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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 13 August 2019 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 11:30am | Welcome |
| 11:35am | Confirmation of minutes of meeting of 09 July 2019 |
| 11:40am | New applications (see over for details) |
| 11:40-12:05pm  12:05-12:30pm  12:30-12:55pm  12:55-1:20pm  1:20-1:45pm  1:45-2:10pm  2:10-2:35pm  2:35-3:00pm  3:00-3:25pm  3:25-3:50pm  3:50-4:15pm  4:15-4:40pm | 19/STH/156 (Jean / Paul)  19/STH/54 **Reconsideration – full committee**  19/STH/135 (Sarah / Mira)  ~~19/STH/137 (Sandy / Jean)~~  Application Withdrawn  19/STH/139 (Dominic / Mira)  19/STH/143 (Sarah / Paul)  19/STH/146 (Jean / Mira)  19/STH/150 (Mira / Sandy)  19/STH/151 (Sarah / Jean)  19/STH/152 (Dominic / Paul)  19/STH/153 (Sandy / Paul)  19/STH/155 (Sarah / Dominic) |
| 4:40pm | General business:  Noting section |
| 4:45pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Sarah Gunningham | Lay (other) | 05/07/2019 | 05/07/2022 | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Apologies |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | 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 | 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 |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |

## Welcome

The Chair opened the meeting at 11:30 am and welcomed Committee members, noting that apologies had been received from Dr Devonie Waaka.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Sandy Gill of the Central HDEC confirmed their eligibility, and were co-opted by the Chair as a member 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 09 July 2019 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **19/STH/156** |
|  | Title: | DUAL-ACS |
|  | Principal Investigator: | Dr Philip Adamson |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 01 August 2019 |

Dr Philip Adamson was present by teleconference for discussion of this application.

Potential conflicts of interest

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

Dr Paul Chin declared a potential conflict of interest which was deemed minor and the Committee decided to allow him to partake in the discussion and retain voting rights.

Summary of Study

1. Coronary heart disease causes the most deaths worldwide and happens when small fatty lumps (plaques) build up, narrowing the blood vessels supplying the heart. If the plaques become disrupted a small blood clot can form reducing the flow of blood and oxygen to part of the heart muscle - and this sometimes leads to a heart attack or chest pains (acute coronary syndrome).
2. The standard treatment after an acute coronary syndrome is to give two blood thinning drugs. This dual anti-platelet therapy helps the fatty lumps heal in order to stop the heart attacks happening again - but thinning the blood can also raise the risk of bleeding. Several trials have shown that taking dual anti-platelet therapy does help stop heart attacks, but it’s not clear how long dual anti-platelet therapy should last to maximise this benefit but minimise the risk of serious bleeding. Recent evidence suggests that giving dual anti-platelet therapy for a shorter time is better because the risk of serious bleeding, or even death, is higher the longer it is given.
3. This study will test long and short durations of dual anti-platelet therapy in an international trial of approximately 19,000 heart attack patients (6,000 recruited within NZ) to settle this unanswered clinical question once and for all. Patients will be recruited from hospital wards and those who decide to take part will get (at random) dual antiplatelet therapy for either 3 months or 12 months. Patients do not need to do anything else for the study but the researchers will review their health records to determine which treatment works best. Patients have been involved in the development of this study and will be involved in looking at progress of the study.
4. New Zealand will also lead a sub-study wherein approximately 3-4,000 patients will be asked to provide a blood sample for future analysis.

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 a brief overview of the study. The Researcher stated they were interested in how long to keep patients on blood thinning medications after a heart attack as their use increases the risk of bleeding. The Researcher stated the traditional view has settled on a 12 month duration but smaller studies have shown there is no harm from shorter regimes. The Researcher stated this was a large study (19,000 participants worldwide; 6,000 in New Zealand) that would hope to definitively establish that it is safe to have a shorter duration of blood thinners.
2. The Committee queried how tissue from the study would be stored. The Researcher stated it would be retained in the Christchurch Heart Institute. The Committee queried whether there were plans to establish a new tissue bank as indicated on the application form. The Researcher stated there were no active plans to transfer the tissue into a new bank but it was difficult to guess what may be discovered in the future and potential future uses for the tissue. The Researcher explained they were trying to ‘future-proof’ the samples.
3. The Committee noted a discrepancy where the application form stated samples would be destroyed after 16 years whereas the PIS stated 10 years. The Researcher apologised for the error and agreed to correct it.
4. The Committee noted the large sample of 6,000 participants in New Zealand and queried whether the Researcher intended to do any analysis by ethnicity and determine if participants who identified as Māori responded differently. The Researcher stated there is inequity both in health outcomes and research involvement and confirmed that they would do ethnic analysis. The Researcher stated they were aiming to get a ‘real world’ sample representative of the New Zealand health population.
5. The Committee queried whether the Researcher expected to recruit any women of child-bearing potential. The Researcher stated they did not but if so it would be a small proportion. The Committee requested the inclusion of pregnancy information in the PIS for the event that a woman of child-bearing potential is recruited.
6. The Committee queried whether there was evidence of a higher risk of bleeding when receiving the drugs long term. The Researcher stated there was clear evidence of that and currently no evidence of a downside to a shorter duration. The Researcher stated most studies have been too small to definitively answer the question but because bleeding is a more common issue in recurrent heart attacks the evidence shows that a longer duration is associated with more bleeding. The Committee requested information highlighting the risks of different durations (3 month vs 12 month) be included in the PIS.

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

1. A The Committee requested the word ‘revoke’ be replaced with the more lay-friendly ‘withdraw’ on the main PIS
2. The Committee requested the inclusion of a named Māori health contact person.
3. The Committee queried whether the study’s use of a participant’s data upon withdrawal was a genuine option for them to decide. The Researcher confirmed it was. The Committee stated it currently reads as if it could be an automatic use and requested a revision of the PIS to explain that it is the participant’s choice.
4. The Committee requested the removal of the ‘yes / no’ box for informing the GP on the consent form. The Committee considered that in a trial of this nature the participant’s GP should be informed as a mandatory condition of enrolment.
5. The Committee requested the removal of all ‘yes / no’ tick boxes on the FUR consent form unless it is for an item that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the future unspecified research).
6. The Committee requested the FUR form split future uses of tissue into commercial and non-commercial uses (as some participants may wish to agree to one and not the other). The Researcher agreed to the change and stated there were no active plans for commercial use and this was another way to ‘future-proof’ the samples.

Decision

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

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

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| **2** | **Ethics ref:** | **19/STH/54** |
|  | Title: | SAGE-ANZ |
|  | Principal Investigator: | A/Prof Rachael Parke |
|  | Sponsor: |  |
|  | Clock Start Date: | 28 February 2019 |

A/Prof Rachael Parke, Dr Shay McGuinness and Dr Colin McArthur were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a re-consideration of a study previously declined by the Southern HDEC.
2. The purpose of the study is to prospectively assess the management of moderate-severe ARDS in intensive care units in Australia and New Zealand. This data will then be compared to the data generated by a similar US study to report regional trends.

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 when it originally assessed the application it had considered that right 7(4) of the [Code of Health and Disability Services Consumers' Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/) had applied but now acknowledged it did not. The Committee acknowledged that as nothing would be done to the participants and only their data would be collected the code would not be applicable in this scenario.
2. The Committee explained that in order to grant a waiver to access data without consent the following conditions must be met:

* The act of seeking consent would be likely to cause undue anxiety for those whose consent is sought, and:
* It would prejudice the scientific validity of the study if a proportion of the data was not included, and:
* There would be no disadvantage to the participants or their relatives or to anyone involved in collecting the data and the public interest in the potential benefit of the study outweighs the individual’s right to privacy.

1. The Researcher stated contacting participants to obtain consent would likely cause undue anxiety in some individuals. The Researcher stated participants dropping out of the study would harm the scientific validity. The Researcher stated they believed the study was low risk and in the public interest for potential benefit.
2. The Committee queried why consent could not be sought retrospectively. The Researcher stated it would be impractical as some participants would not survive, it could cause undue anxiety approaching surviving participants and having to withdraw some of the data would harm the scientific validity of the study. The Researcher explained the long-term objective is to improve outcomes but this cannot be done without first establishing how patients are currently managed and this knowledge is not yet known.
3. The Committee agreed the research was important but stated it had reservations about the lack of informed consent. The Researcher stated they support consumers of health care knowing that their de-identified data may be used and has information available outside the ICU.
4. The Committee reminded the Researchers that knowledge (i.e. health data) is a taonga and that previous research in New Zealand has created negative stereotypes and social stigmas for Māori. The Committee requested the Researchers be mindful of this when undertaking the study.

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **19/STH/135** |
|  | Title: | Stress, dopamine, and motor deficits in PD |
|  | Principal Investigator: | Dr Rebekah Blakemore |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 July 2019 |

Dr Rebekah Blakemore was present by teleconference for discussion of this application.

Potential conflicts of interest

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

Dr Paul Chin declared a potential conflict of interest which was deemed minor and the Committee decided to allow him to partake in the discussion and retain voting rights.

Summary of Study

1. The researchers have recently demonstrated that emotional stress can worsen the motor impairments of individuals with Parkinson’s disease (PD). These findings are consistent with previous studies in animal models of PD, however it remains unclear how stress disrupts the control of movement and alters dopamine in the brain.
2. This study will build on earlier research by investigating changes in brain activity (using functional brain imaging) that are associated with impaired movement during stress in people with PD. Understanding the impact of acute stress on movement control may inform development of emotion-movement interventions to improve motor function in people with PD.

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 what sort of unpleasant images participants may be exposed to. The Researcher stated they were colour photographs from a database of approximately 1,000 images. The Researcher stated they could range from ‘low intensity’ (e.g. a rubbish bin, cigarette or syringe) to ‘high intensity’ (e.g. a person dying in a hospital bed, pictures involving blood, a car accident). The Researcher stated for this study they would likely use ‘medium to high’ images but not the most unpleasant in the database.
2. The Committee queried whether the database was frequently used in neurological research. The Researcher stated it was for research focusing on emotions and especially in this group of participants.
3. The Committee requested clarification on whether participants would have to miss their PD medication or all medication. The Researcher confirmed only the scheduled PD medication dose for motor symptoms from the night before would be missed and participants could take any other medication they needed. The Committee requested a clarification on page 2 of the PIS so participants understand they can take other medicine as needed.
4. The Committee queried whether it was standard for participants with PD to miss a dose. The Researcher stated it was common in studies to halt the medication the day before. The Researcher confirmed that participants would take their regular morning dose after the study exercise. The Researcher confirmed that study procedures involving participants would be exclusively performed during mornings.

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 process to manage unexpected findings on the MRI was outlined in the application and queried whether there was a similar process for any concerning results from the mental health questionnaires. The Researcher stated they were just screening tools and not diagnostics and so were just looking at cut offs. The Committee explained that if a participant indicated severe distress, depression, anxiety or suicidal ideation there would need to be a process to manage this. The Researcher stated they would be managed by the leading clinician, Professor Tim Anderson. The Researcher stated most participants would have received these types of questionnaires in the past and those types of issues are part of the exclusion criteria. The Committee agreed it would most likely not be a major issue but requested the protocol be amended with details on how this would be managed for the event it did occur.
2. The Committee advised that for future applications it would be helpful to include any relevant statistics on the health outcomes / prevalence of the disease in Māori when answering P.4.1. The Committee advised that the answer for F.1.2. would be more appropriate for P.4.1. and that F.1.2. is for other ethnic groups (e.g. Pasifika).
3. The Committee advised that whakamā is likely to be present in Māori participants with Parkinson’s and requested the Researcher bear this in mind.

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

1. The Committee requested a lay-friendly titled to the study and to be added to the PIS.
2. The Committee requested a general revision of the PIS to correct any typos, missed words and grammar.
3. The Committee requested the PIS use more lay-friendly language. The Committee requested a thorough revision to remove (or explain) technical terms and medical jargon
4. The Committee requested an explanation of what ‘healthy controls’ are in lay terms.
5. The Committee noted ‘research grant’ is also not lay-friendly and requested a revision to simply state that funds are not available.
6. The Committee advised that it is appropriate to tell participants they are invited to take part due to having Parkinson’s rather than their medical history.
7. The Committee advised that the mention of damage to the brain on page 2 was potentially unsettling (e.g. making participants think the MRI may cause brain damage or they already have brain damage) and requested a revision of the language.
8. The Committee requested an explanation of what the blood tests and questionnaires will be checking for (i.e. why these are being performed).
9. The Committee requested the inclusion of information explaining the participant’s option of informing their GP in the PIS. Currently the option appears on the consent form with no prior context provided.
10. The Committee requested clarification on whether the researchers would inform the GP of the results of the study or only the participation. The Researcher confirmed they would communicate both. The Committee requested this be clarification be included with the information in the PIS.
11. The Committee requested the inclusion of Māori health contact information in both PISs.
12. The Committee requested an explanation of who Prof. Anderson is in the PIS.
13. The Committee requested an explanation of the process for concerning results from the HAD and PSS questionnaires on the PIS so participants are aware of this.

Decision

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

* Please update the protocol to include a safety plan detailing how to manage participants who indicate severe distress.
* Please update the Participant Information Sheet and Consent Forms, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by the HDEC secretariat.

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| **4** | **Ethics ref:** | **19/STH/139** |
|  | Title: | Randomised control trial comparing ACL reconstruction with Quadriceps or Hamstring autograft |
|  | Principal Investigator: | Dr Jessica Mowbray |
|  | Sponsor: | Northland Orthopaedic Centre |
|  | Clock Start Date: | 01 August 2019 |

Dr Jessica Mowbray was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Anterior cruciate ligament (ACL) is a commonly performed operation in active individuals, who struggle with symptoms of their knee giving way with activity.
2. Traditionally the reconstruction uses the patient’s own hamstring tendon or a bone-patella tendon-bone tendon (part of tendon below the kneecap) as a graft. Allograft (donated tendon) can also sometimes be considered, however has been shown to be inferior to autograft (patient’s own tendon).
3. There have been several randomised controlled trails comparing hamstring and bone-patella tendon-bone autografts, and a meta-analysis concluded that bone-patella-bone graft leads to more knee discomfort on the front aspect of the knee with difficulties kneeling on it. The knee stability seems equal between the two graft choices.
4. A third, previously less used option is a strip of the patients own quadriceps tendon (situated above the kneecap). This tendon as a graft choice has traditionally not been used as frequently, but with newer fixation methods has become popular in recent years. The quadriceps tissue seems to have more collagen on histological studies thus potentially providing a stronger graft. There have been no randomised studies comparing the stability or outcomes of a quadriceps autograft to a more commonly utilised hamstring autograft.
5. This study aims to compare knee stability, patient reported outcome scores, re-rupture rates, return to sport, and donor site morbidity between the quadriceps and the hamstring tendon after performing an ACL reconstruction.

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 the Researcher give a brief overview of the study. The Researcher stated they would be comparing hamstring autograft versus quadriceps tendon autograft to compare outcomes, muscular strength after the procedure and the lowest rate of re-rupture. The Researcher stated there is a gap in the literature with no direct comparison of the two procedures
2. The Researcher stated surgeons in Whangarei routinely use the quadriceps method and they wish to prove that it is as good as the hamstring method and potentially superior depending on re-rupture rates and post-operative strength.
3. The Committee queried whether both methods were done clinically and whether the research could be done retrospectively by analysing pre-existing data on procedures already performed. The Researcher stated they were both routinely used but in the interest of having the highest quality dataset they opted to do a rigorous study. The Researcher stated this way they can ensure every surgery is performed in the same way and also collect additional data during follow-up appointments that would not be recorded during standard care.
4. The Committee queried why there were five surgeons in the study. The Researcher stated this was in order to get enough cases as ideally they would collect the data in less than one year. The Researcher explained this would also give a ‘real world’ sample as it would involve multiple surgeons / populations throughout New Zealand.
5. The Committee queried access to the trial as it appeared to be only private surgeons involved. The Researcher stated ACC would be covering the payments so the study would be open to anyone needing an ACL reconstruction.
6. The Committee queried the minimum age of participants. The Researcher stated it would be 16 years.
7. The Committee queried the peer review that was supplied with the application. The Researcher stated it was done by the clinical head of department and confirmed that they were not involved with the study.
8. The Committee noted the extra incision to maintain blinding and requested information explaining this be added to the PIS. The Researcher stated they have since decided not to proceed with the extra incision. The Committee noted this would remove the blinding. The Researcher stated they would instruct participants to wear a stocking that would cover the knee and conceal the scars so the physiotherapist would not know which procedure they had. The Researcher stated the main assessment of muscle strength would be using a machine and the stocking would not interfere with the physiotherapist’s exercises.
9. The Committee queried the answer to question P.4.4. in the application which stated the study would be Māori research methods. The Researcher apologised for the error. The Researcher confirmed the study had undergone consultation with Kaumātua at Whangarei Hospital.

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 advised that for any future applications it would be helpful to include any relevant statistics about the prevalence in Māori when answering P.4.1. The Committee noted the answer to P.4.2. which stated there were no specific cultural issues. The Committee explained that for Māori knowledge is a taonga and there were cultural considerations around respect and face to face conversations. The Committee requested the Researcher be mindful of this for any future applications.

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

1. The Committee requested the Researcher amend the opening statement to remove the suggestive language (regarding benefitting from the surgery) and instead state that participants are invited as they will be having an ACL reconstruction.
2. The Committee requested the addition of a statement advising participants that there may be no benefit to them by participating.
3. The Committee requested a general revision to check for typos (e.g. “What does my participation in the study *involves”).*
4. The Committee requested the inclusion of a Māori health support contact number for participants to dial rather than having to search themselves or contact the hospital.
5. The Committee queried whether participants would receive compensation for any costs incurred with physiotherapy. The Researcher stated all appointments would be covered by ACC as they are routine follow-up.
6. The Committee requested the inclusion of the ACC statement available on [page 5 of the HDEC template](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-february-2019-v2.0-150719.doc). Currently the PIS states that if something went wrong participants would be eligible for compensation whereas it should emphasise that participants would be eligible *to apply* for compensation.
7. The Committee noted the trial would be halted if one technique was found to be ‘vastly superior’ to the other and queried the threshold for this. The Researcher stated they were not aware of a specific number and would consult the statistician that reviewed the study.
8. The Committee requested additional information in the PIS explaining that participants will be randomised. The Committee requested emphasis that this is determined by chance.
9. The Committee noted a statement about potential ineligibility in the PIS and queried the process for if a participant was found to be ineligible. The Researcher explained this would happen if participants were found to have underlying or accompanying pathology that meant they could not be included in the dataset. The Researcher stated they would still have the ACL reconstruction but their data would not be used in the study analysis. The Researcher stated the procedure would be the surgeon’s choice based on clinical need. The Researcher agreed to add a clarification to the PIS.
10. The Committee noted a statement in the consent form regarding audiovisual recordings and queried what these were. The Researcher stated during an arthroscopy the camera would take photos of the inside of the knee and this was part of standard care. The Committee requested the Researcher add information explaining this to the PIS.
11. The Committee requested the inclusion of a footer and page numbers in the PIS.
12. The Committee noted a statement in the benefits and risks section discussion muscular strength testing and queried whether it was routinely done. The Researcher stated machine strength testing was not routinely done but the physiotherapist would do their standard exercises. The Committee requested a revision to clarify this.

Decision

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

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

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| **5** | **Ethics ref:** | **19/STH/143** |
|  | Title: | Response to mass shooting event |
|  | Principal Investigator: | Dr Sandra Richardson |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 August 2019 |

Dr Sandra Richardson and Geoff Sutton were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study aim is to explore the psychological responses and personal stories of healthcare workers and support staff who were involved in responding to the mass shooting event in Christchurch on 15th March 2019. The overall intentions are to collect, record and analyse the individual experiences of staff, volunteers and others who were involved in the provision of health care responses to the terror event of 15 March 2019 in Christchurch. The specific study objectives are:

* To identify the experiences and responses of clinical, administration, and support staff to an unexpected MCI situation.
* To report on the planned and unplanned role and systems adaptations which occurred as a result and explore the future applications thereof.
* To identify and analyse the impact and implications of the responses to the MCI event in relation to individual perceptions of well-being.
* To develop recommendations relevant to a range of health settings in terms of the actual or perceived needs of clinical, administrative, and support staff, which would support them to continue in their roles under such circumstances.

* To track individual staff response to the event over time (the initial questionnaire and interview schedule to be repeated at 1 and 2 years).
* Explore the impact of cumulative exposure to disaster stress – it is anticipated a sub-group of participants will have been present for both the natural disaster (2010 onwards earthquake sequence) and the mass shooting event.

1. The proposed research is a collaborative project between researchers from the Clinical Department of Emergency Medicine, Christchurch Hospital, St John Ambulance Association and the School for Health Sciences, University of Canterbury. The study is planned to include individual interviews and an online survey, repeated at three time points over a three year period.

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 the Researcher give a brief overview of the study. The Researcher stated they believed the research both necessary and useful in terms of contributing to knowledge and as an opportunity for staff / responders to the attack to be involved with something positive. The Researcher stated it was important to understand the impact and behaviour of staff, hospital systems and processes in order to
2. The Committee queried the involvement of senior management and how the Researchers would ensure this doesn’t bias the responders. The Researcher stated no one in senior management was involved on the study team as the investigators that work in ED do not have direct responsibility over other staff. The Researcher stated their previous study on earthquake response found no one felt this type of pressure when participating and staff were happy to come forward with their stories.
3. The Committee noted the high number of investigators involved with the project. The Researcher stated they wanted to be inclusive and involve multiple organisations and to obtain a wide range of expertise. The Researcher stated the research is intended to be a collaborative project.
4. The Committee queried whether the quantitative or qualitative aspect would be done first. The Researcher stated it did not have to happen in any particular order. The Committee noted it was not clear on the PIS. The Researcher agreed to clarify the section.
5. The Committee queried who would be transcribing the interviews. The Researcher stated this has not been arranged yet. The Committee stated there were privacy concerns and that whoever was hired would need to sign a confidentiality agreement.
6. The Committee queried what would happen to the audio recording after transcription. The Researcher stated it would be kept with other study data for 10 years. The Committee queried whether the audio recordings could be de-identified. The Researcher stated they could not and participants would be aware of this. The Researcher stated they could also give participants the option of receiving a copy of the interview.
7. The Committee queried whether the participant’s copy would be provided in hardcopy or digital form. The Researcher stated it would be the participant’s choice. The Committee queried how security of transmission of the copy would be ensured and confidentiality maintained. The Researcher stated this would be managed at the time of transmission.
8. The Committee queried the timeline of the study follow-up. The Researcher confirmed the one year follow up would be one year from the first interview and not one year since the attack.
9. The Committee queried how the Researchers would respond to cut-offs on the questionnaires for any concerning results (e.g. acute stress, depression, suicidal ideation). The Researcher stated some of the instruments did have cut offs but these were not diagnostic tools. The Researcher stated they would identify an area of ‘probing’ to determine where a person was in regards to symptoms. The Committee stated as long as there is a process to ensure participants are appropriately managed.

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 an incorrect response regarding participants in question D of the application form. As a result several subsequent sections in the application form were not populated. The Committee requested answers to the following questions be detailed in a cover letter:

Briefly and in plain English, please describe:

* the procedures to be undertaken by participants in your study, and
* any risks associated with these procedures that potential participants may reasonably wish to be informed of.

**r.1.2.** Will you seek consent from participants to inform health practitioners with responsibility for their health care that they are taking part in your study?

**r.1.3.** Will your study involve withholding standard treatment from participants

**r.1.7.** Will any participants seek or be given treatment by or at the direction of a registered health professional (as defined in the Accident Compensation Act 2001) as part of your intervention study?

**r.1.7.1.** Will any of these participants have given written consent to participate?

**r.4.1.** Might any aspect of your study produce findings that may be both unexpected and clinically significant for participants, donors of existing stored human tissue, or their families

**r.4.1.1.** What might these findings be, and how will participants, donors of existing stored human tissue, or their families be informed of them?

**r.5.1.** Please briefly describe the main source(s) of funding for your study.

**r.5.2.** Does the Co-ordinating Investigator, any Co-Investigator, or any direct member of their families have any commercial interest in the intervention(s) to be studied, or any financial relationship to the study sponsor or funder(s), that may inappropriately influence his or her conduct in the study?

**r.5.3.** Will the Co-ordinating Investigator or any Co-Investigator be remunerated for their involvement in the study in a way that may inappropriately influence his or her conduct in the study (for instance, bonuses for favourable results or high recruitment rates)?

**r.5.4.** Will the Co-ordinating Investigator or any Co-Investigator also be the usual health or disability support service provider for one or more participants in your study?

**r.5.4.1.** Please briefly describe how the risk of a conflict of interest between the research and clinical roles of such Investigators will be minimised and managed.

**r.5.5** Will the usual health or disability service provider for one or more participants in your study receive any remuneration (or any other valuable consideration) for referring potential participants to the research team in your study?

**r.5.6.** Please briefly describe any other potential conflicts of interest that may arise for researchers in your study, and describe how they will be minimised and managed.

**r.6.1.** Please briefly indicate whether the results of your study may risk stigmatising individuals or population groups, and if so, how this risk will be minimised and managed.

r.7.1. Please briefly indicate whether your study may pose any significant risks to researchers and/or third parties, and briefly explain how such risks will be minimised and managed.

**r.8.1.** Please briefly explain why you consider the risks of your study to be proportional to its expected benefits.

**p.1.1.** Briefly and in plain English, please describe what taking part in your study will involve for participants.

**p.1.2.** Will **all** participants in your study give their informed consent to participate?

**p.2.1.** Briefly explain the process by which potential participants in your study will be provided with information on the study, have the opportunity to ask questions, and asked to give their informed consent

**p.2.2.** A **generic** version of the participant information sheet and consent form (PIS/CF) that you will provide to potential participants must be uploaded in the “Documents” tab before submission to an HDEC. You don’t need to submit information sheets specific to each study locality.

**p.2.3.** How have you checked that the participant information sheet is appropriate for your study population?

**p.2.4.** How many words does your participant information sheet contain?

**p.2.5.** What is the Flesch Reading Ease Score for your participant information sheet?

*While there are no hard and fast rules for the readability of information sheets, a score of 65 or above usually indicates that a document is written in plain English.*

**p.2.6.** Does your study involve deliberately withholding or concealing information from participants?  
*Blinding procedures in randomised controlled trials are not normally considered to involve withholding or concealing information from participants.*

**p.2.7.** How will you ensure that participants receive information that becomes available during the study and that may be relevant to their continued participation

**p.2.8.** Will you inform participants of the results of your study?

**p.2.9.** Please *either* explain how you will inform participants or explain why you do not intend to do so.

**p.3.1.** *Generic copies of any advertising that you intend to use to encourage potential participants to take part in your study must be uploaded in the “Documents” tab before submission to an HDEC.*  
Please explain how potential participants will be identified and approached in a way that ensures they can give informed consent free from undue influence

**p.3.2.** Will your study involve potentially vulnerable people – that is, people who may have a restricted ability to make independent decisions about their participation?

**p.3.2.1.** Please explain how your study’s informed consent process takes the needs of these potentially vulnerable people into account.

**p.3.3.** Will participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in your study?

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

1. The Committee requested the inclusion of a statement advising participants that their participation and answers to the questionnaires will not affect their employment.
2. The Committee noted a statement on the consent form that participants understand the risks associated with taking part and how they will managed but could not locate accompanying information in the PIS. The Committee requested a revision to include this.
3. The Committee requested the inclusion of a risks and benefit section and recommended the Researchers [consult the PIS template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-february-2019-v2.0-150719.doc)
4. The Committee requested the inclusion of the standard contact details available on the PIS template.
5. The Committee requested the inclusion of information explaining that participants may be referred as appropriate if they are found to be suffering from acute distress, PTSD etc.
6. The Committee requested the inclusion of a footer and page numbers to the PIS.
7. The Committee requested the removal of all ‘yes / no’ tick boxes on the consent form unless it is for an item that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).
8. The Committee requested an option for participants to directly receive a lay summary of results (once available) as participants should not be referred to the library to search for it themselves.

Decision

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

* Please update the Participant Information Sheet and Consent Forms, taking into account the suggestions made by the Committee.
* Please supply the answers to the missing application questions above.

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

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| **6** | **Ethics ref:** | **19/STH/146** |
|  | Title: | Being a teenager can be stressful. Does being kinder to yourself increase coping? |
|  | Principal Investigator: | Mrs Amanda Helen Smith |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 August 2019 |

Mrs Amanda Smith was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Recognition is growing that adolescents who feel unhappy or stressed are more susceptible to negative mental health outcomes. Research shows that protective measures, such as self-compassion, during these formative years can reduce symptoms of psychopathology and encourage a positive life trajectory.
2. The aim of this research is to explore the feasibility and effectiveness of an adapted version of the Making Friends with Yourself (MFY) programme, for adolescents aged between 14 and 17 years.
3. Specifically, it is hypothesized that as self-compassion increases (adaptive coping, as opposed to maladaptive coping), mild psychopathology should decrease (anxious and depressive symptomology) from pre-intervention to post-intervention. It is also expected that these outcomes will be maintained at three-month and six-month follow up.
4. The proposed research will build on the Making Friends with Yourself (MFY) pilot study (Bluth, Gaylord, Campo, Mullarkey & Hobbs, 2016), and utilize a mixed-methods design consistent with this study to extend the existing literature by adding evidence to the effectiveness of the MFY Programme to guide the prevention and treatment of mild psychopathology. It will be the first evaluation of a self-compassion focused intervention for adolescents struggling with mild psychopathology in a New Zealand context.

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 a brief overview of the research. The Researcher stated they were looking at self-compassion with adolescents as there are not many preventative options for youth in New Zealand. The Researcher stated they were looking at the feasibility and effectiveness of an adapted version of the ‘making friends with yourself’ program.
2. The Committee queried whether the delay group was a control group. The Researcher confirmed it was.
3. The Committee queried how participants would be assigned to the intervention or delay group and whether this would be random. The Researcher stated it would not be random and would be run at specific schools
4. The Committee queried how participants under the age of 16 would be recruited. The Researcher confirmed only those competent to consent would be included. The Committee reasoned that potential participants competent enough to provide consent would not require parental consent in order to participate.
5. The Committee queried whether the research would take place in alternative education or only mainstream schools. The Researcher confirmed only mainstream schools.

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 the research carried a risk of stigmatisation, especially in a school setting. The Committee noted there would also be potential issues with group confidentiality. The Committee requested the addition of a statement in the PIS that the group will be discussing sensitive things so please keep it in the room and do not repeat it to others.
2. The Committee considered that some participants may agree to participate then decide they do not like groups. The Committee requested information explaining that participants can stop at any time for any reason and if they do not like a group setting they can opt out. The Committee advised that there would need to be another pathway to support these participants.
3. The Committee queried whether the study would take place during school time or after school hours. The Researcher stated that would depend on the school.
4. The Committee advised that though teachers won’t be participants they will still need to be aware of the study and so an information sheet for them will be required.
5. The Committee queried what would happen if there were not enough students at a school interested in participating. The Committee advised it would be unfair to those who expressed interest if they were then unable to.
6. The Committee advised that a cluster design would be better suited for this type of trial and the researcher would need to carefully consider how to preserve the scientific validity of the study if groups of 6 cannot be recruited or participants withdraw.

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

1. The Committee noted the PIS may not be written in an appropriate way for teenagers. The Committee recommended some of the content in the application (discussing how compassion leads to doors opening and emotions out) be included in the PIS.
2. The Committee requested the first sentence of the PIS is replaced with the application title (“Being a teenager can be stressful. Does being kinder to yourself increase coping?”).
3. The Committee cautioned against over-promising the benefits (e.g. “showing great results overseas”) and requested the removal of suggestive language.
4. The Committee requested the addition of a section discussing potential risks to participation. The Committee requested information explaining that if issues are brought up there are systems in place to support participants.
5. The Committee requested the addition of a statement to the PIS advising the participants that their teachers will be aware of the study taking place.
6. The Committee requested information explaining whether recordings will be audiotaped and when / where they will take place be added to all information sheets.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph *6.22*).
* Please revise the study protocol, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph *5.4*).

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| **7** | **Ethics ref:** | **19/STH/150** |
|  | Title: | Uromune-C® in the prevention of recurrent vulvovaginal candidiasis |
|  | Principal Investigator: | Dr Nicky Perkins |
|  | Sponsor: | Auckland District Health Board |
|  | Clock Start Date: | 01 August 2019 |

Dr Nicky Perkins was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Vaginal thrush is a very common problem for women and 5-10% of women will have problems with recurrences of thrush during their lifetime. Thrush causes symptoms of itching, soreness, discharge, pain with sexual intercourse and can be chronic and very distressing. Current standard treatment for recurrent thrush involves taking anti-fungal medication by mouth for up to 6 months. This is usually very effective but there is a recurrence rate of up to 50% in the 12 months following a course of treatment and the most commonly used drugs may cause side effects and have interactions with other medications, so are not suitable for everyone.
2. Uromune-C® is a sublingual vaccine spray containing killed bacteria (the 4 most common causative agents in UTI = Uromune®) and killed Candida albicans which is the most common cause of thrush. It is a Section 29 medicine in New Zealand and is not funded. There is currently no published literature on the effectiveness of Uromune-C® but one conference presentation indicating a good effect, and confirmed effectiveness of the base product Uromune® in treatment of UTI.
3. This study is designed to lookout the effectiveness of Uromune-C® spray vaccine in the prevention of recurrences of vaginal thrush. Women who suffer from repeated episodes of vaginal thrush will be recruited for this study. They will be given a 3 month course of Uromune-C® administered by spray under the tongue daily. The women will then be followed for 12 months after study treatment. They will be seen every 3 months for routine thrush culture and review of symptoms. If they experience symptoms during follow-up they will be tested and treated with a standard treatment regimen.

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 the Researcher give a brief overview of the study. The Researcher stated some women have difficulties with recurrent vaginal thrush and would like treatment options that were not medication. The Researcher stated the study would look at using Uromune-C as a ‘vaccine spray’ to prevent recurrence.
2. The Committee queried the intervention product. The Researcher stated Uromune was developed to treat recurrent UTIs and that Uromune-C has been developed to target candida albicans and provide treatment for thrush.
3. The Committee queried the availability of the intervention. The Researcher stated it was available under Section 29 of the Medicines Act 1981.
4. The Committee queried whether this was a phase 1 ‘first in human’ trial of the intervention or whether pharmacokinetic studies had been done before. The Researcher stated they knew animal studies had been done but there was limited data in humans. The Researcher stated Uromune-C has ‘piggy backed’ on the main product Uromune.
5. The Committee queried the lack of a control group. The Researcher stated they had consulted a statistician who advised a pilot study would be need to be undertaken to ascertain feasibility before a comparator 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 expressed concern that safety and efficacy information for the intervention was not available with the application. Participants would not be able to provide informed consent without this critical information.
2. The Committee queried whether Medsafe had any safety data for it to be available under Section 29. The Committee requested the Researcher supply this if it is available.
3. The Committee queried whether Uromune had full approval in New Zealand or elsewhere. The Researcher stated they were not certain.
4. The Committee stated participants had a right to know if this was a ‘first in human’ trial and this information would need to be present on the participant information sheet and consent form.
5. The Committee stated it believed the Uromune manufacturer should be running a proper phase 1 trial and the responsibility for this should not fall on the Researcher.

Decision

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

* Please amend the information sheet and consent form to include safety information on the intervention so participants are able to provide informed consent (*Ethical Guidelines for Intervention Studies* paragraph *6.22*).
* Please update the study protocol to include any safety data (*Ethical Guidelines for Intervention Studies* paragraph *5.4*).

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| **7** | **Ethics ref:** | **19/STH/151** |
|  | Title: | Novel methods of infant feeding in New Zealand - cause for concern or optimism? |
|  | Principal Investigator: | Associate Professor Anne-Louise Heath |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 August 2019 |

Associate Professor Anne-Louise Heath was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. There has been a revolution in infant feeding in NZ in recent years with domination of the market by baby food ‘pouches’, and popular uptake of Baby-Led Weaning (BLW), a virtually unstudied approach to introducing solids in which babies feed themselves 100% finger foods from the start of 'complementary feeding'. The First Foods NZ study will determine the impact of pouches and BLW on iron deficiency, growth, diet, choking, oral motor skills, and dental health in an observational study of 625 Dunedin and Auckland infants aged 8-9.9 months old.
2. Over about two weeks, the study will collect data on infant feeding and health (questionnaire), dietary intake (24-hour recall with photographic prompts), growth (length and weight), eating behaviours (questionnaire and camera recording), iron status (blood test), and dental health (photographs of infants teeth). Consumption of Māori cultural foods will be the subject of a separate ethics application. The researchers will request permission to access the infant’s ‘B4 School Check’ dental health and growth data at 4 years of age to determine longitudinal trends in dental health and growth.
3. In addition, for a randomly selected subsample of breastfeeding mother-infant dyads, the study will obtain accurate data on the amount of breast milk infants consume using the stable isotope (deuterium oxide) ‘dose-to-mother’ technique in which the mother drinks a solution containing the stable isotope which can be measured in saliva samples from the mother and infant. We will also analyse the nutrient content of the mother's breast milk using an expressed breast milk sample.
4. The results from this study will enable the Ministry of Health, health professionals, and Plunket to advise NZ parents on how to introduce solids safely.

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 a brief overview of the research. The Researcher stated they would investigate the impact of baby-led weaning and baby food pouches on nutrition related health outcomes for New Zealand infants. The Researcher stated approximately 70% of baby food is commercially available in pouches but there have not been robust trials on any potential health effects of this. The Researcher stated they were interested in the nutrition, iron status, growth, potential choking risk, oral motor skills and dental health.
2. The Committee noted the PIS for those interested in the welfare of non-consenting participants and queried who the non-consenting participants would be. The Researcher stated technically it was the babies as they cannot give consent and so parental consent is required.
3. The Committee noted there were two pamphlets supplied with the application. The Researcher apologised for the error and confirmed there was only meant to be one pamphlet.
4. The Committee queried the process for if a participant had previously consented to supplying a milk sample and changed their mind at a subsequent visit. The Researcher stated there would be no problem, participants could remain in the study and they wouldn’t take the additional sample. The Committee requested the Researcher add a statement to the PIS to ensure it is clear to participants that even if they have given consent previously they can choose not to give an additional sample at any time.
5. The Committee queried how investigator safety would be ensured on home visits. The Researcher stated they have experience with home visits with the adult nutrition survey and have a careful training process.
6. The Committee queried why the study would not use food diaries. The Researcher stated they had in the previous RCT but with this approach they wanted to lessen the burden on participants and minimise the difficulty for those who may have low literacy. The Researcher stated with the recall method the onus is on the researcher and does not require the participant to make written notes throughout the day. The Researcher stated the photographs are to aid memory recollection.
7. The Committee queried whether the participant’s date of birth was necessary information. The Researcher stated it was to measure infant growth. The Committee clarified that it was the mother’s date of birth it was referring to. The Researcher stated this would not be necessary and could ask for age or year of birth rather than the full date.
8. The Committee advised that it would be more appropriate for the GP to contact participants rather than the research team. The Researcher stated relying on the GP may be impractical as there are access barriers. The Committee accepted the Researcher’s explanation.

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 advised that if the Researcher was taking videos of the baby with other people around (e.g. feeding them or interacting with them) then that will make them participants and they will need to provide consent for the use of that information. The Committee advised that these participants would need to know this in advance of any filming.
2. The Committee queried the dilution of deuterium oxide. The Researcher stated they were not certain and would need to confirm, but that a standard concentration used for clinical studies would be used.
3. The Committee noted question G in the application (“Will your study involve the use or disclosure of health information?”) was incorrectly answered as ‘NO’. The Committee advised that dental records and the ‘B4 School Check’ are health information.
4. The Committee noted the application stated data generated may be made available in future research but this information was not present in the PIS. The Committee queried what potential future uses the data may have. The Researcher stated at this stage they were uncertain. The Committee requested information about potential uses of participant data in the PIS and advised this ought to be up to the participants to opt-in to if they wish. The Committee requested the addition of an optional ‘yes / no’ box on the consent form for this.
5. The Committee noted the pamphlet lacked necessary information and requested the Researcher adapts the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-february-2019-v2.0-150719.doc) The Researcher queried whether they could use the pamphlet in addition to the standard PIS. The Committee advised that as long as the PIS contained all the necessary information and participants understood everything they needed to before signing the pamphlet style could be used.

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

1. The Committee recommended the Researcher consult some of the guides produced by Starship Hospital for easy to read examples.
2. The Committee requested additional information on the side effects of giving blood, the side effects of the ‘special water’ and any other risks of participation. The Committee cautioned against over-promising the potential benefits of participation and requested the removal of any suggestive language.
3. The Committee requested additional information explaining the types of tests and data necessary for the study (e.g. measuring height, weight, accessing dental records).
4. The Committee requested the inclusion of Māori health contact information, advocacy contact information and HDEC contact information in the PIS.
5. The Committee requested the inclusion of a ‘Yes / No’ tick box on the consent form for sending samples overseas to give participants the choice of whether they agree to this
6. The Committee requested information explaining why blood and saliva samples were being taken and what will happen to the samples after testing.
7. The Committee requested the inclusion of a cultural tissue statement (see the HDEC template).
8. The Committee advised that the Researcher can use informal lay language if they wish as long as it contains all the necessary information.
9. The Committee requested information explaining what will happen to any videos or photos, how they will be stored and for how long, who will have access to them, etc.

Decision

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Professor Jean Hay-Smith and Dr Sarah Gunningham.

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| 8 | **Ethics ref:** | **19/STH/152** |
|  | Title: | A Study to Investigate the Safety and Efficacy of ABBV-105 and Upadacitinib in Subjects with Systemic Lupus Erythematosus (SLE). |
|  | Principal Investigator: | Dr Douglas White |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 01 August 2019 |

Dr Douglas White and Ms Denise Darlington were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is designed to investigate the safety and effectiveness of ABBV-105 and Upadacitinib given alone or in combination (ABBV-599 combination) in participants with moderately to severely active SLE, despite standard of care therapy. The study duration will include a 42 day maximum screening period and a 48 week randomised, double-blinded, parallel-group treatment period, and a 30 day follow-up phone call.
2. Study visits will be conducted at Screening, Baseline, Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48.
3. Participants will stop receiving treatment if their disease worsens, they experience intolerable side effects or become pregnant.

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 a brief overview of the study. The Researcher stated it was a phase 2 study looking at new therapeutic agents to treat lupus. The Researcher stated that some patients do not tolerate current treatments well, or do not respond to them. The Researcher stated they would use various combinations of the agent and would involve participants with moderately active lupus. The Researcher stated there would need to be some discernible disease activity but acute cases would be managed outside the trial.
2. The Committee queried involvement from a participant’s usual clinical team during a washout period to halt drugs. The Researcher stated they would be recruiting participants from patients already in clinic so their regular clinician would be in close contact with the study team. The Researcher confirmed that participants would sign the consent form before any washout began.
3. The Committee queried whether participants would continue their regular SLE medication in addition to the study drugs. The Researcher stated it would depend on the combination of treatments and whether it was working for them or not.
4. The Committee queried whether this applied to the placebo group. The Researcher stated that if they are on any permitted medication they can remain on those and that participants will be aware that they may be assigned to placebo. The Researcher stated there is a list of exclusion medications on page 3 of the PIS.
5. The Committee noted an overlap with treating clinicians and the research team and queried how the conflict of interest would be managed. The Researcher stated they had six practicing rheumatologists and a couple of registrars in the clinic with two rheumatologists making up the study team. The Researcher stated all clinicians could potentially recruit eligible participants and if participants entered the study the research doctors would manage the participant for the study period. The Researcher confirmed that the participant’s GP would receive a letter detailing each study visit. The Researcher confirmed all participants would return to usual care after the study period.
6. The Committee queried the approval status of the drugs. The Researcher stated ABBV-105 has been received by Medsafe and is under review and Upadacitinib is still an investigational product.
7. The Committee queried the availability of the medication after the trial. The Researcher stated one agent likely would be but they are not certain if the combination will be. The Researcher stated as it is a phase 2 trial too much is unknown to be able to say definitively.
8. The Committee requested the addition of a statement to the PIS advising participants that they may be unable to receive the medicine after the trial.
9. The Committee expressed concern at what appeared to be a separate opt-out for samples stored for future research. The Committee considered that some participants may be unwell or forgotten they have consented to this and if they withdraw from the main study they should not have to specifically withdraw consent for future research as well. The Researcher agreed that if a participant chooses to withdraw from the study then it should include their sample by default. The Researcher stated they would confirm this with the Sponsor.
10. The Committee expressed concern that the primary endpoint of the study is week 24 and that participants on placebo would be required to take it for another 24 weeks afterward. The Researcher stated they were unsure of the rationale for why and they did not have input on this design. The Researcher stated this was likely due to the study being phase 2 rather than phase 3.
11. The Committee stated its concern was that participants would not know that they would be taking the study treatment for a further 24 weeks when the Sponsor was only interested in an endpoint of 24. The Researcher agreed and stated that if participants were not doing well or responding to the study intervention they would be withdrawn and not forced to remain on it for the full 48 weeks.
12. The Committee queried the intention for the witness signature box. The Researcher stated they generally remove this before use. The Researcher stated it was rarely used but one example is a case when a participant was blind. The Researcher confirmed it was not intended for proxy consent.

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

1. The Committee noted the general readability of the PIS was rather low and the use of language varies. The Committee requested a revision to define and explain technical / medical terms to make it easier to read for a layperson.
2. The Committee queried a statement on the PIS indicating that if participants withdraw the study would stop collecting information on them except for follow up. The Researcher stated it would be the participant’s choice and agreed to revise the section.
3. The Committee requested the Researcher add a statement to the first page of the main PIS advising that the study uses an experimental drug not approved by a regulatory authority in New Zealand.
4. The Committee requested the addition of an easily-understood lay title to the PIS.
5. The Committee noted some of the formatting symbols had printed incorrectly (e.g. the greater to equal ≥ sign runs into the next character) and suggested the Researcher check the master copy.
6. The Committee requested the inclusion of reproductive risks and acceptable contraceptive methods on the main PIS. The Committee recommended the Researcher [adapt the reproductive template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/template-for-reproductive-risks-in-participant-information-sheets-sep17.docx)
7. The Committee advised that the pregnant participant / partner consent form would need an additional signature box for after the birth of the baby. The Committee explained that the pregnant participant / partner can consent to their pregnancy information being collected but upon birth the baby becomes a legal person and requires parental consent for their information to be collected.
8. The Committee requested any references to participants as ‘subjects’ to be amended as the term is not appropriate for a New Zealand context.
9. The Committee requested the addition of Māori health support, advocacy and HDEC contact information to the pregnant participant / partner PIS.
10. The Committee requested the inclusion of information on any samples / data being sent overseas so participants are agreeing to this by signing the consent form.
11. The Committee requested a revision of the table to be simplified and more easily understood.

Decision

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

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

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| **11** | **Ethics ref:** | **19/STH/153** |
|  | Title: | Te Ao Mārama (Phase 1) |
|  | Principal Investigator: | Mrs Bernadette Jones |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 August 2019 |

Mrs Bernadette Jones, Ms Lauren Bailey and Mr Tristan Ingham were present by teleconference for discussion of this application.

Potential conflicts of interest

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

Professor Jean Hay-Smith declared a potential conflict of interest which was deemed minor and the Committee decided to allow her to partake in the discussion and retain voting rights.

Summary of Study

1. Te Ao Mārama Phase 1 will generate insights into ‘disability’ identity and impact from a tāngata whaikaha Māori (Maōri with a disability) perspective which will then inform the development of the questions used later in the project. Insights will be generated by a series of focus-group/hui/ individual interviews with tāngata whaikaha Māori and their whānau across several regions. Kaupapa Māori research analysis approaches will be used to derive thematic elements and inform question domains. A process of whakawhiti kōrero will provide a reflexive feedback and negotiation process with ngā tāngata whaikaha to ensure validity of the resulting question sets.

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 the Researchers give a brief overview of the study. The Researchers stated many Māori do not identify with ‘being disabled’ so they would have a series of interviews with participants to formulate a culturally appropriate way to capture information on Māori disability.
2. The Committee queried whether the interviews would be filmed. The Researchers stated they may offer it as an option as some participants may prefer it but it would not be done by default. The Committee queried what if some participants in a hui wished to be filmed but others did not. The Researchers stated they would arrange it in a way so that only those who agreed to be recorded would be.
3. The Committee queried whether the participant pool would be large enough to compile an appropriate questionnaire. The Researchers stated it was a qualitative approach and not representative of the whole country. The Researchers stated they were building on work already done on Māori disability identity and were looking at fleshing out concepts for further exploration.
4. The Committee queried the process for if a participant needed further support or if it appeared they may have an additional issue that has not been diagnosed. The Researcher stated they would set up processes before the hui or interview with community Whānau Ora providers. The Researcher stated if anyone needs clinical support there is a referral process they can follow. The Committee requested information explaining this be added to the PIS.
5. The Committee anticipated there could be a lot of whakamā when discussing disability and queried how the Researchers would navigate this barrier. The Researchers stated most of the research team has lived experience with disability themselves and ‘live the talk’ rather than research it from afar. The Researcher stated having credibility within the community will aid the discussion and they would also take the required time. The Researcher stated it may take multiple interviews over a period of time to build a relationship that will allow the stories to come out.
6. The Committee queried how many researchers would be conducting the interviews. The Committee stated it would be important to ensure the safety of the study team. The Researcher agreed it was a good point and stated that all of the research team were experienced in this type of research and that no one will be conducting an interview for the first time.
7. The Committee queried whether support people could also be participants. The Researcher stated they have discussed this and some potentially will as they will likely be whānau members. The Researcher stated if a participant wanted whanau involvement then there would be space provided for them to speak as well.
8. The Committee queried whether the study would be open to participants who may have acquired cognitive impairment through a brain injury or other source. The Researcher confirmed it would but any participants that could not reach the legal threshold for informed consent would have to be excluded.
9. The Committee queried whether $50 reimbursement would be enough to cover transport and associated costs for two meetings. The Researcher stated all expenses would be reimbursed and the $50 is in addition in recognition of participants’ time.
10. The Committee queried what would happen to study data already collected if a participant decides to withdraw from the study. The Researcher stated it would be the participant’s choice as to whether the data is deleted or kept. The Researcher stated there was an option on the consent form for this and confirmed they would take out a participant’s data if they wished.

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

1. The Committee noted the support person PIS is identical to the main PIS so also includes the option for them to bring their own support people in an infinite loop. The Committee recommended the Researcher amend the support person PIS to make it clear that they *may* be invited to participate. The Committee suggested the Researcher make it explicitly clear to support people on whether they will be invited to participate or not.
2. The Committee queried whether the PIS would be suitable for a participant with a learning disability. The Researcher stated upon approval the PIS would be a basis for translating an accessible version. The Researcher stated they would also have another translation for participants who speak te reo as their primary language.
3. The Committee advised that the option for guardian consent was not applicable and requested its removal.
4. The Committee advised that any video footage would be difficult to de-identify and recommended revising the PIS to state that if participants agree to be filmed it would mean it is not totally anonymous. The Researcher agreed to amend the sheet.
5. The Committee requested a revision to the invitation letter to make it clear that participants are invited to TWO interviews.

Decision

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

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

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| **12** | **Ethics ref:** | **19/STH/155** |
|  | Title: | NP40435: DOSE ESCALATION AND EXPANSION STUDY OF PD-1/TIM-3 BISPECIFIC ANTIBODY IN PATIENTS WITH ADVANCED AND/OR METASTATIC SOLID TUMORS |
|  | Principal Investigator: | Dr Sanjeev Deva |
|  | Sponsor: | Roche Products (New Zealand) Limited |
|  | Clock Start Date: | 01 August 2019 |

Dr Sanjeev Deva and Mrs Sonya Merry were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a first in human, open label, multicenter, Phase I, dose-escalation and expansion study designed to evaluate the efficacy, safety, tolerability and PK of a novel PD-1/TIM-3 Bispecific antibody, RO7121661, administered by IV infusion as a single agent. The study will consist of 2 Parts (A and B).
2. New Zealand will only be participating in Part B. Data from Part A will be used to select the best dose and schedule for testing in Part B.
3. Part B (Tumour-Specific Expansion Cohorts): Participants with specific tumour types, e.g., non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC) or melanoma will receive RO7121661. Part B will determine the effect of RO7121661 on these tumour types.

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 the Researcher give a brief overview of the study. The Researcher stated they were investigating new immunotherapy techniques to ‘exploit’ the body’s immune system and enable it to recognise cancer cells as a foreign substance and attack them.
2. The Committee queried whether an additional biopsy would be necessary if a participant has an archival sample available. The Researcher stated they would use any archival samples and all participants would have the additional biopsy. The Committee queried whether the additional biopsy was mandatory. The Researcher confirmed it was The Researcher stated it was important to know if there was a particular ‘signature’ they could correlate with the biopsy sample and treatment drug to determine future use. The Researcher stated this information would be used to target types of cancer that may respond to the drug and to prevent it from being administered in those for whom it would be futile.
3. The Committee queried whether an additional consent for the lung biopsy would be undertaken. The Researcher stated the biopsy could be on one of ten different sites and each have a different side effect profile. The Researcher suggested the consent for the biopsy could be done with the main study consent and they use the standard institutional form for the biopsy procedure. The Committee agreed to this approach.
4. The Committee noted Part A of the study was not being undertaken in New Zealand and the application was only for Part B. The Committee queried whether Part A has been completed. The Researcher stated it was currently in progress overseas.

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 advised that it will be difficult to approve Part B until Part A has been completed. The Committee stated that critical safety information (e.g. drug doses, side effects) needs to be in the PIS in order for participants to provide informed consent. The Researcher stated they would not begin the study until Part A has concluded as they would need to review the toxicity profile.
2. The Committee noted the supplied insurance certificate which stated that limits shown may have been reduced or exhausted by payments for other claims. The Committee advised that it requires evidence of ACC equivalent insurance. The Committee requested the Researcher provide protocol specific insurance or evidence that a participant will be eligible for cover in the event of an injury. The Committee requested confirmation on whether the insurance certificate was only for New Zealand or was company-wide for international use.

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

1. The Committee requested the addition of a lay-friendly title to the PIS.
2. The Committee advised that specific information relating to Part A of the study was not necessary to include in the PIS unless it is necessary for Part B participants to know. The Committee advised that the detail at the bottom of page 3 on part A (on how many human participants have received the drug) can be included later on as part of the risks and benefits section of the PIS.
3. The Committee requested information explaining the potential side effects and risks of the biopsy in the main PIS. The Researcher stated there was material on page 17 they would expand.
4. The Committee noted the privacy statement on the WGS PIS was incomplete and requested it be replaced with the statement in the RBR PIS.
5. The Committee requested the inclusion of reproductive risks and acceptable contraceptive methods on the main PIS. The Committee recommended the Researcher [adapt the reproductive template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/template-for-reproductive-risks-in-participant-information-sheets-sep17.docx)
6. The Committee advised that the pregnant participant / partner consent form would need an additional signature box for after the birth of the baby. The Committee explained that the pregnant participant / partner can consent to their pregnancy information being collected but upon birth the baby becomes a legal person and requires parental consent for their information to be collected.
7. The Committee requested the inclusion of information that data may be sent overseas on the pregnant participant / partner PIS and consent form.
8. The Committee requested the addition of a cultural section to the pregnant participant / partner PIS.

Decision

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

* Please amend the information sheet and consent form to include safety information on the intervention so participants are able to provide informed consent (Ethical Guidelines for Intervention Studies paragraph 6.22).
* Please update the study protocol to include any safety data (Ethical Guidelines for Intervention Studies paragraph 5.4).

## 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:** | 10 September 2019, 11:30 AM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

The following members tendered apologies for this meeting.

* Professor Jean Hay-Smith

1. **Problem with Last Minutes**

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

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

The meeting closed at 4:45 pm.