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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 23 May 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12:00pm -12:30pm | 2023 FULL 13747 | The Kaitoh First in Human Study | Associate Professor Andrew Holden | Mrs Helen Walker & Mrs Patricia Mitchell |
| 12.30pm -1.00pm | 2023 EXP 12694 | Comparing Nail versus Locking Plate in displaced three-part proximal humerus fractures | Dr Zohreh Jafarian Tangrood | Albany Lucas |
| 1.00pm - 1.30pm | 2023 FULL 16748 | Phase 3 study of darolutamide plus Androgen Deprivation Therapy (ADT) compared with ADT in high-risk BCR (2) | Mr. Kevin Bax | Dr Patries Herst & Dr Cordelia Thomas |
| 1.30pm - 2.00pm | 2023 FULL 17856 | BRII-835-002: A Study to Investigate the Efficacy and Safety of BRII-835 and PEG-IFNα Combination Therapy Treating Chronic HBV Infection (HDEC)﻿﻿ | Dr Wayne Bai | Mrs Patricia Mitchell & Ms Sandy Gill |
|  |  | **﻿﻿Break 30 Minutes** |  |  |
| 2.30pm - 3.00pm | 2023 FULL 17923 | Cue Health International Influenza Clinical Study | Dr. Tori Middlemiss | Dr Patries Herst |
| 3.00pm – 3.30pm | 2023 FULL 17870 | WP44714: A Phase I/II study to evaluate NXT007 in persons with severe or moderate Haemophilia A | Dr. Laura Young | Mrs Patricia Mitchell & Ms Sandy Gill |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mrs Helen Walker  | Lay (Consumer/Community perspectives) (Chair) | 22/12/2020  | 22/12/2024 | Present  |
| Mrs Sandy Gill  | Lay (Consumer/Community perspectives)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Cordelia Thomas  | Lay (the Law)  | 22/12/2020  | 22/12/2024 | Present  |
| Mrs Patricia Mitchell  | Non-lay (Health/Disability service provision)  | 08/07/2022 | 08/07/2025 | Present  |
| Ms Julie Jones  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2022  | Present  |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Apologies |

Welcome

The Chair opened the meeting at 11.30am and welcomed Committee members, noting that apologies had been received from Ms Jessie Lenagh-Glue.

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 26 April 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 13747** |
|   | Title:  | Kaitoh Atherectomy System: Peripheral Artery Revascularization of Stenotic/Restenotic disease using the Atherectomy System in theperipheral arteries |
|   | Principal Investigator:  | Miss Cynthia Corne |
|   | Sponsor:  | Terumo Medical Corporation |
|   | Clock Start Date:  | 06 April 2023 |

Miss Cynthia Corne was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee asked about the participation recruitment process and the submission process. The Researchers explained that the participants will be recruited through the vascular service team and the participants are patients who are already indicated, and prior to the intervention they will have a visit in clinic from the research team to decide if this study is something the participant would be interested in partaking in. The initial discussion of the study does not happen with the doctor in the room, the research team then gives the participant ample time to respond to the PIS/CFs and answer any questions.
2. The Committee asked about the insurance certificate and asked for reassurance that it will be updated. The Researcher explained the insurance is updated annually and will be reinstated. With the updated insurance certificates being uploaded with the annual progress reports.
3. The Committee asked if it usual for the sponsor representative to be present during the trial. The Researcher explained that for their studies this is the usual case due to a lot of first in human work being conducted and typically the sponsor representative is someone who has been involved in the design and the function of the device so they can provide technical support to the investigator. They will only be present during the study device part of the procedure and limit to 3 people in the room during the actual procedure.
4. The Committee asked about pregnancy during the trial and why participants can not be pregnant. The Researchers explained this is because previously the researcher team did not include the contraceptive information however has added it this time due to feedback from other Committees in other trials not related to this study, and the predicted age range of participants the rate of pregnancy will be low, most probably zero. The Committee further noted that participants reading this information may be confused at this section and agree for it to be removed from the application and participant information sheets.
5. The Committee asked what is in place to make participants feel more comfortable during the procedure and if there is a woman getting the procedure would that be done in a room full of men. The Researcher explained that they are always aware and sensitive to both gender and culture issues and when the patients come into the operating room, they are brought in by the nursing staff who are 95% female staff and prep and drab the patient and not exposed and by the time the procedure is ready the doctors enter the room.
6. The Committee asked about reimbursement and if a flat fee could be better as participants keeping receipts for every trip can be difficult for some. The Researchers explained that they usually do not give out a travel stipend because they will be coming into these visits anyway and if they must come in for non-standard of care visits, they will be reimbursed in the form of taxi voucher or a petrol voucher and will not require to keep any receipts.

Summary of outstanding ethical issues

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

1. Please note that the insurance will expire before the end of the study.

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

1. Please add a lay title to the participant information sheets.
2. Please include what parts of the body will be visible when the threading is happening, this will provide reassurance for the participants.
3. Please include the steps taken to maintain modesty when prepping the procedure to reassure participants.
4. In the side effects section please include the side effects specifically for this research and an appendix for side effects of the standard of care.
5. Please provide more detail around the approach of potential participants and who will be approaching the potential participants.
6. On page 1 please amend the wording: "You may or may not gain personal benefits as a result of taking part in the study; however, knowledge will be gained from your participation that may benefit others" as this is a first in person trial, the wording needs to make the potential participant feel comfortable and make the participant not feel bad for choosing not to participate in the study.
7. In the privacy section please delete “as required by New Zealand law.”
8. On page 2 please reword: "can result in a poor result.”
9. Please amend the multiple references to your doctor, GP, and study doctor. Please only use one.
10. On page 3 please remove "partner”.
11. Please remove "it is expected that the likelihood of experiencing any of the side effects listed above is low" from the side effects table.
12. On page 12 please remove "no additional costs".
13. Please add details to contact the GP with abnormal findings into the consent forms.
14. Please include assessments in the table that highlights what will be part of the study over and above standard care.
15. In the contraception section please remove NuvaRing.
16. Please change Northern A to Central.
17. Please include how many representatives will be anticipated to be present.
18. Please use plain language for more, potentially confusing concepts such as procedure performed per standard of care etc.
19. Please state which company will be used for the live transmission.
20. Please state which country for the following: “all of their personnel are subject to privacy, confidentially and code of conduct laws and regulations.”

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Patricia Mitchell and Mrs Helen Walker.

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| **2**   | **Ethics ref:**   | **2023 EXP 12694** |
|   | Title:  | Comparing Nail versus locking plate in displaced three-part proximal humerus fractures; A multi-centre randomised controlled trial (PHINZ trial), investigating the effect on function post-operatively |
|   | Principal Investigator:  | Dr Zohreh Jafarian Tangrood |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 11 May 2023 |

Dr Zohreh Jafarian Tangrood and Dr Richard LIoyd was present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Committee asked about the participant time frame to respond before the operation and asked why its 24hours to 4 weeks. The Researcher explained that in an emergency they do not know the time of the operation. If participants are ready for surgery the research team has time to approach the potential participants to discuss the study, the informed consent part is not necessarily limited to that 24 hour.
2. The Committee asked about the statement in the application explaining that the surgeon has completed this surgery before at least 5 times, however in the PIS/CF it says 10 times. The Researcher explained that it is 5 times per device, and not 10 times per device.
3. The Committee asked if the participant GP will be contacted if any abnormal findings occur. The Researcher explained that the surgeon will contact the GP in relation to any abnormal findings.
4. The Committee asked if the data will be anonymised and what the plan is for future research. The Researcher explained that during the data gathering it is not possible to omit the identifiable data, but after the research data is processed the data analysis will be used, using codes. Confirming that the data will not be anonymised and will remove that section from the data management plan as it was incorrectly, inputted.
5. The Committee asked about the funding of the study. The Researcher explained that they are at the stage of expression of interest and the funding is still under assessment and not sure if it will be funded or not at this stage.
6. The Committee asked about the Māori data section and asked for more clarification around this section. The Researcher explained that when reading the guidelines from their understanding they must collect cultural data in the case that a governmental body wants the data. The Committee reassured that the researchers could collect the ethnicity details but can not let anyone else have the data and if this will happen this has to be included in the participant information sheets to get permission from the participants. The Researcher confirmed they are not sending the data to anyone.
7. The Committee all agreed that the initial reading of the study does not explain well enough that it is a pilot study and that changes aspects of the study and that the committee notes the pilot study participant information sheet will be different from the main study participant information sheet presented at the meeting

**Summary of outstanding ethical issues**

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

1. Please submit a safety plan for when the research assistant visits participants in their homes. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).*
2. Please submit a scientific independent peer review using the HDEC template. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
3. Please submit a data management plan using the HDEC template and explain the difference between identifiable and coded information, who has access to both types of data, how will it be destroyed, and will the data be used for future research, this is all included in the HDEC data management plan template. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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 spell out PHINZ in full when first mentioned.
2. Please include that there are two stages in the study.
3. Please submit two participant information sheets, one for the pilot study and the other for the main study.
4. Please include that potential participant’ can be given as much time as need to read over the PIS/CF and think about if they wish to join the study, please remove the time of 24 hours to 4 weeks.
5. Please include that it is 5 times per device and not 10 times per device.
6. On page 2 please amend the sentence "we still thank you thinking our request".
7. Please note that $50 voucher for "time and experience" will attract tax, please remove the wording of time and experience.
8. On page 4 please amend "get medicine" to “be treated”.
9. Please include the right to correct info into the participant information sheet.
10. Please add a Māori cultural support contact.
11. Please include that the GP will be informed of participation/abnormal findings.
12. Please proofread the participant information sheet for grammar and missing words.
13. In the participant information sheet please add “that I authorise access to my health records as described in the information sheet”.
14. "I agree that my information may be used in the future research purposes" should be coded information; please reword.
15. Please add footers.
16. Currently it is not clear how many post-op visits will take place, please explain physio visits and when the x-rays will be taken.
17. Please amend the deidentified data section, this application has identified data, as patients’ codes are used and can anonymise data to be used for future research, please amend, and include this in the participant information sheet.
18. Please remove the mention of time and vouchers, this is an IRD issue.
19. Please put anything to do with costs and reimbursements into the costs section.
20. Please remove the importance to Māori paragraph.
21. Please amend the section how many times the surgeon has completed this surgery.

**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:**   | **2023 FULL 16748** |
|   | Title:  | A randomized, double-blind, placebo-controlled Phase 3study of darolutamide plus androgen deprivation therapy (ADT) comparedwith placebo plus ADT in patients with high-risk biochemical recurrence (BCR) of prostate cancer |
|   | Principal Investigator:  | Mr Kevin Bax |
|   | Sponsor:  | Bayer Consumer Care AG |
|   | Clock Start Date:  | 11 May 2023 |

No researcher 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 outstanding ethical issues**

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

Main PIS/CF:

1. On page 2 please add closing brackets.
2. Please amend the "best available" medical care section, this does not guarantee and sounds like a promise to the participants.
3. On page 3 please remove repeats of earlier information and simplify language used.
4. On page 3 please rephrase, "several activities"? and refer to table on page 12.
5. On page 4 please soften the language used referring to the disease worsening.
6. On page 5, paragraphs 2 and 4 are contradictory, please amend.
7. On page 7 please remove "increase" as there may be no benefit.
8. On page 8 please include less common and rare side effects.
9. On page 10 there is a repeat of first sentence under "side effects" please amend.
10. On page 11 please remove all references to NuvaRing.
11. On page 12, risk section please include psychological risks.
12. On page 13 please include if clothing will need to be removed or not.
13. On page 14 please amend the "place on the body" section as it's the prostate so the place on the body is known.
14. Please include consent to GP referring to abnormal results into the participant information sheet.
15. On page 19 please include if future unspecified research will be used.
16. On page 20 please change accept to agree.
17. On page 22 the participant can fully withdraw if they want and, in that case, there should be no further contact.
18. On page 25 "data protection authority" please replace with Privacy Commissioner.
19. On page 26 please remove the 5th bullet point.
20. On page 26 ADT will be reimbursed to you from randomization to the end of treatment visits if ADT cannot be allowed to reimburse by standard of care at this hospital or through insurance. The researchers state there are no costs to the patients so please rewrite this sentence to make that clear.
21. Please include a separate PIS for whole genome testing.

Optional Research PIS/CF:

1. On page 1, it currently says "small number" however page 2 says “all participants”, please amend.
2. Please remove repeat section of cultural information.
3. Please note on page 3 HDEC reviews ethical aspects only.
4. On page 7 it has information relevant to main study but is not applicable to the optional PIS, please remove.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by the Full Committee through expedited pathway.

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| **4**   | **Ethics ref:**   | **2023 FULL 17856** |
|   | Title:  | A Phase 2 Multicenter, Randomized, Open-label Study to Investigate the Efficacy and Safety of BRII-835 (VIR-2218) and Pegylated Interferon Alpha (PEG-IFNα) Combination Therapy for the Treatment of Chronic Hepatitis B Virus (HBV) Infection |
|   | Principal Investigator:  | Dr Wayne Bai |
|   | Sponsor:  | Brii Biosciences Limited & Novotech(New Zealand) Limited |
|   | Clock Start Date:  | 11 May 2023 |

No researcher was present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Committee wanted assurance that the relative risks for participation in this study was appropriate to the potential benefits compared to other products being trialled. The Committee requested that another independent peer review by an expert is provided. They strongly recommended Professor Ed Gane to perform this.

**Summary of outstanding ethical issues**

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

1. The Committee noted that the Committee should be presented with a final document, so things should be finalized OR noted whether this is a master and highlighted what will be site-specific information.
2. There is some repetition that needs to be removed, such as page 1 stating twice what the PIS sets out to do.
3. Withdrawal heading does not then contain information about withdrawal.
4. Māori health support should be changed to Māori cultural support.
5. Please see the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for the updated HDEC contact number.
6. Please remove reference to NuvaRing as that is not available in New Zealand.
7. There is a lot of information regarding the schedule of visits and interventions and risks. The Committee requested this be tabled to ensure the participants have a clearer understanding. The Committee further noted the schedule of visit table has been cut and paste from the protocol which adds to complicated information in PIS.
8. Please consider a plain English review of PIS specifically for: "capability to inhibit viral activities" and other technical language.
9. On page 4 in reference to the physical exam, please state whether they are required to remove any clothing.
10. On page 4, please elaborate on "strenuous activity" as it is subjective and vague
11. On page 4, please amend "if you are a woman of childbearing potential" to "able to become pregnant" as more concise
12. The Committee noted to clarify on page 7 that for the discontinuation monitoring period, participants still need to consent to this
13. On page 7, amend "for female participants" to "if this applies to you"
14. Please include in the risks section a description in words as well as "≥1/10"
15. Regarding reimbursement, a standard payment for clinic visits would be preferable to participants having to keep track of receipts and go through time-consuming process
16. With respect to ‘what happens to my information’, please describe the difference between identifiable and coded data and that only coded data will be shared with sponsors and used for future research. That is unclear from the PIS. One paragraph says that data will be send overseas but that laws may be different, then it says that coded data will be send overseas and that laws may be different. States which countries the info is likely to be send to, then there is mention of data being anonymised. That is not mentioned in the data management plan, please review and amend for consistency and clarity.
17. The trial may be stopped for the Sponsor's Decision for commercial interests. This cannot happen in New Zealand.
18. Please clarify how much participants will be reimbursed.
19. Pages 16 and 17 have repeated information about right to access and correct.
20. Lots of places that say “you will” for things like collecting blood, etc, which is worded incorrectly as the participant is not collecting their own blood.
21. Check whether its correct to state routine drug treatment will need to be paid for, and whether this is state-funded as part of standard care.
22. The CF contains an item to consent to notify GP. This was not outlined in the main body of the PIS, please amend.
23. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e., the participant can answer ‘NO’ and still participate in the study).

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Sandy Gill and Ms Patricia Mitchell.

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| **5**   | **Ethics ref:**   | **2023 FULL 17923** |
|   | Title:  | Cue Health International Influenza Clinical Study |
|   | Principal Investigator:  | Dr Tori Middlemiss |
|   | Sponsor:  | Cue Health Inc. and locally sponsored in New Zealand by IQVIA |
|   | Clock Start Date:  | 11 May 2023 |

Dr Penny Montgomery, Dr Tori Middlemiss, Kshemina Mhaskar, David Tsay, Sonar Pradhan, Kumar Duraiswamy, and Shenjira Landicho were present via videoconference for discussion of this application was present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Committee confirmed with the Researcher that no identifiable data will be collected in the app, and places where it asks for the name etc will be pre-loaded with either the ID or with a generic name.
2. The Researcher clarified that participants are through advertising who will contact researchers, no need for those letters. There are a couple sites linked to GPs, so they may be getting participants who have presented to these practices. The Researchers do not see the participant letter being used at all due to the advertising material being used.

**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 peer review submitted doesn’t meet HDEC requirements of being independent from the study. Please provide an independent peer review. The [HDEC peer review template](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) can be used in order to get an independent expert to comment on methodology, analysis, time frames etc.
2. The Committee noted that the insurance provided is not specific to this study and seems to be more for the company premises and workers rather than participation of the study. The Researchers noted that this covers any trial Cue administers, but the Committee stated this is not typical of what the HDEC expect, and that the study participants for this trial need to be covered with an ACC-equivalent amount.
3. The Committee stated that the cultural answers of the submission missed the Tapu of head. This should be addressed in cultural paragraphs of the participant information sheets.

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

All:

1. Each PIS should state what is meant by flu symptoms. These are only in the 7-11 PIS
2. Māori health support should be changed to Māori cultural support.
3. The Main PIS does not make it clear that BOTH the child's parent AND a study team member are testing the child (cf. p2, p3).

Main PIS and parent/guardian PIS:

1. This is very dense to read, a larger line space maybe 1.15 rather than 1 would help. In some places 1.15 is used and that is much easier to read.
2. Adding a picture of the device would be helpful
3. At the top of page 2, please remove that sentence that says that without investigational research little progress would be made. This could make people feel bad to refuse and be considered coercive.
4. Under Benefits, there are no benefits for individuals: they do not get a diagnosis, they do not get the results from their test sample. So just leave in that last sentence.
5. On page 4 - “You do not waive any liability rights for personal injury by signing and dating this form”. This seems Americanised, and the Committee instead expect a statement saying it is recommended to check with health insurance if they have any if participation in the trial impacts their cover.
6. On page 4 under risk about loss of confidentiality: ‘However, steps have been taken to help make sure this will not happen…’ This cannot be guaranteed, it is better to say ‘make sure this risk is minimized.’
7. On page 5, please note that stopping the study cannot be for commercial reasons
8. On page 5, payment of $69 cannot be for time or else it will be taxed. Please state ‘for your participation.’ Please clarify if this is for travel and parking or if that is separate. The optional PIS suggests there is compensation for travel and parking, however this is not in the main PIS.
9. The Committee queried the amount being $69 when it could be $70 or another rounded number.
10. On page 12, “All research in New Zealand involving humans is reviewed by an independent group of people called a Health and Disability Ethics Committee” should be removed as that is not correct. Just keep that the ethical aspects have been approved by the HDECs.

Optional Future Unspecified Research (FUR) PIS:

1. Please review and amend this PIS to be only for FUR and what happens to FUR samples and data.
2. The Committee noted there is no benefit from those future studies as participants won’t know what they are when they happen or what the results will be.
3. There won’t be a karakia for those future samples upon destruction. Please state this.
4. Page 3. “Any information obtained in connection with this research study that can identify you will remain confidential and will only be used for the purpose of this research study and for future research as described above in this document” This refers to the main study, please amend so it only focuses on the FUR
5. “Any information obtained for the purpose of the future research, that can identify you will be treated as confidential.” But the main PIS states this data will be anonymised. Please be very clear about this and just use anonymised throughout. For future unspecified research Researchers should not have identifiable information at all, anonymised preferably and coded at the very east with no access to links to these codes.
6. Who has access to health records appears to be a cut and paste from the main PIS with a lot of irrelevant information that has nothing to do with FUR. Please remove
7. In the CF there are bullet points that have nothing to do with FUR.
8. Participants won’t be able to withdraw from the study because all their samples and data will be anonymised. They won’t have access to that data. That needs to be made clear as well.
9. On page 3, the data protection law is incorrect for New Zealand.
10. Page 4 states all research in New Zealand involving humans is reviewed by an independent group of people called a Health and Disability Ethics Committee” which should be removed as that is not correct. Just keep that the ethical aspects have been approved by the HDECs.

11-15 PIS/Assent:

1. Under benefits, please include the tests will NOT make them better and there is no direct benefit from taking part.
2. Please state that swabs and health information are going to the USA
3. “Your left-over reference test swab samples may be used for future research studies only if you agree and provide your consent at the end of this form”. They cannot consent for themselves…they give assent and there should be a separate FUR PIS for these kids as well.
4. This information sheet should have a cultural statement like the main PIS.
5. The Researchers cannot promise no one will be upset if they don’t participate, please remove.

7-10 PIS/Assent:

1. There is too much information for this group, some of this could go in the 11-15 PIS
2. Needs simple language, pictures, and more white space.
3. Under benefits, please include the tests will NOT make them better and there is no direct benefit from taking part.
4. Remove reference to helping doctors.
5. ‘Help other children’ is repeated, please amend.
6. A picture of the process would help, please include.
7. The Researchers cannot promise no one will be upset if they don’t participate, please remove.
8. The Committee queried why it states ‘you may feel better while giving samples’. That is unlikely, and the 12-15 PIS says it is not known whether will make them feel better. Please remove.

Optional PISs for 7-11 and 11-15:

1. There is too much information for the 7-11/younger aged participants, please simplify.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please supply an independent peer review for the current version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Dr Patries Herst.

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| **6**   | **Ethics ref:**   | **2023 FULL 17870** |
|   | Title:  | A PHASE I/II STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, PHARMACODYNAMICS, AND EFFICACYOF NXT007 IN PERSONS WITH SEVERE OR MODERATE HEMOPHILIA A |
|   | Principal Investigator:  | Dr Laura Young |
|   | Sponsor:  | F. Hoffmann-La Roche Ltd |
|   | Clock Start Date:  | 11 May 2023 |

Mrs Fadiya Al-Abuwsi was present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Committee confirmed with the Researcher that for now only adults will be recruited, and if teenagers will be recruited, this will be applied for separately.
2. The Committee noted that the peer review provided was a memo from Roche, however noted that as this is a new medicine, this is going to SCOTT which will perform this function.

**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 amount of time required of the participant is significant and should be acknowledged over and above expenses. This is not a payment for their time but can be expressed as an acknowledgement for their participation, such as a koha. This should be outlined in the participant information sheet.

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

1. Please amend the inclusion in the main PIS about having 12–17-year-olds as only 18+ are being looked at for this submission at present.
2. The Committee noted that the PIS needs to be finalised as there are some pieces of missing information or template statements.
3. Regarding the statement “Instead of taking part in this study, you may choose to… Get no treatment.” Given the nature of the condition, no treatment would not be an option. A different study also adds confusion. Get treatment without being in this study should be receive 'usual' treatment. The Committee suggested removing this.
4. Please outline how participants will be replenished with emergency treatment (if it is required to be used more than once during the study).
5. On page 4, "your study doctor can decide to repeat the screening up to three times" should include “with your consent”.
6. It is not clear from PIS whether participants will be paying for accommodation costs if they must stay "at a local motel". Please clarify this.
7. The PIS does NOT explicitly state that the study cannot be terminated for commercial reasons (see page 11). Please include this.
8. From page 7, "if you become upset or distressed as a result of your participation...please call the contact person listed at the end of this form" The Committee noted that they should be able to tell any member of study team in person too.
9. In the CF, it states ‘If you need an interpreter, please inform the site staff’. The Committee queried how would a participant with English as a second language understand this.
10. Pregnancy risk is in the CF yet there is no stated requirement to avoid pregnancy stated. This can be removed.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Sandy Gill and Ms Patricia Mitchell.

## General business

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

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| --- | --- |
| **Meeting date:** | 27 June 2023 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 3:30PM.