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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 02 February 2021 |
| **Meeting venue:** | via <https://mohnz.zoom.us/j/9738756003> Meeting ID: 973 875 6003 |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.15pm | Confirmation of minutes of meeting of 01 December 2020. |
| 12.30pm | New applications (see over for details) |
| 12.30-12.55pm  12.55-1.20pm  1.20-1.45pm  1.45-1.55pm  1.55-2.20pm  2.20-2.45pm  2.45-3.10pm  3.10-3.20pm  3.20-3.45pm  3.45-4.10pm  4.10-4.35pm  4.35-4.45pm  4.45-5.10pm  5.10-5.35pm  5.35-6.00pm | i 21/NTB/1  ii 21/NTB/2  iii 21/NTB/3  Break (10 mins)  iv 21/NTB/4  v 21/NTB/5  vi 21/NTB/6  Break (10 mins)  vii 21/NTB/7  viii 21/NTB/9  ix 21/NTB/10  Break (10 mins)  x 21/NTB/11  xi 21/NTB/12  xii 21/NTB/13 |
| 6.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 20/05/2017 | 20/05/2020 | Present |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 19/03/2019 | 19/03/2022 | Absent |
| Dr Devonie Waaka | Non-lay (intervention studies) |  |  | Present |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 14/12/2015 | 14/12/2018 | Apologies |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 | Apologies |
| Ms Susan Sherrard | Lay (consumer/community perspectives) | 19/03/2019 | 19/03/2022 | Present |
| Dr Patries Herst | Non-lay (intervention studies) |  |  | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Dr Jane Wylie and Mrs Leesa Russel

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Devonie Waaka and Dr Patries Herst confirmed their eligibility, and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 01 December 2020 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **21/NTB/1** |
|  | Title: | Relatlimab and Nivolumab as second-line therapy for advanced liver cancer |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Bristol-Myers Squibb |
|  | Clock Start Date: | 21 January 2021 |

Edward Gane and Sarah Middleton 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. This research project is a phase 2, randomized, open label study testing an experimental treatment for patients with liver cancer. The purpose of the study is to test the safety and efficacy of relatlimab combined with nivolumab against nivolumab alone in patients with primary liver cancer and also to test if patients who had a higher amount of a protein called lymphocyte activating gene 3 (LAG-3) in their tumour tissue would respond better to this combination regimen compared to patients who had a lower amount of this protein in their tumour tissue.

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 there were a number of documents uploaded that cannot be reviewed and acknowledge their receipt, but these were not be reviewed as part of the application.
2. The Committee asked for the researcher to outline the mental health response if distress is detected in participants during the study. The researcher responded that a resident psychiatrist within the District Health Board of the site will be asked for advice and if a significant measure is identified, professional input would be sought within the relevant District Health Board and community. The Committee was reassured that appropriate plans are in place.

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 MPS certificates are no longer current but acknowledged this is likely to be the case for many. Please provide a current MPS certificate when available.
2. The Committee stated that further information is required in the data and tissue management plan about what happens on the sponsor and CRO end, not just the New Zealand site. Please ensure this is study specific.
3. The Committee requested clarification around the use of archival tissue and whether the sponsor will hold or return any residual tissue, if any will be left. The researcher stated they will request for the block tissue to be returned. The Committee requested a mechanism for this to occur to be documented and assure the Committee this is in place.
4. The Committee noted in regard to the response in r.2.1.1 that sponsors are receiving de-identified data as part of patients being pre-screened before consenting. The Committee asked for reassurance that the sponsors will only be receiving generic information about patients. The researcher confirmed that the only information the sponsors will be receiving is the number of patients pre-screened. The Committee requested the template is updated for the response so this can be captured accurately.
5. The Committee noted that ionising radiation is inconsistently stated as being performed at level of standard of care or not standard of care. The researcher clarified that level of radiation for standard of care depends if they have progressive cancer or not. The Committee requested this is clarified in study documentation as it is stated in some places inconsistently that this is or isn’t standard of care levels of radiation.
6. The Committee asked for confirmation that the issuing office of New Zealand is the same as specifying New Zealand as a territory

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

1. Please take out all but a brief reference in the main information sheet information about the optional genetic component.
2. Use of the third party to contact trace participants should be optional. Please include this as a yes/no tick-box option in the consent form.
3. On page 11 of the main information sheet states that radiation exposure is the same as standard of care. Please clarify this and amend accordingly.
4. Please provide real life failure rates of contraceptive options (5-10% in some cases).
5. In the FUR information sheet, please include Māori health support details as included in the main information sheet.

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 supply evidence of ACC-equivalent compensation available to all participants in the event of injury during the study that is New Zealand-specific. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
4. Please update the data and tissue management plan to include what happens beyond the New Zealand site. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15 & 14.17).*

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

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| **2** | **Ethics ref:** | **21/NTB/2** |
|  | Title: | The TRIGS Trial |
|  | Principal Investigator: | Dr Daniel Faulke |
|  | Sponsor: | Auckland District Health Board |
|  | Clock Start Date: | 21 January 2021 |

Daniel Faulke and Davina Mcallister 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 TRIGS Trial (Tranexamic acid (TXA) to reduce infection after gastrointestinal surgery) will enrol 3,300 people having major abdominal surgery and look at outcomes including postoperative infections, the need for blood transfusion, and speed of recovery after surgery.

Summary of resolved ethical issues

1. The Committee requested an update on the Māori consultation for the study. The researcher responded that they have discussed the study with their Māori Health Advisor and Māori Health Advisor group.

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 whether the use of TXA intra-operatively or immediately post-operatively in addition to the study dose results in the withdrawal from the study. The Committee also questioned whether additional intra-operative or immediate post-operative use could pose any risk to participants, or whether there may be hesitation by the clinical team to use additional TXA, given that TXA allocation is blinded. The researcher responded that there is minimal risk due to the low dose given in the study, and any dose they receive that is clinically appropriate will be submitted as a protocol deviation.
2. The Committee requested an independent peer review for the study that addresses the safety concerns raised by the Committee, including additional dosing of TXA and whether participants could be at a higher VTE risk given the target population for the study.
3. The application form indicated that the data safety monitoring committee is independent and refers to the protocol. The Committee noted that the protocol does not specify that there are independent members on the safety monitoring committee. Please clarify the membership of the data safety monitoring committee.
4. The data safety monitoring committee section refers to the pre-determined safety stopping rules. The Committee was unable to locate specific stopping rules in the protocol. Please clarify and document the criteria to stop.
5. The Committee stated the data management plan is lacking in the protocol and associated documents. The information in the participant information sheet does not cover data management adequately. The Committee referred the researcher to Chapter 12 of the National Ethical Standards (<https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health>) and the HDEC templates for the information sheet (<https://ethics.health.govt.nz/updates/new-participant-information-sheet>) and data management plan (<https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans>) that highlights what the Committee expects.
6. The Committee queried the recruitment process and how much time a potential participant has to digest the information. The researcher responded that patients come into the clinic a few weeks prior to their surgery and will have that time to digest, but there may be on occasion a patient who comes in on the day of the surgery and may have only a few hours. The Committee requested if this could be reflected in the information sheet and provide avenues for getting more information about the study easily before they make their decision.
7. The Committee requested clarification around the exclusion criteria of “poor spoken or written language comprehension”

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

1. As this study is assessing TXA for an unapproved indication, the risks of the drug should be more clearly spelt out, together with frequencies.
2. 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).
3. Please clearly identify the global and NZ sponsors at the top on the first page, identifying them in their positions.
4. Please state in the data section that data will be shared with researchers in Australia; and that data will not be used for research in the future without additional consent.
5. Please outline in a bullet point form the situations in which the study may be terminated, noting that it cannot be for commercial reasons in New Zealand.

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 supply an independent peer review that addresses the safety concerns raised by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
3. Please supply an updated 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).*
4. 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).*
5. Please supply details of the DSMC. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*

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

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| **3** | **Ethics ref:** | **21/NTB/3** |
|  | Title: | The RAPID Study |
|  | Principal Investigator: | Dr Ian Crozier |
|  | Sponsor: | RRR Manufacturing NZ Ltd |
|  | Clock Start Date: | 21 January 2021 |

Michael Hume and Matthew Daly 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. A multi-centre, pRospective, safety and efficacy evaluation study on Automated external defibrillation in PatIents with CellAED (The RAPID Study)

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 the benefits of the study over the obvious risks of having patients who haven’t otherwise undergone ventricular fibrillation (VF) having that induced. The researcher stated that inducing VF is routine care for patients getting or checking defibrillators to ensure the device can adequately respond to VF. Inducing VF is also routine practice for checking the mechanism behind patients who have regular cardiac arrest. The participants of the study will however not stand to benefit from this procedure for the study purposes, but the risk of responding to an induced VF immediately is very minor. The Committee requested independent peer review around the risks of inducing VF to be assured that the risks posed on participants are ethically appropriate.
2. The Committee queried if there is a risk around sedation for these patients. The researcher confirmed there is, and the Committee requested this is additionally covered in the requested peer review and the risks around this are outlined also in the participant information sheet.
3. The Committee queried if a support person for the participant is required for this procedure given the nature of it. The researcher stated that since many of these patients have had cardiac arrest, they are relatively used to recovery periods afterwards and will be kept in care until they are assessed as recovered. The Committee requested that this is identified in the information sheet that the participant will be kept under observation until they are well enough to be discharged.
4. The Committee requested that the researcher seek with the sponsor the possibility of compensating the participants for their time and other associated costs as they gain no benefit from the study procedure, and justify the amount decided on.
5. The Committee noted that the MPS certificate expired but acknowledged this is likely to be the case this time of year and to please provide the updated documents in the response.
6. Please ensure the insurance certificate is protocol specific and that New Zealand is named as a territory.
7. The Committee requested an investigator’s brochure that includes information about the device.
8. The Committee stated that the protocol contains insufficient information around data management and referred the researcher to the HDEC template that can be used and adapted for the study. Use of the template is optional but is a helpful guide for what the Committee looks for (<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 review for typos and grammatical errors.
2. Please ensure a Māori health support details is added.
3. Please review and remove irrelevant sections of the consent form, such as references to pregnancy.
4. Please make it clear on the first page in a warning box that this is the first time this device is being used in humans.

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 supply an independent peer review that addresses the safety concerns raised by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
4. Please supply evidence of ACC-equivalent compensation available to all participants in the event of injury during the study that is New Zealand specific. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
5. 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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Kate O’Connor and Stephanie Pollard.

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| **4** | **Ethics ref:** | **21/NTB/4** |
|  | Title: | A Phase III Study of Belantamab Mafodotin plus Pomalidomide and Dexamethasone vs Pomalidomide, Bortezomib and Dexamethasone in Participants with RRMM. |
|  | Principal Investigator: | Dr Hugh Goodman |
|  | Sponsor: | IQVIA RDS PTY LTD. |
|  | Clock Start Date: | 21 January 2021 |

Kate Ives 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 research study is being done to learn more about multiple myeloma (MM), and if the study drug, called belantamab mafodotin, can improve MM in participants who have already received at least one other treatment and whose MM has worsened.

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 under r.1.6 in the application form, it is stated that the sponsor can end the study for any reason. The Committee stated that GSK cannot end the study for commercial reasons
2. The Committee asked for clarification around the difference between the rechallenge and restart information sheet. The researcher stated the possible side effect of liver damage from the study treatment, and the difference of the form is whether a haematologist determines if abnormal liver function is a result of the study treatment or not after stopping treatment and monitoring recovery. If it is determined as the study treatment, then the rechallenge information sheet will be used. If it is determined it is unrelated to the study treatment, then the restart information sheet will be 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 Committee noted that on page 10 of the main information sheet, there is a reference to an item on the consent form that is optional to allowing GSK to use coded study samples and data, however there is already an optional information sheet. The Committee requested clarification if the reference in the main information sheet is the same as the optional information sheet, or if these are different.

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

1. Please remove the repeated paragraph under page 11 under possible benefits of the main information sheet.
2. Please clarify the sponsor and their address on the first page header in the main information sheet.
3. Please ensure Māori contact support details are provided on all information sheets.
4. On page 3 of the rechallenge information sheet, please rephrase “Your study doctor believes that any alternative treatments are less suitable for you than the study treatment.” and “You should discuss the specific reasons why the study doctor thinks the study treatment is a better choice than any alternative treatments that might be available.” to simply state that “your study doctor will discuss alternative treatment options with you” as the current wording is coercive.
5. The Committee noted that the pregnant partner information sheet does not cover pregnant participants. The Committee further noted that in New Zealand you cannot gain consent for use of the infant’s health information until after the baby is born. Please separate this out onto a separate consent page.

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 John Hancock and Patries Herst.

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| **5** | **Ethics ref:** | **21/NTB/5** |
|  | Title: | ALICE Study |
|  | Principal Investigator: | Dr Matt Hart |
|  | Sponsor: | Auckland District Health Board |
|  | Clock Start Date: | 21 January 2021 |

Matt Hart and Davina Mcallister 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 ALICE study will assess the incidence and types of anaemia (due to iron deficiency, vitamin B12 and / or folic acid deficiency, or kidney or chronic disease) in patients before surgery. This is a prospective observational study anonymously collecting data obtained via the routine care and investigation of anaemic elective surgical patients.

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 protocol refers to consented study despite this being an unconsented study. The researcher clarified that this is consent “where required” depending on region to help accommodate sites in other District Health Boards that have smaller departments that do not have capacity to approach every patient. The Committee requested the protocol is updated to outline the non-consenting process, what countries are functioning in a similar manner, and justification for waiver of consent to be provided. Please refer to the National Ethical Standards for what justifications need to be made (<https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/7>)
2. The Committee noted that if there is a participant has not had a sample ordered as part of their standard of care, it should be documented in the protocol that a sample cannot be obtained from the participant if they have not consented.
3. The Committee requested that any recruitment material used should be uploaded for HDEC review.
4. The Committee requested a data management plan specific for New Zealand and referred the researcher to the template on the HDEC website for what information they are looking for. (<https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans>)
5. The Committee asked for an update on the Māori consultation for the study. The researcher responded that it is still undergoing the consultation process and a letter of the outcome will be provided.

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 upload any advertisements being used (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*
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).*
4. 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 Tangihaere Macfarlane and Stephanie Pollard

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| **6** | **Ethics ref:** | **21/NTB/6** |
|  | Title: | (duplicate) (duplicate) (duplicate) Gastrointestinal Dysfunction in Critical Illness - (GIFT study : Part II)22Dec2020 |
|  | Principal Investigator: | Ms Varsha Asrani |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 21 January 2021 |

Varsha Asrani 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 proposed research is designed to develop and validate a novel ‘gut dysfunction scoring tool’ relevant to patients with critical illness.

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 they were satisfied that focusing on gut dysfunction in a standardized way was acting in the best interest of a person who cannot consent for themselves.
2. The Committee asked the researcher for an update on Māori consultation. The researcher responded that it is pending HDEC approval to complete their review.
3. The Committee noted for future reference that contradictory to the answer in the application form around cultural issues is incorrect and that any taking, storing, transportation and destruction of tissue is a Māori concern.
4. The Committee queried if the samples being stored for future analysis will be identifiable. The researcher responded that these will only be labelled with a coded study number, and the data will be stored in a similar manner.

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 intensivists count as participants and require their own participant information sheet and consent form. Please create and upload a suitable information sheet/consent form for their involvement.
2. The Committee noted that there is still information pertaining to gaining consent from next-of-kin in the protocol from a previous version and to ensure this states opinion is being sought but whānau is not consenting on behalf of the participant.
3. The Committee queried how best-interest enrolment is being documented for the study. The researcher responded that there is a template document that will be used to document this. The Committee requested that this best-interest template is uploaded and noted to be careful that the wording indicates the physician is not consenting on behalf of the patient, but are enrolling in their best interest.

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

1. Please review the past-tense used in the Continued Participant information sheet and reword as necessary.
2. Please review the whānau information sheet to be specific for the whānau, and remove the page 7 statements.
3. In the whānau information sheet, the statement “It is unknown if your relative/ whānau member will receive any benefits from taking part in this study.” is not in-line with the best-interest position. Please amend the statement.
4. The Committee noted that three sponsors are identified in the application form and to please document in the participant information sheets on the front page header who has oversight on 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 Susan Sherrard and Patries Herst.

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| **7** | **Ethics ref:** | **21/NTB/7** |
|  | Title: | 5F9009 ENHANCE: Magrolimab + Azacitidine versus Azacitidine + Placebo in Untreated MDS |
|  | Principal Investigator: | Dr Leanne Berkahn |
|  | Sponsor: | Gilead Sciences |
|  | Clock Start Date: | 21 January 2021 |

Leanne Berkahn, Maggie Fung and Sophie Goodger 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. This is a Phase 3, randomised, double-blind, placebo-controlled multicenter study investigating magrolimab + azacitidine compared to azacitidine + placebo in previously untreated patients with intermediate/high/very high risk myelodysplastic syndrome (MDS) by Revised International Prognostic Scoring System (IPSS-R).

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 there is both a mandatory and optional genomic component to the study.

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 confirmation if the questionnaires will be paper or via an app and make this clear in the participant information sheet and data management information.
2. The Committee noted their concern of participants potentially being excluded from the study if they cannot complete questionnaires if English is not their first language. Please provide either evidence of validated translated versions or that these people would not be excluded from the studies if this component cannot be completed by them.
3. The Committee noted that the MPS certificate expired but acknowledged this is likely to be the case this time of year and to please provide the updated documents in the response.
4. The Committee queried the relevant around the questions in the quality of life questionnaire around sexual activity. The researcher responded that loss of sex-drive is an important side-effect to note. The Committee requested that there is a statement included at the start of the questionnaires that participants have the option to skip questions if they are uncomfortable answering them.
5. The Committee requested evidence of Māori consultation.

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

1. Please remove the written component requesting that samples are destroyed.
2. On page 28 it is stated that health information will not be accessed until after the study. Please amend to state that for reasons for maintaining the blind, preference is to not have participant access it, but if they did, it could result in the withdrawal from the study.
3. On page 16, please state risks in real numbers not just percentages.
4. Please remove receipt requirement for reimbursement.
5. Please state under cultural section whether there will be karakia given at time of disposal and include a statement acknowledging Māori data sovereignty.
6. Please ensure Māori health support contact details are included.
7. The FUR information sheet seems to have wording on page 7 that comes from the main information sheet. Please review for consistency for relevance and amend.
8. In the FUR information sheet please acknowledge that a participant can withdraw consent from FUR but still participate in the main 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 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).*
3. 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 Kate O’Connor and Stephanie Pollard.

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| **8** | **Ethics ref:** | **21/NTB/9** |
|  | Title: | Dysphagia after stroke from admission to 6 months. |
|  | Principal Investigator: | Mrs Marion VALLET |
|  | Sponsor: | University of Canterbury - Rose Centre for Stroke |
|  | Clock Start Date: | 21 January 2021 |

Marion Vallet and Maggie-Lee Huckabee 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 better understand the evolution of dysphagia and clinical outcomes of patients with PSD. This information has the potential to inform accurate and specific rehabilitation, which would ultimately improve patients’ symptoms and QOL.

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 the researcher to clarify the supported-consent process. The researcher responded that this will take place in the presence of their family/friends and depending on the assessment of the clinician, difficulties identified will be addressed accordingly through different communication techniques or abbreviated information sheet and assistance from friends/family.
2. The Committee noted their concern of gaining consent within 2 days considering the distress the potential participant could be under. The researcher stated that the time they gain consent can be adapted and changed depending on the needs of the potential participant, but the early time point of data collection for 3 days is important. The potential participant will not be forced and information would be gathered from the medical notes for that time point. The Committee was reassured with this answer.
3. The Committee confirmed with the researcher that the video taken of the participants is for the use of this study only and will be destroyed after the data is disseminated.

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 whānau information sheet/consent form is inappropriate as they cannot provide proxy-consent on behalf, and the role of the whānau is to support the participant. Please remove this as a study document and amend any protocol information that refers to proxy-consent from whānau.
2. The Committee queried if a tikanga Māori protocol is in place for home visits, and if the researcher will be going alone. The researcher responded that each visit will be discussed with the participant prior to ensure their needs are met, and that the researcher will either have someone with them or notify another. The Committee requested that there are baseline tikanga protocols in place that is documented.

Decision

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

* please update the study protocol, taking into account the feedback provided by the Committee
* please ensure tikanga/cultural expectation protocols in place for home visits are documented.

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| **9** | **Ethics ref:** | **21/NTB/10** |
|  | Title: | COVERS trial |
|  | Principal Investigator: | Dr Andrew Cameron |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 January 2021 |

Andrew Cameron 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 proposed study is a randomised control trial comparing cerebral oximetry values in anaesthetised patients who are allowed to breathe for themselves vs patients who are 'ventilated' (a machine breathes for them).

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 the researcher if they were satisfied that patients have enough time to consider their participation in the study. The researcher stated that those recruited through private practice will have information well in advance, and those recruited through the District Health Board will have a shorter time-frame but still have access to a physician who can talk them through the information. The Committee were satisfied that there is no pressure being applied to patients for their participation due to a time-limit.

Summary of outstanding ethical issues

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

1. The Committee requested that the protocol includes more information around the analysis plan and power calculation.
2. The Committee requested a data management plan as either part of the protocol or as a standalone document that should cover what data is being collected, how this is protected, where it is being stored and for how long. The HDEC template is available for use or as a guide (<https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans>)
3. The Committee queried who the sponsor is of the study and who has oversight. The researcher clarified this would be Counties Manukau District Health Board. The Committee requested this is identified in the front page header of the information sheet.

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

1. Please include information around data management and rights for participants to access this information. The HDEC template can be used for guidance on this section or adapted for the current study (<https://ethics.health.govt.nz/updates/new-participant-information-sheet>)
2. Randomisation and blinding and what this looks like should be explained in lay-terms to participants.
3. Please state that muscle-relaxants will be used and is standard of care for most and provide information and likelihood around the risks of muscle-relaxant.
4. Please provide a direct-dial or extension number for the Māori support contact.

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 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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Tangihaere Macfarlane and Stephanie Pollard.

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| **10** | **Ethics ref:** | **21/NTB/11** |
|  | Title: | (duplicate) Brain Injury Incidence and Service Access New Zealand in the Community (BIONIC2) |
|  | Principal Investigator: | Dr Kelly Jones |
|  | Sponsor: | National Institute of Stroke and Applied Neuroscie |
|  | Clock Start Date: | 21 January 2021 |

Kelly Jones and Nicola Starkey 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. This is a new population-based study of traumatic brain injury (TBI) will confirm the nature of TBI in New Zealand from 2021-2022. This information will be compared to similar population data from 2010-2011 to determine the true extent of any changes in TBI over time.

Summary of resolved ethical issues

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

1. The Committee discussed with the researcher the inclusion of whānau and clarified that the participation of whānau is only to discuss their own experience and not the person with TBI.

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 discussed part-one of the study which is collecting data and seeking a waiver of consent. The researcher justified the secondary re-use without consent under scientific and practical considerations and noted the benefits of capturing this data to help inform future rehabilitation and care for patients with signs of TBI. The Committee acknowledged that scientific justification is there for part one of the study and was content, however they requested this justification is documented clearly and consider potential harms. Please document in the protocol the justification for waiver for secondary re-use of identifiable health data as required by National Ethical Standards 12.28-12.30.
2. The Committee requested that the data management plan is adjusted to be more specific to the context of the study. In particular, please confirm that data will either be re-identifiable or anonymised prior to analysis, having attention actionable incidental findings.
3. The Committee queried how 100% of the population pool required will be obtained for part one. The researcher responded that daily checks with Waikato Hospital will be performed to screen for injuries where a TBI could have occurred. After identified, the Hospital will on behalf of or allow an approved researcher to make initial contact to find out more about the injury to check if they meet the criteria of TBI. In addition, all GP practices will be aware of this study and invited to have an initial brief conversation with a patient who may meet the criteria and will obtain verbal consent to receive follow-up information. Self-referral from advertisements is also an avenue. The researcher also noted organization cross-checking being performed in a similar manner to the first BIONIC study. The Committee requested that this is detailed in the data management plan, including who is holding the master file of identifiers, and if organizational cross-checking has encrypted identifiers or data-files.
4. The Committee noted that date of birth is an identifier and to please remove collection and storing of this data point if these do not need to be used for cross-checking.
5. The Committee noted that older children could answer questions around racism provided they are age-appropriate and understandable, and acknowledged that their voices on the matter are valuable.
6. The Committee requested the comments from the HRC to provide assurance around scientific rigour and feasibility of the study.
7. The Committee queried if participants who turn 16 at during the study will be re-consented. The researcher stated they would be using the adult information sheet. The Committee requested a specific re-consent at age 16 information sheet and consent form explaining the transition and the change.

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

1. Please change on page 1 “suffer” to “experience”
2. Please remove the consent form tick-box to obtain permission to get information from medical records as this is not optional. Please also clarify that medical records will be accessed only for this study and will not be otherwise released.
3. The 12-15 age group information sheet is too similar to the 8-11 year old sheet, please provide more information for this older age-group.
4. Please remove ACC-sections as these are observation studies.
5. Please remove sponsor references as this is publicly funded.
6. Please review and amend inconsistency around withdrawal of data and ensure the participants have the option to withdraw their data from study use.

Decision

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

1. Please address all outstanding ethical issues, (including provided a justification for the waiver of consent for Part (NES #.##), 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 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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Susan Sherrard and Patries Herst.

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| **11** | **Ethics ref:** | **21/NTB/12** |
|  | Title: | VLX-401: A study assessing the safety and effectiveness of Volixibat for the treatment of intrahepatic cholestasis of pregnancy. |
|  | Principal Investigator: | Dr Joanna Gullam |
|  | Sponsor: | Premier Research (New Zealand) Limited |
|  | Clock Start Date: | 21 January 2021 |

Joanna Gullam 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 assessing the safety and effectiveness of Volixibat for the treatment of intrahepatic cholestasis of pregnancy.

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 justification for placebo and clarify the standard treatment. The researcher responded that UCDA recently was removed as a standard treatment based on recent published research. The Committee requested that this information is provided in the information sheet as this is not currently evident.
2. The Committee noted that the study documentation refers to an organization that does not operate in New Zealand. The researcher clarified that research midwives within the department will be performing home visits who follow a safety protocol and tikanga Māori.
3. The Committee noted that the HDEC application contains a statement referring to potential conflicts of interests. The researcher clarified that this relates to un-related members of their study organization but would not pose any direct conflict to the study.

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 study flyer does not mention that there is a placebo arm.
2. The Committee stated that the cord blood is not approved for being submitted for optional future unspecified research.
3. The Committee stated that the data and tissue management plan does not address the data from the electronic diary and requires updating.

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

1. Please add a warning box on the first page that this is a first in pregnant women study.
2. Please add sponsor address under sponsors name to front page header.

Decision

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

* please update the study flyer, taking into account the suggestions made by the Committee
* please include information around the electronic diary in the data and tissue management plan
* please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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| **12** | **Ethics ref:** | **21/NTB/13** |
|  | Title: | A Study of Subcutaneous Nivolumab in Previously Treated Advanced or Metastatic Clear Cell Renal Cell Carcinoma |
|  | Principal Investigator: | Dr Carmel Jacobs |
|  | Sponsor: | Bristol-Myers Squibb |
|  | Clock Start Date: | 21 January 2021 |

Carmel Jacobs, Sophie Goodger and Amy Tong 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 main purpose of this research study is to assess the pharmacokinetics of nivolumab when it is given as an injection under the skin (subcutaneously [SC]) compared to when it is given as an infusion into a vein (intravenously [IV]).

Summary of resolved ethical issues

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

1. The Committee queried if the participant has disease progression and was on the subcutaneous arm, would the researcher consider moving them over to the approved transfusion option. The researcher responded that this would need to be a discussion between the physician and patient to explore all options as the approved treatment is not funded and is a high cost.

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 use of Greenphire/Connex and if they will deal with participants directly. The researcher stated that in New Zealand it is an option for sites but the main site has no intention. The Committee raised concerns about a third-party organizing flights or accommodation and the participant’s only contact if something goes wrong is overseas. The Committee requested this is clarified with the sponsor and clearly outlined in the information sheet.
2. The Committee requested that the optional biomarker testing outlined in the main information sheet be removed and included as part of the optional information sheet.

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

1. Please distinguish any COVID-19 tests taken for the purpose of this study (with/without symptoms), and the relationship between these and any standard COVID-19 tests taken as part of the public health regime.
2. Please make table on pages 10-12 in smaller font and landscape to fit on one page.
3. Terminology about referring to GP is scattered and inconsistent i.e. usual doctor, primary care physician, etc. Please ensure this is consistent in the term that is used.
4. Define all acronyms when they first appear, please review.
5. If imaging is being sent for central review please document this in the information sheet and the format it is going to be reviewed in.
6. Please review for missing commas and grammatical errors.
7. On page 2, please remove the sentence around the study doctor still sending additional safety information to the sponsor or clarify the wording as this is inconsistent with other sections.
8. On page 5, please change description of performance status review to be that the doctor will ask participant questions about their daily activities.
9. On pages 5 & 6, in the paragraphs to do with blood samples, please put in brackets the location of each laboratory.
10. On page 14, please add “or koha” after “donation”.
11. Please state whether or not there will be an opportunity for karakia at time of sample destruction.
12. Please include contraceptive language for male participants as the consent form notes responsibility to tell partner of risks. Please reinstate the HDEC template wording.
13. Under right to access health information, please amend statement that some information will not be available until the end of the study, as participants have a right to access and correct their own health information gathered as part of the study.
14. In the treatment beyond progression information sheet, there are statements taken from the main information sheet but the specific text for what it applies to is not detailed enough. Please provide more information pertaining to this information sheet context.
15. Please localise contact details to New Zealand.

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 Kate O’Connor and Patries Herst.

## 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:** | 02 March 2021, 12:00 PM |
| **Meeting venue:** | ONLINE - Zoom 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.

1. **Matters Arising**

The meeting closed at 6.10pm