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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 13 March 2018 |
| **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 13 February 2018 |
| 11:45am | New applications (see over for details) |
|  | i 18/STH/57  ii 18/STH/61  iii 18/STH/55  iv 18/STH/54  v 18/STH/49  vi 18/STH/58  vii 18/STH/59  viii 18/STH/60  ix 18/STH/56 |
| 3:30pm | General business:   * Noting section of agenda |
| 3:40pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 27/10/2015 | 27/10/2018 | Present |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Nicola Swain | Non-lay (observational studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Melissa Cragg | Non-lay (observational studies) | Co-Opt CEN | Co-Opt CEN | Present |
| Dr Anna Paris | Lay (other) | 24/08/2017 | 24/08/2020 | Present |
| Dr Fiona McCrimmon | Lay (the law) | 27/10/2015 | 27/10/2018 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that apologies had been received from Dr Sarah Gunningham and Assc Prof Mira Harrison-Woolrych.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Dr Melissa Cragg confirmed her eligibility and was 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 01 and 13 February 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/STH/57** |
|  | Title: | Evaluation of an Individual Placement and Support prototype in Waitemata DHB |
|  | Principal Investigator: | Dr Sheryl Jury |
|  | Sponsor: | Ministry of Social Development |
|  | Clock Start Date: | 01 March 2018 |

Dr Sheryl Dury, Kamal Acharya, Leanne Teh, and Diane Anderson were 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 ethical issues (resolved)

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

1. The Committee questioned how serious the mental health issues of participants will be, and whether they would be able to freely provide fully informed consent. The Researcher explained that although participants will have serious mental health issues they will all be stable and living within the community, as functioning members of society. The Researcher explained that if participants become more unwell during the study they can postpone their participation until they are less unwell.
2. The Committee questioned whether a clinician will check the stability and ability of participants to consent. The Researcher confirmed that a clinician will confirm this for all participants.
3. The Committee discussed the plans for protecting participant’s confidentiality. The Committee requested that as much as possible identifiers are removed before the data is shared. The Committee stated that if possible the fidelity team should not have any identifiable information on participants shared with them.
4. The Committee questioned the process for if a participant becomes unwell during the study. The Researcher explained that there is a process for handling this situation involving building trust between the IPS team and the mental health team to allow these situations to be discussed between the teams if they occur.
5. The Committee questioned who identifies potential participants. The Researcher explained that as part of the mental health team process they identify those who are interested in employment and can refer these potential participants to the study.
6. The Committee noted that the peer reviewer mentioned that further cultural consideration would benefit the study and questioned how this has been addressed. The Researcher explained that they have sought further cultural consideration since the peer review and feel they have fully addressed this concern.
7. The Committee questioned whether the people interviewing Māori participants will have suitable cultural expertise. The Researcher explained that they will try to match participants culturally.

Summary of ethical issues (outstanding)

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

1. Please ensure a header with site logos is added to participant facing documents.
2. Please ensure a footer with page numbers, the study title, ethics reference number, and version number is added to all participant facing documents.
3. Please clarify in the Participant Information Sheet that the service is being provided within the mental health service, not the mental health team.
4. The Committee questioned what identifiable information is being sent to MSD about participants who are receiving a benefit. Please reframe the language and making it clearer. The Committee noted that the Consent Form is much clearer than Participant Information Sheet. In the Participant Information Sheet please explain that ‘as part of the study we need to collect XYZ (bullet points) and some of this information may be shared with MSD as part of the study’. The Committee emphasized how important it is to be upfront with participants about how their data will be used.
5. The Committee noted that the Participant Information Sheet indicates that benefits participants may be receiving will not be impacted by study participation, however, this is incorrect as if participants get a job from study participation this will impact their eligibility for a benefit. Please clarify this in the Participant Information Sheet.
6. Please provide the correct dates in the Participant Information Sheet, this includes the dates when a summary of results may be available to participants. It may be better to indicate that study results will be available after the study than to give a specific date if this could be delayed.
7. Please state upfront in the Participant Information Sheet how much time will be involved in study participation, where participants need to go, who they need to talk to, and what they will be expected to do.
8. Please adjust the formatting of the Participant Information Sheet to improve readability, the Committee suggested increasing the white space would help.
9. Please add a lay title to the Participant Information Sheet and Consent Form.
10. Please add the details of the researchers to the Participant Information Sheet, including the name and contact number.
11. Please add more detailed information to the Participant Information Sheet about who the researchers are, who the reviewers are, who employs them, and the location of the study.

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by Dr Nicola Swain and Dr Anna Paris.

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| **2** | **Ethics ref:** | **18/STH/61** |
|  | Title: | Evaluation of 'Take Charge' - an Individual Placement and Support (IPS) prototype in the Community Youth Mental Health Service at Odyssey House in Christchurch |
|  | Principal Investigator: | Ms Fleur McLaren |
|  | Sponsor: | Ministry of Social Development |
|  | Clock Start Date: | 01 March 2018 |

Kereama Carmody, Debbie Bradshaw, Nigel Loughton, Kamal Acharya, Leanne Teh, and Diane Anderson were 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 ethical issues (resolved)

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

1. The Committee questioned whether participants will know each other before meeting in the study groups. The Researchers explained that they probably will not know each other before the study.
2. The Committee questioned how participants will be identified and recruited. The Researcher explained that MSD will identify potential participants from clients who have a GP letter on file indicating that they have mild-moderate mental health issues, these potential participants will be cold-called to invite them to an information seminar about the study. The Committee expressed how it is essential that it is clearly explained to all potential participants that this is a study, not a programme or a service.
3. The Committee questioned whether participants would be required to consent in the group, or if they would meet with the researchers individually to consent. The Researcher explained that the study would be explained to the group but that each interested participant would be able to meet with the researcher privately to provide informed consent.
4. The Committee questioned the justification for a group size of 15. The Researcher explained that this is based on their past experience of similar groups, including a pilot programme, they have found that this group size works well.
5. The Committee questioned whether there is a risk of participants disclosing concerning behaviours. The Researcher explained that they haven’t experienced this in the past and don’t expect it to be an issue in this group, however, if participants do express something concerning the researchers are well prepared to check in with participants and offer support as required.
6. The Committee noted that health information collected as part of this study needs to be stored for 10 years.

Summary of ethical issues (outstanding)

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

1. Please clarify in the Participant Information Sheet that as the study involves group sessions and that this will reduce the ability to protect confidentiality and the other participants will know each other have mental health issues.
2. Please rephrase the Participant Information Sheet where it states that support will be available if participants want to change jobs, please clarify how long ongoing support will be available for and avoid suggesting that participants change jobs.
3. Please ensure a header with site logos is added to participant facing documents.
4. Please ensure a footer with page numbers, the study title, ethics reference number, and version number is added to all participant facing documents.
5. Please clarify in the Participant Information Sheet that the service is being provided within the mental health service, not the mental health team.
6. The Committee questioned what identifiable information is being sent to MSD about participants who are receiving a benefit. Please reframe the language and making it clearer. The Committee noted that the Consent Form is much clearer than Participant Information Sheet. In the Participant Information Sheet please explain that ‘as part of the study we need to collect XYZ (bullet points) and some of this information may be shared with MSD as part of the study’. The Committee emphasized how important it is to be upfront with participants about how their data will be used.
7. The Committee noted that the Participant Information Sheet indicates that benefits participants may be receiving will not be impacted by study participation, however, this is incorrect as if participants get a job from study participation this will impact their eligibility for a benefit. Please clarify this in the Participant Information Sheet.
8. Please provide the correct dates in the Participant Information Sheet, this includes the dates when a summary of results may be available to participants. It may be better to indicate that study results will be available after the study than to give a specific date if this could be delayed.
9. Please state upfront in the Participant Information Sheet how much time will be involved in study participation, where participants need to go, who they need to talk to, and what they will be expected to do.
10. Please adjust the formatting of the Participant Information Sheet to improve readability, the Committee suggested increasing the white space would help.
11. Please add a lay title to the Participant Information Sheet and Consent Form.
12. Please add the details of the researchers to the Participant Information Sheet, including the name and contact number.
13. Please add more detailed information to the Participant Information Sheet about who the researchers are, who the reviewers are, who employs them, and the location of the study.

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by Dr Nicola Swain and Dr Anna Paris.

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| **3** | **Ethics ref:** | **18/STH/55** |
|  | Title: | (duplicate) An exploration of the experience of inpatient mental health for tāngata whaiora Māori |
|  | Principal Investigator: | Dr Margaret Dudley |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 01 March 2018 |

Dr Margaret Dudley and Hugh Tran 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 ethical issues (resolved)

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

1. The Committee discussed who the CI for the study is. The Researchers explained the relationship between the listed CI and the primary researcher, clarifying that although Margaret is listed as the study CI, Hugh is the main researcher as the study is being done for his doctorate degree.
2. The Committee questioned how participants will be recruited. The Researcher explained that they will be recruited by staff in the service who will refer interested potential participants to the study recruiters.
3. The Committee questioned how much koha for the study is as it is inconsistent in study documents. The Researcher confirmed it is $50.
4. The Committee noted that as the study will use quotes in study publications, because these could identify participants the Committee requested that any quotes are run past the participant, to ensure they are comfortable with them, before they are used in the publication.
5. The Committee questioned whether there will be follow up with participants after sending out the transcripts to ensure they are happy with them. The Researcher confirmed that they will follow up by phone to ensure the participant’s received and are happy with the transcripts.
6. In addition to stopping the interviews if participants become distressed, please provide all participants with an information sheet of who they can contact if they become distressed after the study.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether the student conducting the interviews has sufficient experience to ensure both participant and researcher safety. The Committee stated that due to the lack of experience and qualifications of the student conducting the interviews, suitable supervisors must be present during the interviews to ensure the safety of both the researcher and the participants. The Committee stated that detailed plans of this must be provided to the Committee. Studies must be conducted or supervised only by investigators with the necessary skills and resources to conduct the study and deal with any contingencies that may affect participants (Ethical Guidelines for Observational Studies paragraph 5.9).
2. The Committee requested that suitably independent peer review is provided of the study protocol, the Committee suggested that the HDEC peer review template is used. Investigators should submit their proposals to independent peer review to help optimise scientific validity, additionally HDECs require evidence of adequate peer review (Ethical Guidelines for Observational Studies paragraph 5.8).
3. The Committee questioned who determines if participants have sufficient capacity to provide informed consent. The Researcher explained the plan to use key workers. The Committee stated that it must be suitably qualified clinicians who determine that participants have sufficient competency to provide their own informed consent. Please make provision for a clinical psychologist to confirm that participants have are able to provide their own informed consent.

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

1. Please add the contact details to the Participant Information Sheet for a cultural support person who is not involved in the study, although they can be from within the same service.
2. Please add contact details to the Participant Information Sheet for any participants who have concerns or complaints.
3. Please clarify in the Participant Information Sheet that this study is being done for a doctorate thesis and this may mean that limited service improvements can be expected from the study, and that the primary purpose of the study is for the student to attain a qualification.
4. Please add the study title to the Participant Information Sheet footer.
5. Please update study documents to reflect that study data will be stored for 10 years.
6. Please revise the Participant Information Sheet to remove double ups.
7. The section in the Participant Information Sheet titled ‘cultural safety’ must be revised to not read as a box ticking exercise. The heading of this section should be removed and the section rephrased.
8. Please revise the phrasing of the Participant Information Sheet in regards to the destruction of the audio recordings. The phrase ‘termination’ and audio ‘tape’ should be revised.
9. The step-by-step overview in the Participant Information Sheet feels like box ticking, please revise the wording to make the statements more general and friendlier to participants.
10. Please remove the optional tick box from the Consent Form for the statement about telling the participant’s GP if a risk to self or others, this must be mandatory for safety.
11. Some statements from the Consent Form can be removed as they do not apply for this study, for example the statement about compensation for injury.
12. In the study poster please refer the HDECs as the ‘Health and Disability Ethics Committee’.

Decision

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

* Please provide assurance to the committee that the researcher conducting the interviews has sufficient experience and skills to safely conduct these (Ethical Guidelines for Observational Studies paragraph 5.9).
* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please respond to the outstanding ethical concerns detailed above.

This following information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine and Dr Devonie Waaka.

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| **4** | **Ethics ref:** | **18/STH/54** |
|  | Title: | CardiAQ Mitral Valve Study |
|  | Principal Investigator: | Dr Rajesh Nair |
|  | Sponsor: | Edwards Lifesciences LLT |
|  | Clock Start Date: | 01 March 2018 |

Dr Rajesh Nair and another member of the research team 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 evaluates the safety and function of the CardiAQ-Edwards™ Transcatheter Mitral Valve (TMV) System in patients with moderate to severe mitral regurgitation who are at high risk for surgery.
2. Mitral regurgitation is a condition in which blood flowing through the mitral valve flows in the incorrect direction during part of the cardiac cycle.
3. Current available treatment for this condition is by open heart surgery.
4. The TMV system replacement takes place by being introduced into the vein in the groin and taken to the heart. Once the right side of the heart is entered the catheter is passed through a puncture in the septum or wall between the right and left heart chambers.

Summary of ethical issues (resolved)

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

1. The Committee questioned why there was the intention to split the study across 3 different sites. The Committee expressed concern regarding safety as this is a novel device and therefore is better to have the expertise in at one site. The researcher confirmed that the study mentioned 3 sites in the proposal but the intention is to start at the Waikato Hospital and may extend at a later date. The Committee advised that adding more sites would be classed as an amendment to the study.
2. The Committee queried the existence of a learning curve for the surgeons using this device. The Researcher confirmed that a sufficient amount of hours / training programme is provided for surgeons using this device.
3. The Committee questioned the safety of the device and its clinical exposure to date. The Researcher confirmed that this was the first clinical trial using this device which had previously been used for therapeutic purposes in compassionate use settings only. The researcher stated that as a result of early outcomes technical changes had been made to the device and procedure, such that outcomes were significantly improved in cases undertaken in 2016/2017. The researcher also confirmed that the patient population would be carefully selected and more robust than those who had received the device under compassionate use.
4. The Committee noted it was good that the study included an independent Data Monitoring Committee (DMC) to help monitor all safety data related to the study participants.

Summary of ethical issues (outstanding)

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

1. The Committee queried the study design where the protocol says ‘”with no more than one patient treated per day at an individual site.” The Committee requested participants undergoing the procedure are staggered more widely to ensure an adequate period of post-operative observation / surveillance after each case. This allows identification of unexpected acute adverse events, which may impact on the decision to proceed with the next scheduled case. Please modify the study protocol to formalise this.
2. The Committee noted that that the decision to participate in the study is made by the participant and not the Heart Team as stated in the response to question r.5.4.1 of the application form. The Committee requested that eligible participants are presented with additional options when approached by the Heart Team. Please avoid use of words such as “selected” and “chosen”.
3. Please ensure there is clear separation between who determines if a participant is eligible for the devise and the investigator team. The Researcher confirmed that eligible participants are patients attending a high risk clinic and the physicians at this hospital would be responsible for selecting patients to take part in the trial.

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

1. Please change the image in the Participant Information Sheet to ensure the valve is clearer.
2. The Committee questioned if the Participant Information Sheet could be more specific that the study is high risk. Please amend the information sheet and give a lay summary of experience with the device to date.
3. Please use shorter sentences and more lay friendly language.
4. The Committee queried whether the participant’s GP would be informed of the participant’s involvement in the study. The Researcher confirmed that that this would happen. Please ensure the Participant Information Sheet and Consent Form is amended to reflect this.
5. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: “*If you were injured as a result of treatment given as part of this study, which is unlikely, you won’t be eligible for compensation from ACC. However, compensation would be available from the study’s sponsor, Edwards Lifesciences in line with industry guidelines. We can give you a copy of these guidelines if you wish. You would be able to take action through the courts if you disagreed with the amount of compensation provided. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee 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 provide assurance to the Committee that participants enrolled in the study undergoing the procedure will be staggered appropriately.
* Please respond to the outstanding ethical concerns detailed above.

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| **5** | **Ethics ref:** | **18/STH/49** |
|  | Title: | vTv Therapeutics TTP488303/ Open Label Extension |
|  | Principal Investigator: | Dr Nigel Gilchrist |
|  | Sponsor: | vTv Therapeutics LLC |
|  | Clock Start Date: | 01 March 2018 |

Larissa Roberts 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. The Committee noted that this is an extension study for an already HDEC approved study.
2. This study will include 5 participants who have Alzheimer’s disease and can provide informed consent.
3. The study uses the same competency assessments throughout the study as the earlier approved study.

Summary of ethical issues (resolved)

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

1. The Committee noted that the references to the Treaty of Waitangi in the application form are incorrect, please ensure these are correct in future applications.
2. In future applications please include the incidence of the condition being studied in Māori.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **18/STH/58** |
|  | Title: | In my own words |
|  | Principal Investigator: | Dr Brigit Mirfin-Veitch |
|  | Sponsor: | Donald Beasley Institute |
|  | Clock Start Date: | 01 March 2018 |

Dr Brigit Mirfin-Veitch and Paul Milner 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.

Dr Anna Paris declared a potential conflict of interest, the Committee decided to allow her to fully participate in the consideration of this application.

Summary of ethical issues (resolved)

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

1. The Committee questioned why the study is being conducted. The Researcher explained that they want to produce an online library of life story narratives of people with learning disabilities on their relationships and sexual experiences, to help with self-advocacy of future people with learning disabilities.
2. The Committee questioned what is meant by ‘learning disability’ in the context of the study. The Researchers explained that ‘learning disability’ is the preferred term, although it would commonly be understood as ‘intellectual disability’.
3. The Committee questioned whether all participants will be able to provide informed consent. The Researcher explained that they will be able to understand the study and give their own informed consent.
4. The Committee questioned whether the researcher will go through the Participant Information Sheet with all participants. The Researcher confirmed that they will go through the Participant Information Sheet will all participants and make sure they understand the study.
5. The Committee questioned whether participants will be diversity matched with the researchers. The Researcher confirmed that they would do their best to diversity match participants.

Summary of ethical issues (outstanding)

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

1. The Committee explained that the study protocol must fully detail the inclusion criteria, including how it will be determined whether participants can provide their own informed consent. The Committee noted that a suitably qualified clinician will need to confirm participants are able to provide their own informed consent, the study protocol should state that referrals will only be accepted for participants who have had a clinician confirm that they can provide their own informed consent.

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

1. The Committee noted that the consent form front page has two boxes that say ‘consent’, one with a tick and another with a cross, the Committee explained that they found these confusing. The Committee suggested that the word ‘consent’ is removed from these boxes to help clarify this, or ‘consent’ is replaced with another term (such as ‘not consent’) on the box with a cross.
2. The Committee stated that in their view the Consent Form is excessively long and some of the points could be combined without losing any content, however the Committee noted that the researchers are the experts at working with this population and will have a better understanding of what is appropriate.
3. The Participant Information Sheet indicates that participants can send back the completed consent form by post, please adjust the Participant Information Sheet as participants will provide consent in person with a researcher.
4. Please revise the Participant Information Sheet to remove all typographical errors.
5. Please revise the Participant Information Sheet to better reflect the confidentiality arrangements for the study, not all information can be kept private as it will be published online, but it wont include the participant’s name.
6. Please change the reference to the approving ethics committee to be the Southern HDEC.
7. Remove this statement ‘The Health and Disability Ethics Committee only approve projects that they think are safe and the researchers will work with people in a kind and respectful way’ from the Participant Information Sheet.
8. Please remove the HDEC logo from the Participant Information Sheet as this seems like the project is HDEC endorsed.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please respond to the outstanding ethical concerns detailed above.

This following information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine and Dr Nicola Swain.

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| **7** | **Ethics ref:** | **18/STH/59** |
|  | Title: | Evaluation of Early Start Denver Model Direct Therapy in addition to Parent Coaching for Young Children with Autism Spectrum Disorder. |
|  | Principal Investigator: | Ms Hannah Waddington |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 March 2018 |

Ms Hannah Waddington 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 ethical issues (resolved)

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

1. The Committee noted that the peer reviewer who completed the HDEC peer review template didn’t give a recommendation (e.g. approve). In future, please try to have this section of the form completed as it assists the Committee in assessing the application.
2. The Committee noted the emailed responses to missed questions in the application form and stated that they were satisfied with the answers provided.
3. The Committee questioned whether the study protocol has been adjusted in response to the peer reviewer suggestions. The Researcher confirmed that they had carefully considered their suggestions and adopted most but not all of them, they explained the justification for not adopting all of the changes.
4. The Committee questioned the number of proposed participants and questioned whether only one parent can be involved in the study. The Researcher explained that they will recruit up to 6 parent/child dyads, with only one parent formally involved in the study (although other family members can attend if they wish).
5. The Committee questioned how confidentiality would be maintained throughout the study. The Researcher explained that the children would be given as pseudonym and their parent would be referred to as ‘pseudonym’s mother/father’.
6. The Committee questioned whether participants may need to pay a ‘subsidized donation’ for study involvement. The Researcher confirmed that they would not need to and that this is included in their broader pamphlet.

Summary of ethical issues (outstanding)

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

1. Please clarify in the Participant Information Sheet whether data collected for this study may be made available to researchers for other studies, if it may only be available to other researchers for the purpose of this study this does not need to be mentioned in the Participant Information Sheet.
2. Please state early in the Participant Information Sheet what the purpose of the study is.
3. The paragraph on the first page of the Participant Information Sheet that details who is in the Participant Information Sheet can be moved to later in the Participant Information Sheet.
4. Please ensure a footer with page numbers, the study title, ethics reference number, and version number is added to all participant facing documents.

Decision

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

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

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| **8** | **Ethics ref:** | **18/STH/60** |
|  | Title: | E Oho Rangatahi |
|  | Principal Investigator: | Dr Kahu McClintock |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 March 2018 |

Dr Kahu McClintock and co-investigators 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 ethical issues (outstanding)

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

1. The Committee requested what kinds of outcome measures will be taken during the study and how the health effects of the intervention will be measured. The Committee stated that these kinds of details must be included in the study protocol. The study protocol should contain an overview of the planned statistical analyses, and these planned analyses should be adhered to in conducting the study (Ethical Guidelines for Intervention Studies paragraph 5.7).
2. The Committee stated that the application form had been very poorly completed for this application. For example, the application form indicates that there are no risks to researchers, and no risk of stigmatisation, and whakama is not identified as a potential cultural issue, however there are real risks of these in this study. Please ensure more care is taken with the application in future.
3. The Committee stated that it is not clear from the study protocol how participants will be identified and recruited. Please provide these kinds of details in the protocol for future applications.
4. The Committee questioned what study participation will involve for participants. The Researcher explained that they will have focus groups with participants and discuss their knowledge base. The Committee requested that this is more clearly explained in the study protocol, application form, and Participant Information Sheet.
5. The Committee requested further information on the potential for impact and scale from the study.
6. The Committee requested further information on how stakeholders and policy makers will be engaged with, such as the Ministry of Education, the Ministry of Health, and NGOs.
7. The Committee requested that clarification is provided in the study protocol about the study question the study is trying to answer. Investigators should develop clear study questions that identify the participant population, the intervention and the main outcome of interest (Ethical Guidelines for Intervention Studies paragraph 5.2).
8. The Committee explained that the study protocol must include significantly more detail to allow ensure that the results are useful, this includes knowing if the study has been successful or not. Scientific soundness is ethically important. Projects without scientific merit needlessly expose participants to risk and misuse their time, and waste resources (Ethical Guidelines for Intervention Studies paragraph 5.5).
9. Please clarify in future applications who the CI for this study is, with regards to both who will be primarily conducting the study and who will have overall responsibility for the study conduct.

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

1. Please provide suitable information sheets and assent forms. This includes an information sheet and consent form for parents of participants unable to provide informed consent, an information sheet and consent form for participants able to provide their own informed consent (this includes all participants aged 16 years or older and may include some younger participants if they are deemed competent), and an information sheet and assent form for children. Guidance on assent can be found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>.
2. Please clarify in the Participant Information Sheet what kind of information will be collected about participants, the current phrasing around ‘health and social matters’ is unclear.
3. Please state in the Participant Information Sheet that participants don’t need to answer all questions.
4. The Committee requested that compensation wording is added for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
5. Please clarify in the Participant Information Sheet that health information collected about participants will be stored for 10 years, and for participants under 16 it will be stored for 10 years after the participant turns 16.
6. Please remove the yes/no columns from the Consent Form for all statements that are not truly optional, meaning that a participant could respond ‘no’ and still participate in the study.
7. The Committee noted that a re-consent form may be necessary for participants aged under 16 when recruited, who have consent obtained from their parents on their behalf initially, who turn 16 during the study and must provide their own consent to their ongoing participation. Please either provide a suitable form for this or confirm that any participant who would turn 16 during the study provides their own informed consent when initially recruited.
8. Please ensure that the study commencement date is accurate on study documents.
9. Please ensure a footer with page numbers, the study title, ethics reference number, and version number is added to all participant facing documents.
10. Please revise the Participant Information Sheet to remove all typographical errors.

Decision

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

* Investigators should develop clear study questions that identify the participant population, the intervention and the main outcome of interest (Ethical Guidelines for Intervention Studies paragraph 5.2).
* Projects without scientific merit needlessly expose participants to risk and misuse their time, and waste resources (Ethical Guidelines for Intervention Studies paragraph 5.5).
* The study design should be the one best suited to answer the study question, while minimising harm, maximising benefit and meeting other ethical standards (Ethical Guidelines for Intervention Studies paragraph 5.4).
* The study protocol should contain an overview of the planned statistical analyses, and these planned analyses should be adhered to in conducting the study (Ethical Guidelines for Intervention Studies paragraph 5.7).

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| **9** | **Ethics ref:** | **18/STH/56** |
|  | Title: | MK-7264-030:Phase 3 study in adult participants with chronic cough |
|  | Principal Investigator: | Dr Conroy Wong |
|  | Sponsor: | MSD |
|  | Clock Start Date: | 01 March 2018 |

Dr Conroy Wong and Catherine Howie 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 3 arm, double-blind, randomized, placebo-controlled, worldwide study in people with chronic cough.
2. The main objective of the study is to examine the safety and efficacy of MK7264 in reducing cough frequency in people with chronic cough.
3. There will be a screening phase of up to approximately 2 weeks. Eligible participants will be randomly assigned to one of the 3 treatments: MK7264 45mg twice daily, MK-7264 15mg twice daily, or placebo. Participants will take study drug for about 52 weeks and they will be followed up 2 weeks after the end of treatment, meaning that each participant will be in the study for approximately 56 weeks.
4. Participants will visit the study site about 14 times.
5. Study procedures include measurement of body weight, vital signs, physical examination, ECG, Chest X Ray, Spirometer, haematology and biochemistry blood samples and the completion of electronic diaries.
6. Participants will be asked to wear a cough monitor for a 24h period several times during the study. This monitor will measure the number of times participants cough.

Summary of ethical issues (resolved)

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

1. The Committee questioned how the risk of an unequal power relationship between the clinician-researcher role and patient will be managed so as to avoid a risk of coercion. The Researcher explained that recruiting participants through the community, rather than via a database, will help reduce this risk. This will help minimise the risk of a conflict of interest between the research and clinical roles.
2. The Committee questioned if a compensation claim is made, whether the CI will advocate for the participant and if the claim can be mediated in New Zealand. The Researcher confirmed that such claims will be mediated in New Zealand.

Summary of ethical issues (outstanding)

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

1. The Committee questioned why genetic testing is mandatory, noting that the only mandatory aspects of study participation should be those that are required for the primary purposes of this study. There must be a fair distribution of burdens from participation in a study (Ethical Guidelines for Intervention Studies paragraph 4.5). The Research agreed that this should be an optional part of the study. Please amend the study protocol and Participant Information Sheet to formalise this.
2. The Committee questioned how much participants will be paid and how this will be calculated. All payments, reimbursements and health services provided to study participants must be disclosed to an ethics committee (*Ethical Guidelines for Intervention Studies* paragraph 6.36). The Researcher advised that payment for participation would vary across sites due to variation in petrol costs etc. for different distances travelled. The Committee would like to see details of the amounts to be provided for participation at each of the sites.
3. The Committee queried why the participant’s date of birth and initials will be sent the Sponsor. The Research agreed that this was not best practice and will remove this from the all study documentation.
4. The Committee questioned what data the site will share with the sponsor's insurer in the event of a compensation claim and whether this will this be restricted to information already gathered by the site in relation to the study. The Research will clarify with the sponsor and ensure this is accurately reflected in all study documentation.
5. Please provide the Universal Trial Number (UTN).
6. Please clarify who will be giving the potential participants the Participant Information Sheet.

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

1. Please ensure a lay title is used on the Participant Information Sheet.
2. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.*
3. Please consider adding an image of the cough monitor.
4. The contraception section is inadequate given age range of participants and the length of the study. Please ensure the full standard comprehensive contraceptive statement is needed to prevent pregnancy is added to the Participant Information Sheet. The Committee suggested using the standard HDEC template (available at: <https://ethics.health.govt.nz/system/files/documents/pages/template-for-reproductive-risks-in-participant-information-sheets-sep17.docx>)
5. Please ensure there is a point about the requirement for contraception in the consent form.
6. The statement in the consent form "you also agree to let the sponsor...use and share your health data" is too broad. Please ensure this statement is more specific.
7. Please add detail to the Participant Information Sheet as to how recordings will be stored anonymously.
8. Please add more detail to explain the breadth of the genetic testing to section 8 of the Participant Information Sheet.
9. Please review and correct the statement in the Participant Information Sheet that says the trial may be stopped due to decisions made in the commercial interests of the sponsor. Studies should not be terminated simply for reasons of commercial interest or public relations (*Ethical Guidelines for Intervention Studies* paragraph 6.65).
10. Please review and correct the statement in the Participant Information Sheet that says the participant’s date of birth and initial will be sent to the sponsor.
11. The Committee noted that there is no information in the Participant Information Sheet to describe the withdrawal of samples collected if participants withdraw from the study. Please ensure this is added to the Participant Information Sheet.
12. The Committee questioned what the risks of the study drug are and stated that these should be acknowledged more clearly in the Participant Information Sheet.

Decision

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

* 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 respond to the outstanding ethical concerns detailed above.

## 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 April 2018, 08:00 AM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

The following members tendered apologies for this meeting.

* + Dr Fiona McCrimmon
  + Dr Devonie Waaka
  + Dr Nicola Swain

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.

The meeting closed at 3:40pm.