
4. The Committee noted that the study involves quite a large time commitment, especially for the parents, however there is no compensation or reimbursement for their involvement in the study. The Researcher agreed to look into some form of compensation for participants, for instance a petrol voucher for the parents traveling to the child with autism home.
5. Please ensure the ethnicity question on the demographics questionnaire is the standard ethnicity question for health research in New Zealand.
6. The Committee expressed concern over the risk of challenging behaviour for the autistic child, the peer and the therapist. The researcher advised that the therapists are highly training in dealing with risky situations.
7. Please ensure the age range of children involved is consistent throughout the study documentation. (3-6 years and not 1-5 years).
8. Please consider including a Participant Information Sheet for the peer child.
9. Please provide the Committee with more information around the filming and consenting process in an ECE.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please provide clearer and simplified information in the Participant Information Sheet around how the intervention and different groups work. Consider a timeline graphic to show the series of interventions and what part of the study applies to the different groups.
2. Please avoid jargon in the Participant Information Sheet.
3. Please use a lay friendly way to describe the different stages of the study in the Participant Information Sheet.
4. Please ensure the correct tense is used consistently throughout the Participant Information Sheet.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please respond to the outstanding ethical concerns detailed above.

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| **5** | **Ethics ref:** | **18/NTA/38** |
|  | Title: | The Effect of OLE on High School Athletes |
|  | Principal Investigator: | Dr Andrea Braakhuis |
|  | Sponsor: |  |
|  | Clock Start Date: | 08 March 2018 |

Mr Vaughn Sommerville was present by teleconference 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 study

1. This is a double blind RCT with parallel design that requires 50 participants (school aged athletes). Participants will be given either OLE or placebo for two months, during their sporting season, while recording their respiratory illness symptoms in a questionnaire twice a week. The questionnaire will also contain three daily food records inserted randomly to assess nutritional and polyphenol intake. If identified as having a URI, participants will have three swabs taken to assess for three common URI pathogens (Respiratory Syncytial Virus (RSV), Influenza A&B and Group A Streptococcus (Strep A)).
2. Participants will be asked to complete a booklet as this has been found to be more accessible than an app and researchers will keep the booklets at school and hand them out to participants before each training session.

Ethical issues (outstanding)

1. The committee noted that the researchers are trialling the supplement in a vulnerable group and the researcher confirmed that they plan to trial mostly in the over 16 age group but that there may be some younger participants (12-16) playing at higher levels who they would like to include. The committee explained that it needs to be sure that the study cannot be done in an adult group before it will accept the trial taking place with children/young people. The committee would prefer that the researchers first trial in a cohort of over 16 year olds and if results from that trial are convincing then the researchers can come back to the committee with evidence of this. At the moment, the committee is not satisfied that there is evidence to support the trial being done in participants who are under the age of 16.
2. A secondary objective of the study is to validate the questionnaire in capturing upper respiratory tract infections and that this is being done for the first time provides the committee with further reason for needing evidence that it has been done in an adult population first.

The committee requested the following changes to the participant information sheets and consent forms:

1. The researcher clarified for the committee that this research is part of a PhD study and that a Masters student will help with the data collection aspect. The committee asked that this information be included up front in the information sheets up.
2. The researcher confirmed that 16-20 year olds will be eligible to take part in the trial and the committee asked that the eligibility criteria for age be included.
3. Please review the language in the participant information sheets so that it is more accessible to lay readers. For example, will the reader know what “polyphenol products” are?
4. The committee noted the answer stated at question p.2.1 on page 18 of the application form and noted that this information was not included in the participant information. As this study is being run as a placebo controlled, randomised control trial that the details about this are included in the information for participants.
5. Please don’t collect names and identifiable information on diaries. Include study codes only
6. The committee recommended that the information about the study procedures be made much clearer for the potential participants. For example: what information and tissue the researchers are going to collect, that participants will be asked to take tablets and be asked about their symptoms.
7. Nasal swabs will be analysed at University of Auckland, Grafton. They will put them on ice for 24 hours as per protocol and will be discarded after the test. The committee noted that there is no mention in the study protocol that the researchers will return results from the swabs to participants and noted that the researchers have a duty of care to treat group A strep if it is found. Please advise participants of this.
8. The committee noted that the researchers had not acknowledged in the participant information sheet that they are using WURSS 21 questionnaires. The researchers explained that the reason for this was to avoid the possibility of bias to the results should people look them up and investigate how to use them. The researchers have permission from the owners of the questionnaire and the committee suggested that they acknowledge this out of respect.
9. If you decide to collect ethnicity data please use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan) please state.
10. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
11. Please include contact details for a Maori support person.
12. The researchers will seek permission form schools and the committee asked that the information for schools is clear about what they have to do and what is required of participants. Please make clear that non-participation will not impact on their position at school or on their team

Decision

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

* Studies should not be performed with vulnerable groups if they can adequately be performed with other groups. Where a study with a vulnerable group is conducted, it should involve the least vulnerable group (eg, older rather than younger children). *(NEAC Ethical Guidelines for Intervention Studies, para 5.30)*
* Please amend the information sheet and consent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This information will be reviewed, and a final decision made on the application, by Dr Christine Crooks and Dr Brian Fergus

The committee noted its concern that the research team has done several studies recently in children only and asked that the HDEC Secretariat contact the Auckland University Research Office to query this.

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| **6** | **Ethics ref:** | **18/NTA/41** |
|  | Title: | Mental health and wellbeing of high risk Pasifika youth |
|  | Principal Investigator: | Dr Julia Ioane |
|  | Sponsor: |  |
|  | Clock Start Date: | 08 March 2018 |

Dr Julia Ioane was present in person 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 study

1. This study will look at the prevalence of mental health issues in Pasifika youth offenders. Study results from overseas have shown an increase in rates of mental health disorders across youth in a justice setting that is higher than in general youth population and a knowledge gap exists in this regard in relation to Pasifika youth.

Summary of ethical issues (outstanding)

1. The committee noted that this is an important study looking at an important question in this population and asked that the researchers revisit the study protocol to include the study purpose, objectives, methods and safety information and that the information in the protocol is linked to the information requested in the participant information sheet. The committee also asked that the researchers include a clear plan in their protocol about how they are going to manage any findings.
2. The above is also not currently well expressed in the participant information sheets and consent forms and the committee would like to see the information sheets and consent forms reworked to more clearly reflect the above and the points of discussion that follow. The committee would like to see participant information sheets and consent forms for the parent/caregiver and for participants aged 16 years and older and a participant information sheet and assent form for participants 15 years and younger. The committee noted that the young person information sheets and consent/assent forms would need to state that the young person consents to their parents seeing information about them.
3. The researcher confirmed that she will be interviewing young people and their parents together in the first interview only and that this is appropriate from a cultural perspective. Young people will be freely able to express themselves and not feel restricted or worried about consequences. The young people will also be interviewed separately and no information will be shared with their parents.
4. The researcher confirmed that the lead investigator and two researchers who are experienced in working with Pasifika youth and their families will conduct the qualitative interviews. If they are known to the participants and their families they will not be involved in interviewing those participants. The committee noted that if the researchers plan to record the interviews that they think through what they will do with the recordings.
5. The researcher confirmed that parents and the young people will each be given a different questionnaire. The committee noted the questionnaire for the parent/caregiver was not uploaded and it would usually expect to see both. In regard to the questionnaire the committee noted there is lots of duplication in the current format and it is not easy to follow. Also, there is a high risk of young people disclosing sensitive information to the researcher and the committee asked that the researcher think about the process and how she will manage this. There may be situations where the researcher will need to refer the young person and the committee noted the need to be clear to the young person that there will be situations where the researcher may need to disclose information and in such instances this will be done in their best interests. The committee also suggested that the researcher might consider collecting information about the young person’s exposure to violence.
6. The length of the questionnaire has been guided by the Christchurch Health and Development Study. The researcher explained that the length of 2.5 hours will give space to the process and participants will be assured that they can stop if they get distressed.
7. The committee recommended that the Adolescent Health Research Group at the University of Auckland research group might have more recent information on Pasifika groups that could be useful when comparing results - it would be useful to have a comparator group even if it is at the population level. The questionnaire used for the national youth health surveys are available here: <https://www.fmhs.auckland.ac.nz/en/faculty/adolescent-health-research-group/collaborations-and-access-to-datasets.html>. The committee also asked the researcher to think about justifying the questions included - standard medical and sexual history when going through advisory group.
8. The researcher confirmed the recruitment process: at a standard meeting after appearance in court the young person will be introduced to the study and if they express interest in taking part they can contact the researcher. The committee noted that the study flyer needs to say that the parents and child will be involved in the study together and the committee asked the researcher to think about how to manage the possibility of coercion. The committee suggested that the researcher be clear on the flyer that this is independent research and there is no obligation to be involved. The researcher explained that she will contact family to organise a time to meet and then meet with them to explain the study and give them an opportunity to respond or to think about and respond. The committee noted that it would prefer that people are given time (up to a week), to respond so that it doesn’t look like they are being coerced to take part. In this regard the committee noted also that the assent process needs to be clear that the young person does not have to be in the study if they do not want to be and that that is fine.
9. The researcher explained that data collected will be managed and coded. At the first meeting identifying details will be given but the researchers will code them straight away and the lead researcher will be only one who has access to the data, which will be password protected. The researchers may use the data as a platform to start building on and might go back to families again in 1-2 year follow up. The committee asked that the researcher make the above clear to participants in the information sheets – i.e where and how information will be stored, for how long and what will happen at the end and that they consent to being contacted after 1-2 years.
10. The committee noted again that this is an important study but it agreed to decline the study to allow the researcher to address the points discussed and to resubmit a new application with a revised protocol and patient information and consent forms.

Decision

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

* All intervention studies should be conducted according to written protocols. The amount of detail in the written protocol and the extent of protocol review processes should be sufficient to ensure appropriate conduct of the study and to cover the level of risk the study presents to participants. *(NEAC ethical guidelines for intervention studies, para 5.41)*
* Informed consent is essentially a matter of good communication between people. Information should be provided to potential participants in a form and way that assists their informed decision-making (*Ethical Guidelines for Intervention Studies* *para 6.22*). Please amend the information sheet and consent forms, taking into account the suggestions made by the Committee.

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| **7** | **Ethics ref:** | **18/NTA/43** |
|  | Title: | Biomarkers and Intestinal Flora in Children with Gut Diseases |
|  | Principal Investigator: | Mr Andrew Day |
|  | Sponsor: |  |
|  | Clock Start Date: | 08 March 2018 |

Dr Jacqui Keenan and Dr Shaun Ho were present by teleconference 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 the study

1. In this study the researchers would like to include children diagnosed with Coeliac disease or Inflammatory Bowel disease and a healthy control group to evaluate the roles of specific biomarkers with a view to negate the need for invasive tests in future.

Summary of ethical issues (outstanding)

1. The committee queried why the researchers wish to conduct this study in a vulnerable population and asked whether they could first do it in adults as the committee needs to be satisfied that studies that can be done is less vulnerable populations are. The researchers explained that the biomarkers in children are different to adults and the tests are less sensitive in adults. Children present with different symptoms to adults and a study in adults would not be translatable to children.
2. The committee was not satisfied that the study could not be done in adults first, noting that this is a burdensome and invasive study for children to be involved in and it asked that the researchers get a second scientific peer review from an expert independent of the study who can answer the questions of whether this study is justified in children and whether similar results could be gained from an adult population. The committee suggested that this could come from a gastroenterologist.
3. The following questions from the committee were based on the provision that the study cannot be done in an adult population:

Coeliac disease study

1. The committee noted that a number of information sheets were submitted with this application and that it was not clear which form was for which group. The committee asked that the researchers review the forms so that it is clear which form is for which group and that the following forms are included: parents/caregivers, participants 16 years and older, participants 12-15 years and participants 7-11 years. For guidance on assent please see: <http://ethics.health.govt.nz/guidance-materials/assent-guidance>.
2. Please make clear in the information sheets that in relation to the use of biomarkers to monitor gut healing that the results from this research will be compared with standard of care results to see whether biomarkers can be used to monitor gut healing.
3. The committee noted that New Zealand law requires that health data be retained for 10 years after it is collected. Please note this and state in the participant information sheet that you will be keeping their data for 10 years.
4. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
5. Please include information about the return of results to participants.
6. Please include information about how much time participants will need to be involved in the study.
7. Please state up front in participant information documents that this research is for a PhD study

Inflammatory Bowel disease group

1. The committee queried the inclusion of siblings as a control group in this study. The researchers noted that they are using the microbiome and asking the question why one sibling develops the condition when the other does not.
2. The committee noted that this is a separate study and that it would like to see a separate protocol and separate participant information sheets and consent/assent forms.
3. The committee noted that it would like to see a rewrite of the information sheets and consent/assent forms and suggested that the researchers refer to the pro forma on the HDEC website for guidance when rewriting these: <https://ethics.health.govt.nz/>
4. Please state up front in participant information documents that this research is for a PhD study.
5. The committee noted that it is not clear in protocol and information sheets that siblings will not have endoscopes and that they will have tissue biopsies as part of clinical requirements. This would also need to be made clear to participants in the information provided to them.
6. The committee noted that it was not clear whether the researchers plan to do specified tests on any tissue collected and then discard it or whether they would want to do future unspecified research. The two are distinct and have different ethical elements. The committee noted that there needs to be a separation between the clinician and researcher taking tissue.
7. The committee noted that again that the current application and supporting documents do not clearly reflect what the researchers intend to do and agreed to decline the application so that the researcher can separate out the study into two aspects and rewrite the protocol. The committee would also like to see peer review that provides a strong justification for why the study needs to be done in children. If this justification can be provided the committee would like to see revised participant information sheets and consent/assent forms.

Decision

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

* Studies should not be performed with vulnerable groups if they can adequately be performed with other groups. Where a study with a vulnerable group is conducted, it should involve the least vulnerable group (eg, older rather than younger children). *(NEAC Ethical Guidelines for Intervention Studies, para 5.30)*
* Informed consent is essentially a matter of good communication between people. Information should be provided to potential participants in a form and way that assists their informed decision-making (*Ethical Guidelines for Intervention Studies* *para 6.22*). Please amend the information sheet and consent forms, taking into account the suggestions made by the Committee

## Substantial amendments

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| **1** | **Ethics ref:** | **NTX/10/03/018/AM09** |
|  | Title: | The Middlemore Tissue Bank (MTB). |
|  | Principal Investigator: | Professor Peter John Browett |
|  | Sponsor: |  |
|  | Clock Start Date: | 08 March 2018 |

Prof Peter Browett and Dr Cherie Blenkiron were present in person for discussion of this amendment.

Potential conflicts of interest

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

Dr Kate Parker and Dr Karen Bartholomew declared a potential conflict of interest, and the Committee decided they could stay in the room but not take part in the discussion or decision-making for this amendment.

Summary of the amendment

The ARTB seeks HDEC approval for collection of tissue samples from children and adolescents for future unspecified research. Residual samples taken with consent for clinical trials have could be banked locally and these tissue samples have great research value for New Zealand researchers to investigate ‘in-house’ paediatric illnesses. Issues are relevant to New Zealand populations and the children, adolescents and their families are keen to collaborate and contribute. The ultimate goal is to have a sample stored for all children.

Summary of ethical issues (resolved)

1. The committee noted that there needs to be a strong justification to do this with children’s tissue for future unspecified research. Researchers will need to have a clear and ethically approved process to answer their research questions to receive HDEC approval for use and the HDEC would not accept approval for use from overseas committees. The committee stated again that it would not approve overseas access to the tissue without an HDEC first approving this. The researchers noted that this process is already contained in their tissue bank protocol.
2. The researchers also noted that their software provider has worked up a system that checks date of birth that prompts them to get re consent from the person after they reach 16 years of age and samples can’t be released unless consent is given. If they cannot re consent a patient who is still alive in cases where they cannot be contacted, the sample will not be used. If the patient has survived many remain followed up into their 20s. The committee recommended that a mortality check is done before researchers start the re consent process.
3. The researchers will need to follow up on what processes are allowed if the parents don’t agree to tissue being stored. The committee recommended they consider possible scenarios and how to deal with them as children are different from adults.
4. The committee noted that two versions of the form are not needed – just one for the parents and then assent forms that are age appropriate. The form needs to make clear to parents what will be required of them and what they are consenting to.
5. The committee asked that the researchers be clear in their protocol about the hierarchy of decision making and what will happen should a child change their mind and wish to not be in a study or to withdraw their consent and that this be reflected in the information sheets/consent forms. Please provide contact details including contact details for a Maori support person.
6. The committee asked that the researchers keep the committee informed in the future if they have questions.

Decision

This amendment was *approved* by consensus.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The committee discussed a query from the ARTB that raised two questions about quality assurance processes and clinical annotation. In relation to the first question about quality assurance for samples collected for the past 5 years the committee advised that the researchers can do this under the Tissue Act and noted if they want to be thorough they could add what types of research.

In relation to the second question about the collection and storage in ARTB of basic clinical data associated with each banked tissue sample the committee noted that it thought ARTB were already doing this. The consent form states researchers use samples to access clinical data. ARTB need to annotate themselves and want confirmation they can hold a minimal dataset but can’t define as samples are so different. In terms of future research ARTB could include a sentence to say that they can access clinical information relevant to future studies that the tissue is used in, but guaranteeing that this information is anonymised to ensure privacy. The previous forms were looser and the committee agreed that ARTB did not need to re-consent people as that was the intention and people signed up to it.

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

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| **Meeting date:** | 17 April 2018, 08:00 AM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

Dr Kate Parker

The meeting closed at 5.20pm.