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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 16 November 2021 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 1:30 - 2:00pm | 2021 EXP 11562 | Effect of Exercise on Sleep Quality in Children with Autism Spectrum Disorder/Takiwātanga: A Pilot Study | Dr Gloria Dainty | Catherine / Kate |
| 2:00 - 2:30pm | 2021 FULL 11105 | A Long-term Follow-up Study of Sotatercept for PAH Treatment | Dr Henry Gallagher | Jonathan / Sotera |
| 2:30 - 3:00pm | 2021 FULL 11513 | Assessment of a New Automated Insulin Delivery System | Dr Martin de Bock | Leonie / Jade |
| 3:20-3:50pm | 2021 FULL 11218 | Walk a mile in their shoes - Developing a virtual reality experience of FASD | Dr Joanna Ting Wai Chu | Jonathan / Kate |
| 3:50-4:20pm | 2021 FULL 11225 | The Orthopaedic Device Infection Network (ODIN) | Mr Simon Young | Catherine / Jade |
| 4:20-4:50pm | 2021 TB 11672 | TRAIL: A Biorepository/Biobank in the Dunedin School of Medicine, University of Otago | Professor Michael Eccles | Leonie / Sotera |
| 4:50-5:20pm | 2021 FULL 11431 | ALXN1840-WD-204: A Study to Assess ALXN1840 in Participant's with Wilson Disease | Prof. Edward Gane | Catherine / Kate |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Apologies |
| Dr Kate Parker | Non-lay (observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Ms Catherine Garvey | Lay (the law) | 19/03/2019 | 19/03/2022 | Present |
| Dr Sotera Catapang | Non-lay (observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Mr Jonathan Darby | Lay (law/ethical reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Dr Leonie Walker | Lay (ethical/moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (intervention studies) | 15/08/2021 | 15/08/2024 | Present |

## Welcome

The Chair opened the meeting at 1:00pm and welcomed Committee members, noting that apologies had been received by Dr Karen Bartholomew.

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 19 October 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2021 EXP 11562** |
|  | Title: | Effect of Exercise on Sleep Quality in Children with Autism Spectrum Disorder/Takiwātanga: A Pilot Study |
|  | Principal Investigator: | Dr Gloria Dainty |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 November 2021 |

Dr Gloria Dainty 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 Study**

The study aims to pilot an exercise intervention to promote exercise and examining its impact on sleep quality among children with autism spectrum disorder (ASD).

**Summary of resolved ethical issues**

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

1. The Committee noted the researcher’s confirmation that the poster submitted is the only advertising material that they plan to use for social media.
2. The Committee noted the researcher’s clarification that they will trust the parents to administer the rewards to children for completing activities as requested and will not be monitoring this.

**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 Pasifika people are a target recruitment group for this study, yet there is no plan for Pasifika consultation on the study design. The researcher clarified that formal consultation has been undertaken with a Māori liaison group in Dunedin. The Committee suggested that the researchers, if interested in Pasifika consultation, could contact Aiono Manu Fa'aea at MIT’s Pasifika Community Centre.
2. The Committee requested the script for the video that will be used to provide study information to child participants is submitted for HDECs review.
3. The Committee requested a copy of the daily diary is provided to the HDECs for review.
4. The Committee advised that the Data Management Plan is missing key elements. In particular, a description of the identifiable and de-identified data that is collected, whether that data can be linked and who is able to link it, who has access to the data, and how data from the smart watches and daily diary is obtained by the researchers. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).* Please use the [Data Management Plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) available on the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) to address this and ensure the template is modified to appropriately reflect the data management requirements of this study.
5. The Committee queried how the electronic consent process will work. The researcher advised that as part of the study is conducted online, the consent form will be available on the REDCap platform and attached to the demographic questionnaire. The Committee requested that the consent form is removed from the demographic questionnaire and attached to the information sheet. This is because the participant is consenting to what is referenced in the information sheet and it should be a standalone document. Please also ensure that participants are provided with the PIS/CF and given an opportunity to discuss the study, before they consent and complete the questionnaire. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.7.)*
6. The Committee requested that during the recruitment process potential participants are given the opportunity to talk with a member of the research team that is not involved in their clinical care. This is in order to mitigate pressure to take part in the study which may be present due to the doctor-patient relationship. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *11.23 – 11.24).* Please update the protocol accordingly.
7. The Committee requested the protocol and participant documentation clearly describe how data from the Fitbit is uploaded by the researchers and what is done with it (i.e. that data is downloaded remotely).

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) in addition to those mentioned above:

1. Please reword the Adult PIS/CF to reflect that the parent is consenting for their child/child’s data and not themselves.
2. Please review the 'What happens to my information section' of [HDEC’s PIS/CF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) and incorporate relevant components into the PIS/CF. This section should align to the information in your data management plan. Please ensure the following issues are addressed;
   1. their right to access and correct information that is held about them
   2. the fact that there will be contact with their usual health provider about their enrolment in the study and notification of any findings of clinical significance, and
   3. that data will be deidentified. This is different from the collection of anonymous data and the references to anonymity should be removed.
3. Please include the advocacy contact details in the Adult PIS/CF and please note that these are incorrect on the child form ([advocacy@advocacy.org.nz](mailto:advocacy@advocacy.org.nz)).
4. Please state clearly in the PIS/CF that participants are required to return the Fitbits at the conclusion of the study in the Adult PIS/CF and child form.
5. Please amend the retention statement to say that the data will be kept for 10 years after the youngest participant turns 16.

**Decision**

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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).*
* Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Kate Parker and Ms Catherine Garvey.

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| **2** | **Ethics ref:** | **2021 FULL 11105** |
|  | Title: | A Long-term Follow-up Study of Sotatercept for PAH Treatment |
|  | Principal Investigator: | Dr Henry Gallagher |
|  | Sponsor: | PPD Global Limited |
|  | Clock Start Date: | 04 November 2021 |

Christine Tuffery and Chloe Logue 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 Study**

The primary aim of this open-label, LTFU study is to evaluate the long-term safety and tolerability of sotatercept when added to background PAH therapy in adult participants with Pulmonary Arterial Hypertension (PAH). The secondary objective is to follow participants from parent sotatercept studies that were treated with sotatercept or placebo and assess continued efficacy.

**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 if there will be self-monitoring of blood pressure at home for those participants self-administering the drug given the study is dealing with pulmonary arterial hypertension. The researcher advised that it is not practical as they would need to provide each participant with a blood pressure monitoring machine and, instead, will monitor participants’ vital signs at the follow-up visits.
2. The Committee noted the researchers clarification that pregnant and breastfeeding women are excluded from the study as the study drug is experimental and the risk to an infant or foetus is yet unknown.
3. The Committee noted the researchers confirmation that they understand that it is not acceptable to stop a therapeutic study for administrative or commercial reasons in New Zealand. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.37).*

**Summary of outstanding ethical issues**

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

1. The Committee noted that there are two parent studies that will feed into this extension study which will potentially be running for more than 12 months. It was advised that there is a high chance the study documentation will require amendment in response to information discovered in the parent study (e.g. side effects, risks, etc.), and which is key information for participants to provide fully informed consent. The Committee requested justification for why this extension study has been submitted at this point in time when the first participant may not be enrolled into the extension study for some time, and indicated that in the Committee’s view the application was premature. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.9, 7.15 – 7.17).*

The Committee requested clarification on recruitment for the study as follows:

* 1. As there are two parent clinical studies involved in recruiting participants, there might be variation in the duration of treatment that may affect the drug or efficacy endpoint. Please clarify if there is stratification of the duration or amount of the treatment drug taken especially with the placebo group.
  2. Please clarify if there is stratification of pulmonary arterial hypertension therapy in single and multiple dose therapies.

1. The Committee requested clarification on the procedure for missed doses and follow-up visits. The researcher advised that there are provisions to do home visits and for participants to self-administer. Please update the protocol with the intended procedure.
2. The Committee requested the following changes to the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7):*
   * There will be pharmacokinetic (PK) analysis done during the study. Please update the protocol to detail the frequency and amount of blood to be taken for PK determination.
   * Please include side effects of the study procedures, in tabular form if possible, to be consistent with Participant Information Sheet and Consent Form (PIS/CF).
   * Please include the specific analysis that the central laboratory will undertake.
3. The Committee requested the data management plan is expanded to include the management of tissue. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.17).* For guidance, please see the [Data and Tissue Management Plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/hdec-data-tissue-management-template-oct2020.docx) available on the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/).
4. The Committee noted that the data management plan refers to an image vendor but the PIS/CF has no information for participants about this. Please provide more detail in the data management plan and the PIS/CFs.

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

MAIN PIS/CF

1. Please provide more detail on how the third parties will be collecting, storing and using the data from the app for self-administration of sotatercept at home. For example, if data is provided to the sponsor in real-time using the app and if the participant is not identifiable, when the app requires identifiers to be set up, etc.
2. Please include the effect of long-term sun exposure, in relation to possible occurrence of telangiectasia.
3. Please replace ‘researchers’ with ‘participants’ in the following statement under ‘Using samples for research’ section, “researchers approved to use the samples for future research”.
4. Please include the effect of radiation 4-5 times higher than the average yearly background radiation exposure.
5. Please state whether or not there is the possibility of karakia for disposal of tissue samples.
6. Please change HDEC from Central to Northern A.
7. The document references Medicines New Zealand Guidelines which is only relevant if the sponsor is a member of Medicines NZ. Please revise wording if they are not a member.

SCALE RATING

1. For the Borg CR10 scale documents, please include a title for these documents and specify what they are to be used for to avoid confusion. Please also provide instructions for participants on how to rate their feelings/experience and who will rate the verbal expression. If both of these scale documents are for the same test (e.g. the 6-minute walk test), please combine them as a single document.

**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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| **3** | **Ethics ref:** | **2021 FULL 11513** |
|  | Title: | Assessment of a New Automated Insulin Delivery System |
|  | Principal Investigator: | Dr Martin de Bock |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 04 November 2021 |

Dr Martin de Bock 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 Study**

A first-in-human study utilising a new automated insulin delivery system designed to control glucose levels of people with type 1 diabetes without them having to announce meals with an estimation of carbohydrate content before they eat. This study will explore the performance of the algorithm in a real-world setting.

**Summary of resolved ethical issues**

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

1. The Committee noted that the main risk of the study is if the algorithm is aggressive and administers too much insulin. To manage this risk, participants are monitored remotely using accurate sensors that can identify this issue and set off an alarm to signal treatment to prevent hypoglycaemia is required. In addition, researchers will be monitoring participants closely (daily for the first week) for adverse events.
2. The Committee noted that the algorithm has been modelled based on data from overseas population and queried if this data modelling is translatable to a New Zealand population. The researcher responded that he does not have any reason to suspect people in New Zealand with type 1 diabetes would be any different to those around the word. He added that the modelling has been done using a large and diverse population.
3. The Committee noted the researcher’s confirmation that the inclusion/exclusion criteria used to recruit New Zealand participants is broad and the categorisation for type 1diabetes used here is equivalent to the American Diabetes classification for type 1.
4. The Committee asked for confirmation that the YpsoPump insulin pump and Dexcom G6 CGM is not currently commercially available in New Zealand as the protocol states. The researcher clarified that the Dexcom G6 sensor is commercially available in New Zealand, however the model of pump being used in the study is a later model and is not yet available in New Zealand. He added that they require two-way Bluetooth technology for this study and the pump on the market in New Zealand only has one-way Bluetooth. He further confirmed that the two pumps are similar, and the research team have experience using the standard older pump model.
5. The Committee queried if participants must keep their android phone near them in order for the study product to work and the safety implications if they do not. The researcher clarified that there is a safety measure in place should the product lose connectivity with the phone, where it will revert to baseline and manual settings that are always running in the background whether or not Bluetooth is connected. He added that when the phone reconnects with the CGM, it will backfill the data.
6. The Committee noted the researcher’s clarification that they will be practicing staggered treatment, where participants will be added to the study one at a time to limit the number of participants who might be exposed to an unanticipated safety risk.
7. The Committee noted the researcher’s clarification that at day 7 of the run-in, the sensor will be replaced with a new sensor and clipped onto the same transmitter that has been used for the first 7 days.
8. The Committee noted the researcher’s confirmation that the number of participants that have used the Gen1 version of TypeZero’s closed loop algorithm is in the hundreds of thousands.
9. The Committee noted the researcher’s clarification that they are in the process of registering the study with the Australian New Zealand Clinical Trials Registry.

**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 YpsoPump insulin pump is an investigational product and requested supporting documentation is provided that shows it’s development, use in studies, and how many patients have used it, etc. If nothing else is available, the Committee would accept the IB for the previous (standard) model.
2. The Committee noted that the insurance certificate is not New Zealand specific, and it is unclear if this insurance will cover is specific to this study or the amount of coverage that will be available to New Zealand participants. Please clarify. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.5).*
3. The Committee advised that the Data Management Plan is missing key elements. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a.)* Please use the [Data Management Plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) available on the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) to address this. In particular, please ensure the following is addressed;
   1. details of Dr Barnard who is arranging the qualitative interview; where is her research site as data is to be stored there
   2. state if interview data is stored as a recording or transcription and if so where?
   3. details of transcribers (if used) of qualitative interview if not done by Dr Barnard
   4. Ypsomed pump data, where will this be sent/stored and who will have access to it?
   5. include Māori Data sovereignty statements.
4. The Committee requested a copy of the “A Summary of Clinical Studies and Outcomes Related to TypeZero Algorithms and Technology” reference in the IB is provided to HDECs.
5. The Committed requested the protocol, Data Management Plan and PIS/CF address Māori data sovereignty. For guidance, please review document templates on the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/).
6. The Committee noted that, contrary to the adult questionnaire, the late teens questionnaire does not include questions about alcohol or sex life. It queried why, given both topics are potentially important considerations for that age group. Please clarify.

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

1. Please provide more information on the optional interviews on page 3. In particular, where data will be stored and who will have access to it (i.e. that Dr Katharine Barnard will be arranging the qualitative interviews and that participant data information will be collected and stored securely at her research site – please state where this) (page 3).
2. Please correct the typo in the following sentence on page 10, “The insulin delivery systems used in this study may cause other side effects that are now yet known”.
3. Please remove reference to Medicine’s New Zealand’s guidelines in the compensation section as these guidelines are not relevant for medical devices.
4. Please align data retention period with what is stated in the protocol (e.g. 10 years vs 15 years) (page 9).
5. Please include a statement advising participants to avoid sunscreen and insect repellent as per the Dexcom-G6-Pro-Blinded-Patient-Guide.

**Decision**

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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).*
* Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Jade Scott and Dr Leonie Walker.

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| **4** | **Ethics ref:** | **2021 FULL 11218** |
|  | Title: | Walk a mile in their shoes - Developing a virtual reality experience of FASD |
|  | Principal Investigator: | Dr Joanna Ting Wai Chu |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 04 November 2021 |

Dr Jessica McCormack 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 Study**

The study seeks to explore the feasibility and efficacy of using wearable cameras as a method for collecting data on the individual experience of FASD. The study also seeks to answer the question of if it is possible to recreate the experience of those with FASD via virtual reality in order to raise awareness and educate. The study will also collect data from participants regarding their experience with FASD in the form of artwork, stories or other creative means of expression which participants will submit directly to the researchers.

**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 diagnosis is confirmed by multidisciplinary team due to its complexity and that recruited individuals will not be limited to those with a formal diagnosis. A larger proportion of people without a formal diagnosis will likely comprise 50% of the creative narrative study.
2. The Committee clarified that there would possibly be crossover between each study cohort.
3. The Committee queried the consent process for the filming portion of the study. The researcher informed that there would be a release, not a consent for the immediate household residents and that any external contacts may be notified as well as supplied on request with a pamphlet providing details of the research.
4. The Committee clarified that the age limit of the study would be 21 years old. The researcher acknowledged the Committee’s concerns regarding the involvement of participants as young as 8 years old and agreed to recruit older participants (age range to be confirmed).
5. The Committee clarified that the narrative study data would be deidentified via Research Electronic Data Capture (REDcap).
6. The Committee clarified that there would be no reproduction of participant artwork without consent.
7. The Committee clarified that there was Māori consultation being arranged.
8. The Committee clarified that there would be only self-report of health information.
9. The Committee clarified that the camera would be at a height where faces and the environment would both be captured.

**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 requires the consent or release forms that will be used for anyone being filmed and for those who are filming.
2. The Committee queried the age of those participating and expressed concern that putting younger children in positions where they may be dealing with confrontational members of the public whilst filming. The Committee also noted that while filming in a public place where there is no expectation of privacy may be acceptable, further considerations arise in relation to how that footage or photographs is then stored and used.
3. The Committee queried the capacity for consent of individuals with FASD. If there is an additional form or method of consenting those with limited capacity, please supply this.
4. The Committee requested more information in the provided documentation around the processes for footage editing and review. In particular, the Committee requested that the researchers ensure they considered whether participants would have the ability to download or save images, with associated concerns arising around confidentiality.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

1. The Committee requests review of consent forms (CF) to be age appropriate as well as appropriate for the capacity of those being consented.
2. The Committee requests that the Peer Review be provided.
3. The Committee requests that further detail be provided concerning data acquired through the body-cameras, particularly of the public.
4. The Committee requests assurance of the security of the data be further considered.
5. The Committee queried if there was the potential for purposeful selection of participants by selecting for those with better support systems around them in order to mitigate some of the risk to participants.
6. The Committee requests that it be made clear that there will be a pilot study of the VR tool that is created and that it is a separate application. In this regard the Committee requested the researcher to consider assurances regarding who will have access to identifiable data.
7. The Committee queried the ability of participants to manage the technology and processes involved in the editing of collected data given the potential for participants with reduced capacity.
8. The Committee would like to be provided with criterion for the selection of participants without formal diagnosis.

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

1. Please provide the consent forms for each environment filming may occur in as well as for any individual who will be filmed and for those who are filming.
2. Please include all the instructions for how privacy will be upheld in the narrative study section of the participant information sheet (PIS).
3. Please include a statement in the CF about the reproduction of artwork.
4. Please include in the PIS/CF details of the events that may lead to referral to Oranga Tamariki and how this will be dealt with and the support participants would receive around this.
5. Please include details for the process of reviewing and deleting video/photos collected on the wearable camera to ensure that this process protects the confidentiality and privacy of those whose images are captured. Include clarification regarding any restrictions on participants retaining footage/photographs.

**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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| **5** | **Ethics ref:** | **2021 FULL 11225** |
|  | Title: | The Orthopaedic Device Infection Network (ODIN) |
|  | Principal Investigator: | Mr Simon Young |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 November 2021 |

Mr Simon Young and Dr Chynna Gleeson 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 Study**

The study seeks to further the Orthopaedic Device Infection Network (ODIN) by creating an international registry that records in-depth data about peri-prosthetic joint infection (PJI) patients and their treatment outcomes.

**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 there was an emphasis first on making the database and using data from North Shore, Auckland City and Middlemore hospitals before then contributing data towards the international directory. Initial data collection will commence at North Shore Hospital.
2. The Committee clarified that there would not be any general practitioner contact as a response to data obtained in the study.
3. The Committee clarified that data from other hospitals would be collected in the way that audit data is shared and that it is likely the data is going to be more retrospective and collected primarily by a summer student.
4. The Committee clarified that the questionnaires are not too onerous and are all standardised. The burden of these is considered low as there has been much review of these in the past in order to ensure maximal return of data. The researcher clarified that there will be no attempt to contact participants whose retrospective data is included, for the purpose of obtaining responses to questionnaires.

**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 requests further information about the international governance of the ODIN registry as per [Chapter 12 of the National Ethics Advisory Committee Standards](https://neac.health.govt.nz/national-ethical-standards/part-two/12-health-data/).
2. The Committee requests that the address and contact details of investigators be corrected in the protocol.
3. The Committee queried if the statement “an enduring power of attorney could opt out on behalf of the participant” held true and if this would be relevant for the participants in this study. The Researcher asserted that there would be no inclusion of data in the case that the power of attorney addressed concern on behalf of a participant lacking capacity to consent or withdraw.
4. The Committee noted that the identifiable data option in the data management plan (DMP) is in fact applicable as the study will use pre-existing District Health Board (DHB) health information as source documents.
5. The Committee requests that the statement in the DMP about the “imaging vendor” be removed as it is not applicable.
6. The Committee notes that the statement “The participants will be informed of the potential risk of sending data overseas” will need to be clarified and included in the Participant Information Sheet (PIS) once the international registry is established.
7. The Committee requests that the protocol includes a statement as to what countries the deidentified data may be sent to.
8. Please address Māori Data Sovereignty in the protocol.
9. The Committee requests clarification of if the North Shore Hospital (NSH) registry staff will input data for all 3 Auckland DHBs.
10. If so, the Committee will the registry staff at NSH be notified that a participant from Auckland District Health Board or Counties Manukau District Health Board is eligible for the study.
11. The Committee requests clarification as to who will be carrying out follow-up contact and in what manner.
12. The Committee requests a copy of the Data Use Agreement.
13. The Committee requests clarification of the responses to D9 and D15 of participants who are “Unwell” and unable to consent/opt-out and why it is believed they would not regain the ability to consent.
14. Please review the PIS forms to identify the different hospitals and clarify data collection as previously mentioned.
15. Please see the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) to assist with better insurance that relevant information is provided, such as how data will be deidentified, who will have access to it; how to opt out. This should not be as stated, by contacting the ODIN registry directly because only the hospital where the participant was seen should have their identifying details.

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

1. Please ensure there is either forms for each hospital involved or one overarching form once locality approval is given.
2. Please clarify the international data storage as per the governance received internationally. Please see the [HDEC Patient Information Sheet template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) for the statement around storage and sending of data overseas.
3. Please add information as pertaining to the answer given to question A.9, if this data will not be used for advertising for external companies, please remove.
4. Please clarify whom “Authorised Personnel” refers to regarding access to data.
5. Please include a statement concerning participant access to and correction of data.
6. Please also include a statement to whether the participants can request results from the research.
7. Please include a statement as to how long the participants data will be stored.
8. Please see the [HDEC Participant Information Sheet Template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) for specific wording concerning registries and for the emails and contacts for HDEC auditing etc.
9. Please clarify to whom the participant should contact in the event of withdrawal.
10. Please clarify the time it will take (for example in minutes) to complete the survey.

**Decision**

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* 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).*
* Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Jade Scott and Catherine Garvey.

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| **6** | **Ethics ref:** | **2021 TB 11672** |
|  | Title: | TRAIL: A Biorepository/Biobank in the Dunedin School of Medicine, University of Otago |
|  | Principal Investigator: | Professor Michael Eccles |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 04 November 2021 |

Professor Michael Eccles 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 Study**

The application seeks to establish the Te Ara Tikanga Rare and Investigator-Led (TRAIL) Biorepository/Biobank at the Dunedin School of Medicine.

**Summary of outstanding ethical issues**

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

1. The Committee queried the practicalities of re-contact of children that have reached adulthood and if there was a method of flagging contacts in the event of a death.
2. The Committee queried the non-optional return of incidental findings and request that information to this effect be included in the necessary documentation as well as an outline of the risks, not only to the patient, but to their whanau also.

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

1. Please include a statement on the deidentification of images collected.
2. Please provide another Participant Information Sheet (PIS) for participants under the age of 16.
3. Please clarify who will be approaching participants to consent them.
4. Please change mention of “This study” to “The tissue bank”.

**Decision**

This application was *approved* by consensus, subject to the following non-standard conditions:

* Please address all outstanding ethical issues raised by the Committee
* Please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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| **7** | **Ethics ref:** | **2021 FULL 11431** |
|  | Title: | ALXN1840-WD-204: A Study to Assess ALXN1840 in Participant's with Wilson Disease |
|  | Principal Investigator: | Prof. Edward Gane |
|  | Sponsor: | Alexion Pharmaceuticals Ltd |
|  | Clock Start Date: | 04 November 2021 |

Ms Courtney Rowse 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 Study**

The study aims to evaluate how safe and well tolerated ALXN1840 is, in participants with Wilson’s Disease (WD) with regards to blood and excreted levels of the trial drug as well as copper and molybdenum.

**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 facilities were adequately prepared for the length of the stay for participants.
2. The Committee clarified the period of time between receiving samples and results would be sufficient in order for the principal investigator (PI) and the Safety Review Committee to make an informed and safe decision about an increase in dosage.
3. The Committee clarified that there were considerations in place in the event of smoking cessation in potential participants given the length of stay.

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

1. Please include information about being able to go for walks and the privacy of participants staying for extended periods.
2. Please include some information around participants remaining in the unit in the outpatient stage.

**Decision**

This application was *approved* by consensus, subject to the following non-standard conditions:

* Please address all outstanding ethical issues raised by the Committee
* Please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

## General business

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

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| **Meeting date:** | 15 February 2022 |
| **Zoom details:** | To be determined |

The meeting closed at 5:20 pm.