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| Committee: | Southern Health and Disability Ethics Committee |
| Meeting date: | 10 November 2020 |
| Meeting venue: | Via Zoom: Meeting ID: 965 0758 9841 <https://mohnz.zoom.us/j/96507589841> |

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| Time | Item of business |
| 10.00am | Welcome |
| 10.15am | Confirmation of minutes of meeting of 13 October 2020 |
| 10.30am | New applications (see over for details) |
| 10.30-10.55am  10.55-11.20am  11.20-11.45am  11.45-12.10pm  12.10-12.30pm  12.30-12.55pm  12.55-1.20pm  1.20-1.45pm  1.45-2.10pm  2.10-2.20pm  2.20-2.45pm  2.45-3.10pm  3.10-3.35pm | i 20/STH/127  ii 20/STH/184  iii 20/STH/185  iv 20/STH/189  Break  v 20/STH/190  vi 20/STH/191  vii 20/STH/192 [CLOSED]  viii 20/STH/193  Break  ix 20/STH/194  x 20/STH/200  xi 20/STH/195 |
| 3.35-3.40pm | General business |
| 3.40pm | Meeting ends |

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| Member Name | Member Category | Appointed | Term Expires | Apologies? |
| Dr Sarah Gunningham | Lay (other) | 05/07/2016 | 05/07/2019 | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 28/06/2019 | 28/06/2020 | Present |
| Dr Paul Chin | Non-lay (intervention studies) | 27/10/2018 | 27/10/2021 | Present |
| Professor Jean Hay-Smith | Non-lay (health/disability service provision) | 31/10/2018 | 31/10/2021 | Apologies |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 19/08/2020 | 19/08/2021 | Present |
| Mr Dominic Fitchett | Lay (the law) | 05/07/2019 | 05/07/2022 | Present |
| Dr Pauline Boyles | Lay (consumer/community perspectives) | 05/07/2019 | 05/07/2022 | Present |

## Welcome

The Chair opened the meeting at 10am and welcomed Committee members, noting that apologies had been received from Jean Hay-Smith

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 13 October 2020 were confirmed.

## New applications

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| 1 | Ethics ref: | 20/STH/127 |
|  | Title: | NATO |
|  | Principal Investigator: | Mrs Helen Houston |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 August 2020 |

Helen Houston 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

1. The NATO study has been designed to see if non-anaemic iron deficiency slows down recovery after surgery for colorectal cancer, or if non-anaemic iron deficiency increases complications after surgery, such as infection.

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 answer in the form that the anaesthetist “is unlikely” to recruit or be involved in the research and stated they should not be involved to ensure a degree of separation with those involved in direct care. The researcher clarified that the participant would already be recruited prior to meeting the anaesthetist.

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 stated that the main ethical concern is that standard of care at a site-specific level may be withheld and asked the researcher to explain the guidelines at the hospital for standard of care. The researcher explained that the guidelines is referral to blood management to see if they are suitable for treatment based on their HB and Ferritin results. The Committee asked if there is potential for some patients to not be approached for inclusion in the study. The researcher confirmed this. The Committee requested that this is written into the protocol as a clarification note for all New Zealand sites, as this is only referred to in the participant information sheet.
2. The Committee requested formal Māori consultation to be undertaken as Māori are not specifically excluded.
3. The application form states that blood and serum will be disposed of, but there is reference to tissue being stored and used for other purposes outside of the study elsewhere in the form. The application form also mentions a sub-study. The researcher clarified this is incorrect and is a discrepancy in the protocol from Australia, and New Zealand are not currently planning to conduct a sub-study. The Committee requested this be clarified in the protocol.
4. The Committee noted the recruitment process of a research team approaching patients. The Committee requested that they are first briefly approached by someone in their clinical care team to remove the cold-call approach.
5. Please clarify that the exclusion criteria is elective colorectal surgery, not emergency colorectal surgery.

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

1. The Committee referred the researcher to the HDEC template to guide the corrections. (<https://ethics.health.govt.nz/updates/new-participant-information-sheet>)
2. Change sentence about taking iron as ‘recommended’ rather than essential. Many instances where this is written, please amend all.
3. Section 9 says “current guidelines do not recommend” which contradicts the hospital guidelines, please amend to state there is a group of patients who will be recommended iron therapy.
4. The use of samples for additional research will require written consent from participants, not consent provided over the phone.
5. Page 2 refers to lead doctor being in Australia – please note the lead doctor in New Zealand.
6. The stated aim to investigate "the effect that having inadequate iron stores has on the ability of the body to recover after major surgery" sounds alarming and should be rephrased to be more positive.
7. The Committee stated that many participants would not consider their poor outcome an exciting new frontier. Please reword.
8. A Māori tissue statement in relation to sending samples overseas, and the use of samples for research purposes, is required. Please refer to the template for wording.
9. Please provide the laboratory name and address in Australia where samples are being sent.
10. Please remove options referring to sub-study/extra research in the consent form.
11. A section on data management is required. Please refer to the HDEC template.
12. Please use a simple lay title as the title for the PISCF.
13. Please refer to the HDEC template for the general layout for accessibility.
14. Please review for lay-language.

Decision

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

1. Please supply evidence of Māori consultation to ensure the study is appropriate for a New Zealand context (National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7).
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).

(The link to the National Ethical Standards is found at <https://ethics.health.govt.nz/home> under the Quick Links section).

After receipt of the information requested by the Committee, a final decision on the application will be made by Devonie Waaka and Sarah Gunningham.

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| 2 | Ethics ref: | 20/STH/184 |
|  | Title: | Hip Abduction Strength in Musculoskeletal Conditions |
|  | Principal Investigator: | Dr Samantha Wong |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 29 October 2020 |

Samantha Wong and Hamish Osborne 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

1. The purpose of this study is to determine the rates of hip abduction weakness in lower limb musculoskeletal injuries, low back pain and upper limb musculoskeletal injuries.

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 for clarification of whether the 340 people without musculoskeletal injuries that have data collected about them are included in the study. The researcher clarified that they are not but will be acting as a historic comparator control group for the purposes of this study. The committee queried if permission for use of this data had been obtained. The researcher stated that this data is deidentified and consent was provided at the time of collection for this use.
2. The Committee queried the inclusion of youth. The researcher stated that growth spurts have been observed as an onset cause of weakness, so it is present very young. The Committee were satisfied with this response.

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 stated that it was unclear how 1000 participants would be included as the list of diagnoses was not outlined in the protocol, and hypothesis was not specified. Please amend this.
2. The Committee stated that the research being performed at two different centres needs to be clarified in the protocol.
3. The Committee noted that the age when consent is presumed in New Zealand is generally 16, not 18. However, a young person can still participate without their parent’s agreement if they are deemed by the researcher to be competent to consent in their own right and there is no fixed age at which a young person is presuemd incompetent (although obviously the younger they are, the less likely they are to possess the necessary capacity).
4. The Committee noted that data retention is 10 years following the last child turning 16.
5. A data management plan is required. Please refer to the HDEC template for guidance (<https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans>)

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

1. Please add a Māori health contact. In each locality, please identify who is capable of and is willing to act as a cultural support person for Māori in the study. Local District Health Boards may be able to suggest contacts.
2. Please remove repetitive statements.
3. Description of the study needs to be clearer, and the use of diagrams would assist in this. Please remove the exam reference.

Decision

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

1. 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).
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 supply a data governance plan to ensure the safety and integrity of participant data (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).

(The link to the National Ethical Standards is found at <https://ethics.health.govt.nz/home> under the Quick Links section).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mira Harrison-Woolrych and Pauline Boyles

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| 3 | Ethics ref: | 20/STH/185 |
|  | Title: | The Rakeiora Primary Care Pathfinder Study |
|  | Principal Investigator: | Professor Stephen Robertson |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 29 October 2020 |

Stephen Robertson and Phillip Wilcox 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

1. The purpose of this study is to assemble a secure and anonymised research database of data from 200-300 people who are registered with Ngāti Porou Hauora that combines their genetic and healthcare data to improve accuracy and quality of healthcare.

Summary of resolved ethical issues

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

1. One of the researchers declared their conflict as an HRC ethics committee member. The Committee acknowledged this and allowed them to participate in the meeting in their capacity as a co-investigator
2. The Committee queried the purpose of storing samples indefinitely. The researcher stated that the sample collection being stored this way is to acknowledge the gift status from Māori and to not assign the meaning of it being something easily re-collectible. It remains under the ownership of the participants.
3. The Committee stated it was not clear if those invited to the study will only be Māori or if other ethnicities will be invited to participate. The researcher responded that the study is blind to ethnicity and is open to anybody as long as they are registered with Ngāti Porou Hauora.

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 procedure around unexpected findings. The researcher clarified that there are provisions for incidental findings, but the likelihood is low due to the particular genes being investigated. The Committee requested this be reflected in the protocol and explained that there is potential for clinically actionable results that the researcher has a duty to disclose.
2. The Committee stated that data must be retained for 10 years to be in line with the National Standards.

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

1. Please state you are testing other genes, and that some of the genetic research is exploratory. Make it clear that these are not used for clinical decisions so participants will not get these results. Clinical actionable variants will be notified to the GP.
2. In the purpose of the study section: “several hundred people” is vague. Please specify 200-300 as per protocol.
3. Please review for lay-language.
4. Please specify what happens to sample after patient’s death.
5. On Page 3, you don’t specify who is doing the short-read. Please include this information.
6. On page 5, there is some duplication. Please amend.
7. Please use the ACC statement from the HDEC PIS template (<https://ethics.health.govt.nz/updates/new-participant-information-sheet>)
8. Please review for typos and grammatical errors
9. Please remove the tick-boxes as they are not necessary.
10. Because you are dealing with genetic data, please let participants know that even though you are doing everything you can to protect that data, there is a risk there could be a privacy breach. Please acknowledge this risk.

Decision

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

1. 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).
2. 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).

(The link to the National Ethical Standards is found at <https://ethics.health.govt.nz/home> under the Quick Links section).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dominic Fitchett and Paul Chin.

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| 4 | Ethics ref: | 20/STH/189 |
|  | Title: | Tokēke |
|  | Principal Investigator: | Dr Peter Carswell |
|  | Sponsor: | Synergia Ltd |
|  | Clock Start Date: | 29 October 2020 |

Heather Kongs-Taylor 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

1. The purpose of the research is to identify an effective model(s) of collaboration between the Work and Income case management service and contracted employment support providers that maximise employment outcomes for people with addiction and/or mental health issues.

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 for clarification around the role of the sponsor in regard to who will have ownership of the data collected. The researcher responded the sponsor will not have ownership of the data.
2. The Committee queried the lack of koha or reimbursement in the application form and asked for justification. The researcher said a koha is provided to whaiora and some of the organizational participants. The koha being provided is $200 to each organization that is participating (excluding DHB), and $30 food voucher for whaiora participants
3. The Committee queried how participants are identified as having mental health issues. The researcher responded that the criteria for offering these services by the organizations recruited into the study have identified these issues.

Summary of outstanding ethical issues

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

1. The Committee queried if names or places will be redacted from transcripts. The researcher responded that they would not as they will typically be relevant to the study. The Committee stated these are potential identifiers and these need to be redacted (names, specific locations, etc.)
2. The Committee stated there is a large potential for a privacy/confidentiality breach when sending participants transcripts via mail (email or postal) and asked for the researcher to offer the option to check the transcript in person after confirming the participant wants to check.
3. The Committee asked why ethnicity data is not being collected. The researcher stated that due to targeted recruitment, it is assumed most participants will be Māori. As participants were engaging with these organizations because they were Māori, the assumption would be that there is no need. However, the researcher stated they will reconsider this stance and collect this data.
4. A data management plan is required, either as a standalone document or integrated as part of the protocol. The HDEC template can be referred to as a guide. While it is not mandatory to use, it is helpful at outlining the amount of detail required. (<https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans>)
5. The Committee stated that more detail is needed about the service-user interviews, such as eligibility criteria, interview methodology (such as sites of interviews, planned audio transcription, etc.). Include detail about conducting videoconferencing interviews.
6. The Committee stated that risk of disclosure indicating worsening mental health is not properly outlined. Please provide detail of this to the Committee and include this information in the participant information sheet.
7. The Committee asked for the protocol to have a footer with page numbers, version number, title and date.
8. The Committee requested that all other information sheets are uploaded for the Committee to sight, and noted that the below changes will be applicable to those.
9. The Committee requested more information regarding how the workshop briefings will work, given that the peer reviewer identified a demonstration model to be more effective.

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

1. Please review for typos and grammar.
2. Please review for lay-language, such as “collaborate”.
3. Purpose: 'see as the benefits.....' - please also add drawbacks or issues.
4. Please state that the decision to participate will in no way affect services provided to the client and state that the interview data will not be provided to WINZ or other support services.
5. Please state where the interview will be conducted.
6. Please state that no health-related questions will be asked.
7. Please state that, should the participants disclose information that suggests significant risk to themselves or others, the interviewer has a legal duty to disclose the information.
8. Please state the form in which data is collected; when it is de-identified; and when the link between identifiers and codes is destroyed.
9. Please state options for withdrawal of data (purely observational study; data withdrawal should be permitted to the point of analyses).
10. Please state clearly that data will not be made available for future research.
11. Please amend to state that health data generated during the study must be retained for at least 10 years.
12. Include risk of confidentiality / privacy breach.
13. Include a cultural statement regarding the taonga of Maori health data.
14. Include contact numbers of free support services in event of distress etc. caused by interview.
15. Please include information on the sponsor in the information sheet.
16. Please add footers with page numbers, version number, title and date.
17. The Committee stated that the HDEC template should be referred to in order to assist with the above requested changes (<https://ethics.health.govt.nz/updates/new-participant-information-sheet>)

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 supply a data governance plan to ensure the safety and integrity of participant data (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).
* 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 Helen Walker and Devonie Waaka

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| 5 | Ethics ref: | 20/STH/190 |
|  | Title: | BP02-101: A study comparing Herceptin® and the trial drug BP02 in healthy men. |
|  | Principal Investigator: | Mr Christian Schwabe |
|  | Sponsor: | CuraTeQ Biologics Private Limited |
|  | Clock Start Date: | 29 October 2020 |

Christian Schwabe and Celina Capistrano 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.

Devonie Waaka declared a potential conflict of interest and excused herself from discussion.

Summary of Study

1. CuraTeQ has developed their own preparation of trastuzumab, called BP02. This study aims to show that BP02 has a high degree of similarity to Herceptin, in terms of levels of drug in the blood over time, safety and side effects, and the development of anti-drug antibodies.

Summary of resolved ethical issues

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

1. The Committee requested further clarification for what ‘at-risk’ for COVID-19 means in this context as the whole population is considered at risk, and that a chest-x-ray would be required if considered at risk. researcher clarified that the protocol regarding this has been provided from overseas sponsor, but local practice will be investigator discretion based on symptoms. A swab will be performed as part of usual clinical care.
2. The Committee queried if the echo is enough given the danger of administration on the heart. The researcher responded that this is the preferred tool to monitor for cardiac toxicity in this context, but the risk in healthy males in single dose is exceedingly small.

Summary of outstanding ethical issues

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

1. In addition to hepatitis B etc, COVID-19 is also notifiable to the Medical Officer of Health.
2. Risks of BP02 section: some risks do not have % reported e.g. anaemia = very common (>10%), neutropaenia = very common (>10%), cardiomyopathy = common (1-10%) – please add, as this is known with Herceptin e.g. <https://medsafe.govt.nz/profs/Datasheet/h/Herceptininf.pdf>
3. Please clarify if there is additional reimbursement (to the $3700) for the 6, 9 and 12 month post-dose extra tests, or if reimbursement be only for travel.
4. Please include information about how many participants have had BP02.
5. Please include a lay-title.
6. Please highlight that this is a single dose only.

Decision

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

* please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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| 6 | Ethics ref: | 20/STH/191 |
|  | Title: | A randomised controlled trial of oral BBT-401-1S in Subjects with Moderate to Severe Ulcerative Colitis |
|  | Principal Investigator: | Dr Richard Stubbs |
|  | Sponsor: | Covance New Zealand Limited |
|  | Clock Start Date: | 29 October 2020 |

Richard Stubbs 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

1. This is a randomised, double-blind, placebo-controlled study of oral BBT-401-1S in participants (pts) with moderate to severe ulcerative colitis (UC), with a double-blind extension phase.

Summary of resolved ethical issues

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

1. The Committee queried the increased dose level in the patient group as compared with the dose that was safe for healthy volunteers, and if the researcher was satisfied with this increase. The researcher commented that the drug is not absorbed and not expected to be an issue with blood levels.
2. The Committee queried if there is a chance participants could be denied their usual medication. The researcher clarified that taking prohibited medication would be an exclusion criteria rather than requesting them to stop to participate.
3. The Committee asked how often the diary is being checked for mental health concerns. The researcher stated that the diaries are physical and only looked at each in-person visit and commented that depression and anxiety are unlikely to be observed in participants.
4. The Committee asked for justification that participants with active UC are prohibited from starting other immunosuppressants. The researcher clarified that they are not prohibited, but that them taking these will just result in them being taken off the study drug.
5. The Committee stated that the protocol implies that tissue sampling is optional whereas the information sheet states it is mandatory. The researcher confirmed it is mandatory.

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 asked for clarification around a.1.5. stating those who experienced remission in induction continue on same Rx in extension (thus participants receiving placebo will continue to receive placebo, while a.1.6 states all participants will receive IMP in the extension phase. The researcher stated that if participants are assessed as being fine to continue on the placebo, they will remain on the placebo. However some might be required to receive IMP in the extension phase. The Committee requested to make it clear in the protocol and to participants that they could be on a placebo in any extension of the study.
2. The Committee asked for further information about the referral process. The researcher responded that participants would have been identified and referred through their gastroenterologist. Advertising will also be used. The Committee requested that the patient’s gastroenterologist should check with the patient that they are happy to be referred prior to notifying the research team, and to submit any advertisement material to the Committee for review by way of an amendment.

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

1. Please amend lay-title to avoid use of ‘subjects’ and replace with participants.
2. Please include further detail around inclusion and exclusions (such as age, weight, important medical disorders.)
3. Please make it clear what access there is for participants to BBT-401-1S post-study
4. There is currently an inadequate explanation of biomarkers and genetic research on page 5. Please explain the types of research clearly and in lay terms, in a separate subsection
5. On page 16, please include information about future research (as indicated may be undertaken in app form)
6. For the pregnancy information sheet, please note that separate consent must be obtained in order to collect infant health information post-birth. The Committee noted that these are typically not submitted until a pregnancy within the study has occurred.
7. Please correct participation from “20” weeks to “22” weeks.
8. On page 9, conflicting statement around what happens to samples after withdrawal needs to be clarified.

Decision

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

* please submit any advertisement material to be used as an amendment
* please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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| 7 | Ethics ref: | 20/STH/192 [CLOSED] |
|  | Title: | Efficacy and Safety of Guselkumab in Participants with Moderate to Severe Ulcerative Colitis |
|  | Principal Investigator: | Dr David Rowbotham |
|  | Sponsor: | Janssen-Cilag Pty Ltd |
|  | Clock Start Date: | 29 October 2020 |

David Rowbotham and Dee Yang 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.

CLOSED SESSION

Decision

This application was provisionally approved by consensus

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

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| 8 | Ethics ref: | 20/STH/193 |
|  | Title: | MINT Trial |
|  | Principal Investigator: | Professor Harvey Douglas White |
|  | Sponsor: | Rutgers Robert Wood Johnson Medical School |
|  | Clock Start Date: | 29 October 2020 |

Caroline Alsweiler 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

1. This multi-center randomized clinical trial compares two strategies for red blood cell transfusion. The trial will enroll 3500 hospital inpatients diagnosed with myocardial infarction who are anaemic (have blood counts less than 100g/L) to receive either a liberal or a restrictive transfusion strategy.

Summary of resolved ethical issues

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

1. The Committee stated a key ethical issue was whether participants would be denied standard of care treatment. The researcher explained that there is no current consensus for standard of care for these kinds of patients, and it is often up to the individual institution or clinician to determine whether transfusion is appropriate. The participating institutions have agreed the design of the study is in line with their practices.
2. The Committee was satisfied that the public repository of deidentified study data is covered well in the data management plan and information sheet.
3. The Committee queried what plans were in place if the participant reports acute problems in response to questionnaires. The researcher stated that this is done in a clinical setting, so a response can be provided straight away.
4. The Committee were satisfied after discussion with the submission of the NIH process as a peer review.

Summary of outstanding ethical issues

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

1. The Committee requested that participants receive a primer from their clinical care team to check they are okay to be approached by a member of the research team.

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

1. Please lay out the risks of blood transfusions more clearly.
2. A more appropriate lay title is needed
3. Please review for lay-language. The Committee also suggests the use of diagrams if applicable.
4. Please review font, layout and formatting for readability.
5. Please display risks as bullet-points.
6. Under benefit section, please state that there could be no benefit.
7. Please review for language such as “you will” to be amended to “you may”
8. Please replace “subject” with “participant” throughout the document.
9. “Your doctor has given us permission…” statement should be removed (and in brochure). Amend to reassure participant that their doctor is okay for the participant to take part.
10. Please amend American units to New Zealand units.
11. “You may not take part in this study if your red blood cell count does not fall below 100g/L”. is unnecessary given that the patient shouldn’t be approached if Hb < 100 g/L
12. “They will call you twice, once at 30 days and again at 6 months to see how you are doing and to find out if you have had any additional hospitalisations” Please state who will do the phone call, duration.
13. “Sponsor study monitors, to make sure the study is being run properly and that the data collected is accurate.” Please state if Rutgers Robert Wood Johnson Medical School have study monitors looking at identifiable data for New Zealand participants of this study.
14. “The time frame for this will be in approximately xx years” Please state what xx is.
15. “I understand and consent to all of the conditions listed here” must be yes to participate so please remove yes/no that are not truly optional.

Decision

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

* please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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| 9 | Ethics ref: | 20/STH/194 |
|  | Title: | (duplicate) Physiological pain regulation and the buffering effect of social support in patients with chronic pain |
|  | Principal Investigator: | Dr Maria Kleinstaeuber |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 29 October 2020 |

Maria Kleinstaeuber 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

1. This study seeks to investigate cardiovascular changes in patients with chronic pain compared to healthy controls using an experimental approach with acute pain stimulation.

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 many things raised in the previous application has been addressed, with a few outstanding issues.
2. The Committee queried if information about use of a confederate could be provided to participants and queried the deception. The researcher stated that the social support aspect needs to feel real to the participant, so the research assistant should not be highlighted as a confederate to allow for replication in real scenarios. The manipulation effect will be monitored. The Committee were satisfied with the researcher’s previous experience with deception of this nature and participants not being upset when very similar deceptions were revealed.
3. The Committee queried how the researchers would handle responses to questionnaires that would indicate mental health concerns. The researcher stated that this is completed in-person and results are immediately viewed and able to have a swift response by a clinical psychologist and medical staff.

Summary of outstanding ethical issues

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

1. The Committee queried if participants with chronic pain would be restricted to those with mild chonric pain, due to the exclusion of analgesic use. The researcher clarified that this is a general group with various degrees of pain, as analgesic use does not not necessarily correlate with the pain severity. The Committee requested the medication criteria is clearer in the protocol.
2. The protocol and participant information sheet requires completion of footers with title, date, page and version number.
3. The Committee queried the mention of the German research team being transferred coded data with no prior mention. The researcher clarified that there was intention for a German co-investigator collaborating in person, but due to COVID-19, this is not possible anymore, so a data transfer is required. The Committee said that it should be made clearer in the information sheet that a German research team are overseeing or assisting with the research.

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

1. “You will be asked to refrain from exercising, food intake, and caffeinated beverages 2 hours and from consuming alcohol and drugs (excluding your regular medication) 12 hours before the appointment.” Should expand drugs to include analgesic medicines, which might be taken on an as required basis and available over the counter e.g. ibuprofen.
2. Please state that specific aspects of cardiovascular health may be discussed and examined as part of participation, and other aspects of responses may be examined in a debrief. This can highlight there are other aspects to the study without giving away the study design.
3. Please make it clear that data will be made available for other researchers, and whether this is related or potentially unrelated to this type of research. Clearly outline what form this data will take (i.e. deidentified)

Decision

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

* please update the protocol, taking into account the suggestions made by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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| 10 | Ethics ref: | 20/STH/200 |
|  | Title: | GN41791 - FENTREPID Study |
|  | Principal Investigator: | Dr Deborah Fleur Mason |
|  | Sponsor: | Roche Products (New Zealand) Limited |
|  | Clock Start Date: | 29 October 2020 |

Jane Eagle 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

1. A study to evaluate the efficacy and safety of fenebrutinib on disability progression in adults living with Primary Progressive Multiple Sclerosis (PPMS). All eligible participants will be randomized 1:1 to either daily oral fenebrutinib (or placebo) or intravenous (IV) ocrelizumab (or placebo)

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 with the researcher that the answers to F&H in the application form were typos, raising no further ethical issues to discuss surrounding it.
2. The Committee requested that the initial introduction is conducted by the patient’s clinician and the researcher completes the consent process. The researcher clarified that the CI is likely the patient’s clinician and will be referred on to the research nurse if patient is interested in participating. The Committee was satisfied with this separation for consenting.
3. The Committee queried what the standard of care is that is available for patients in New Zealand. The researcher responded that it is predominantly symptom-management, and that this study will offer a treatment option for patients. The researcher noted that ocrelizumab is a self-funded medicine (with no one in their region using it), so standard of care is not being withheld for the placebo arm.
4. The Committee queried what support is in place for responses to mental health questionnaires that indicate concern. The researcher stated that usual protocol is to get in touch with the crisis team.
5. The Committee queried the varied numbers given in the application regarding number of participants. The researcher clarified that there will only be approximately 8 participants in New Zealand enrolled.
6. The Committee noted for future reference that p.4.1. typically should outline prevalence in Māori and health outcomes.

Summary of outstanding ethical issues

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

1. On r.3.10 of the application form, there is reference to an optional stool sample. The researcher stated there is a repository banking project with a separate consent form. The Committee stated that the optional form does not mention the stool sample, please submit this as an amendment later once this has been completed.
2. The Committee requested further information on whether the sponsor would pay for participant’s access to the drug if Pharmac do not fund it in New Zealand within a participant’s lifetime.

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

**Main information sheet**

1. Please review for lay-language and readability.
2. Risks Associated with Fenebrutinib section: please add % incidence given that there are data per the IB
3. The 3 ocrelizumab adverse reactions sections should be consolidated
4. Access to study drug section: clarify access participant will have post-study (i.e. for life)
5. Suicide risk assessment using C-SSRS is performed frequently during this study (per Protocol Appendix 1). Is this done routinely for MS patients? If not, this should be specified in the main PISCF.
6. The pregnancy risk and contraceptive information is found in different places in the PIS/CF. Please centralise to one location.
7. Genome testing (p21) is listed as mandatory in the PISCF; however the protocol states this will be undertaken only where IEC approval for genomic research is given. Genomic research in the setting of this study should be optional for participants and presented separately.
8. Sample storage (p21) discusses tumour tissue (not relevant to this study). Please remove.
9. Identifiable information: please outline situations where results will be shared with others (MOH in the event of a notifiable disease, GP in the event of an abnormal result of CS, the Sponsor in the event of a compensation claim, etc).
10. Please state whether the MRI results will be provided to the participant.
11. On page 23, please explain how data linking will be undertaken, based on the statement 'Your coded study data may be .... linked to other data collected from you'. Discuss how this data linking will occur and what data sets may be linked - particularly considering that the data should be identified by a study-specific participant code onl, and the only data available to the Sponsor should be the participant's de-identified study data.
12. On page 27, please amend 'I agree to my (type of tissue) samples being sent overseas' to specify the tissue types being consented to.
13. Please include a statement regarding cultural issues for Māori associated with the collection and use of tissue in thi study. This section can be found in the HDEC template (<https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates>)

**Pregnant PIS/CF**

1. Given the intent to monitor for 1-year post-partum, a separate post-partum consent form is required for collection of the child's health information.

Optional MRI PISCF

1. Please state that you are using a contrast for the MRI and risks involved.
2. On page 2, please make it clear that the 'central reading centre' is based overseas.
3. Please clarify the information referred to in the statement 'Your information may need to be reviewed to make sure the procedure is being done properly or to check the quality of the information'. 'Roche will keep information collected for this procedure for up to 25 years'. Many people do not equate images with data. Are the images retained, or the data generated from the images? How does the radiology centre manage the imaging data? Is it deleted from the site's records?

**RBR PISCF**

1. Provide a full data management section; it is currently much more abbreviated than the main PISCF, despite the much broader consent requested. There is insufficient information provided regarding the genomic research; return of results (and actionable vs non-actionable findings); risks to blood relatives; risks of re-identification (or linking with other genomic databases including criminal or commercial genomic datasets, etc). The Committee recommend referring to the template for guidance in resolving this. (<https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates>)

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 sheets and consent forms, taking into account feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).

The Committee noted that genetic and stool samples cannot be collected until the amendment is submitted.

After receipt of the information requested by the Committee, a final decision on the application will be made by Dominic Fitchett and Paul Chin.

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| 11 | Ethics ref: | 20/STH/195 |
|  | Title: | DIRECT-SAFE |
|  | Principal Investigator: | Dr Teddy WU |
|  | Sponsor: | THE FLOREY INSTITUTE OF NEUROSCIENCE AND MENTAL HE |
|  | Clock Start Date: | 29 October 2020 |

Teddy Wu 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

1. The research project is testing whether going directly to mechanical removal of the clot without giving IV thrombolysis is safer and reduces the incidence of symptomatic intracerebral haemorrhage and associated complications.

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 how having two differing treatments as options could be in the best interest of the patient. The researcher stated that participants are getting the same end-point treatment of having a clot removed, but the method will differ depending on what they are randomized. The patient will get more intensive monitoring as part of the trial and will be in the best interests of the patient to take part. The Committee were satisfied after considering in detail what is in the best interests of participants following clinician assessing the needs of the patient. The increased follow-up, and potential for associated optimisation of clinical care, was accepted as a justification for best interest.
2. The Committee queried the response in the online form about not collecting ethnicity data. The researcher clarified that ethnicity won’t be used as part of analysis, but it is collected.

Summary of outstanding ethical issues

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

1. Font size seems to vary within the 11 page and 10 page versions
2. The risk of harm from NOT having thrombolysis prior to thrombectomy isn’t clearly discussed, please add further information.
3. The 'right to withdraw' and 'right to withdraw information' sections on page 7 and 9 respectively are currently different. Please amend for consistency or delete any duplication.
4. The whānau information sheet should be clearer on what they are being asked i.e. in their view, would the participate want to take part, rather than stating if the whānau wants the person to take part.
5. Please increase font size in the short PIS, and add a clarifying short statement about right to withdraw and what happens to information collected.
6. Please check personal pronouns throughout information sheets for consistency.

Decision

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

* please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

## General business

1. The Committee noted the content of the “ noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| Meeting date: | 08 December 2020, 10:00 AM |
| Meeting venue: | Online Meeting |

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.

The meeting closed at 3.40pm.