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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 12 June 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 08 May 2018 |
| 11:45am | New applications (see over for details) |
|  | i 18/STH/121  ii 18/STH/122  iii 18/STH/111  iv 18/STH/113  v 18/STH/116  vi 18/STH/119  vii 18/STH/107  viii 18/STH/109 |
| 3:05pm | General business:   * Noting section of agenda |
| 3:10pm | 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 | Present |
| 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 | Present |
| Dr Fiona McCrimmon | Lay (the law) | 27/10/2015 | 27/10/2018 | Present |
| Dr Dr Anna Paris Paris | Lay (other) | 24/08/2017 | 24/08/2020 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members

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 08 May 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/STH/121** |
|  | Title: | A study to test ABI-H0731 to treat patients with Chronic Hepatitis B |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Pharmaceutical Research Associates New Zealand Lim |
|  | Clock Start Date: | 31 May 2018 |

Prof Edward Gane and Olivia Thame 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 study investigates a potential short term treatment for Chronic Hepatitis B, this study involves patients who are not already on standard care.

Summary of resolved ethical issues

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

1. The Committee noted that the application indicated that if updated safety information was discovered that this would be communicated to participants after the Participant Information Sheet is updated. The Committee noted that if the safety information is urgent this must be communicated to participants as quickly as possible and should not wait for an updated Participant Information Sheet to be approved. The Researchers confirmed this is their plan.
2. The Committee questioned if the study involves Future Unspecified Use of Tissue. The Researcher explained that the study only involves pharmacogenetics and pharmacokinetic testing, not Future Unspecified Use of Tissue.
3. The Committee noted that for the optional sample testing only the subject number would be retained and that this was appropriate.

Summary of outstanding ethical issues

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

1. The Committee discussed the CRO for this study. The Researcher explained that they believe PRA will be acting as the CRO for New Zealand. The Committee requested that this is confirmed, the Committee stated that clear details of the relationship between the study sponsor and CRO should be detailed.
2. The Committee queried the level of identification of study samples being sent overseas, noting that study documentation was inconsistent. The Researcher explained that this as recently confirmed and the samples would retain the participant’s subject number, year of birth, and gender. The Committee requested that all study documentation is updated to reflect this.

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

1. Please update the information on identifiability of samples in the Participant Information Sheet.
2. Please update the title of the Participant Information Sheet to reflect that it is an information sheet rather than a consent form.
3. Please update the reproductive risks section of the Participant Information Sheet to be more suitable for New Zealand participants. The Committee noted that a template is available at ethics.health.govt.nz that should be used to guide this section.
4. Please standardise the font size and adjust formatting to increase the white space in the Participant Information Sheet to improve readability.

Decision

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

* Please respond to the outstanding ethical concerns detailed above.
* 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*).

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

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| **2** | **Ethics ref:** | **18/STH/122** |
|  | Title: | A study to test ABI-H0731 with Entecavir to treat patients with Chronic Hepatitis B |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Pharmaceutical Research Associates New Zealand Lim |
|  | Clock Start Date: | 31 May 2018 |

Prof Edward Gane and Olivia Thame 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 study investigates a potential short term treatment for Chronic Hepatitis B, this study involves patients who are already on standard care and the study drug will be additional to this.

Summary of resolved ethical issues

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

1. The Committee noted that the application indicated that if updated safety information was discovered that this would be communicated to participants after the Participant Information Sheet is updated. The Committee noted that if the safety information is urgent this must be communicated to participants as quickly as possible and should not wait for an updated Participant Information Sheet to be approved. The Researchers confirmed this is their plan.
2. The Committee questioned if the study involves Future Unspecified Use of Tissue. The Researcher explained that the study only involves pharmacogenetics and pharmacokinetic testing, not Future Unspecified Use of Tissue.
3. The Committee noted that for the optional sample testing only the subject number would be retained and that this was appropriate.

Summary of outstanding ethical issues

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

1. The Committee discussed the CRO for this study. The Researcher explained that they believe PRA will be acting as the CRO for New Zealand. The Committee requested that this is confirmed, the Committee stated that clear details of the relationship between the study sponsor and CRO should be detailed.
2. The Committee queried the level of identification of study samples being sent overseas, noting that study documentation was inconsistent. The Researcher explained that this as recently confirmed and the samples would retain the participant’s subject number, year of birth, and gender. The Committee requested that all study documentation is updated to reflect this.
3. The Committee queried whether participants in this study would be ensured ACC equivalent compensation if an injury suffered is related to Entecavir, as although this is standard care it is being given as a study drug for this study. The Researcher confirmed their understanding that all participant injuries would be covered as Entecavir is a study drug in this case. Please confirm that the study insurance covers participants from injuries related to Entecavir rather than the study drug.

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

1. Please update the information on identifiability of samples in the Participant Information Sheet.
2. Please update the title of the Participant Information Sheet to reflect that it is an information sheet rather than a consent form.
3. Please update the reproductive risks section of the Participant Information Sheet to be more suitable for New Zealand participants. The Committee noted that a template is available at ethics.health.govt.nz that should be used to guide this section.
4. Please standardise the font size and adjust formatting to increase the white space in the Participant Information Sheet to improve readability.

Decision

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

* Please respond to the outstanding ethical concerns detailed above.
* 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*).

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

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| **3** | **Ethics ref:** | **18/STH/111** |
|  | Title: | The REVERSE study |
|  | Principal Investigator: | Dr Michael Paul Georg Schultz |
|  | Sponsor: | INC Research New Zealand Limited |
|  | Clock Start Date: | 31 May 2018 |

Dr Steve Johnson 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 outstanding ethical issues

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

1. The Committee stated that the question in the application form about equipoise is not well answered. Please provide further information on how the study arms meet the requirement of equipoise. An intervention study meets the equipoise standard if the evidence is ‘equally poised’ as to the overall balance of risks and benefits of each of the interventions offered in the study, so that it cannot be determined in advance which of the groups in a proposed study will be better off (Ethical Guidelines for Intervention Studies paragraph 5.18).
2. The Committee noted that the cultural questions in the application form were poorly answered, including questions p.4.1 not including information about the rates of NASH being higher in Māori. Please review the guidance available at ethics.health.govt.nz and provide updated answers to these questions.
3. The Committee noted that studies should not be terminated simply for reasons of commercial interest or public relations (*Ethical Guidelines for Intervention Studies* paragraph 6.65). The Committee stated their preference that this option is removed from study documentation, and noted that if the study is terminated early for any reason consideration must be given to reducing the disadvantages from this for participants, such as by offering post trial access for participants on compassionate grounds.
4. The Committee queried the makeup of the internal DSMC, noting that they would prefer an external committee. The answer to this question in the application form was unhelpful. Please provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies* paragraph *6.50).*

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

1. The Committee stated that the Participant Information Sheet requires an update and should be completely revised. Specifically, issues exist with the formatting, content, and wording of the Participant Information Sheet.
2. Please revise the Participant Information Sheet to reduce repetition, the Committee noted that a lot of information is unnecessarily repeated in different sections of the Participant Information Sheet and this can be removed.
3. Please revise the Participant Information Sheet to improve lay readability.
4. Please update the information in the Participant Information Sheet on the reasons for not getting pregnant, currently this section has confusing information.
5. Please update the reproductive risks section of the Participant Information Sheet to be more suitable for New Zealand participants. The Committee noted that a template is available at ethics.health.govt.nz that should be used to guide this section.
6. Please remove information from the Participant Information Sheet that is not relevant to participants, for example information that is not study-specific or assessments that are not being done at New Zealand sites.
7. 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 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.”*
8. Please update the Participant Information Sheet footer as currently it is too large and merges with the text of the Participant Information Sheet.
9. Please remove irrelevant information from the Participant Information Sheet, such as stating that ‘side effects’ will be reviewed in the section on screening visits.
10. Please revise the Participant Information Sheet to remove all typographical errors.
11. Please revise the information in the Participant Information Sheet on side effects, this information should give expected rates of these side effects (e.g. 1 in 10).
12. Please remove information on the risks of standard care (such as cholesterol lowering drugs) from the Participant Information Sheet as participants will be given this information as part of their standard care and this will not change from study participation.
13. Please remove references to optional samples and testing from the main Participant Information Sheet, this information is separately contained in the optional Participant Information Sheet.
14. The phone call follow up Participant Information Sheet includes information on tissue samples and compensation, please revise this form to ensure all irrelevant information is removed.
15. Please remove information from the PK sub-study Participant Information Sheet about potential direct benefits to participants, as there are no potential medical benefits from participation in this optional aspect of the study.
16. Please reduce repetition in the Participant Information Sheet for re-starting the study after a potentially drug induced liver injury, this Participant Information Sheet does not need to repeat the information from the main Participant Information Sheet and should instead focus on what participants need to know in this circumstance.
17. Please add information to the Participant Information Sheet for pregnancy about obtaining consent after birth to collect information on the baby. The Committee noted that this consent must be obtained after birth as the parents cannot consent to collection of data about their baby before it is born.
18. Please add a lay title to the Participant Information Sheet, this title should actually describe the study rather than being an acronym.

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.

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

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| **4** | **Ethics ref:** | **18/STH/113** |
|  | Title: | (duplicate) Do Cardio selective Beta-Blockers Affect the Use of Beta-Agonist Inhalers Following Bronchoconstrictionin Asthma? |
|  | Principal Investigator: | Dr Miriam Bennett |
|  | Sponsor: | Respiratory Research Unit Waikato Hospital |
|  | Clock Start Date: | 31 May 2018 |

Dr Miriam Bennett 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. The Committee noted that this study had been previously declined by another HDEC.

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 whether the researcher is a student, noting the references in the application to supervisors. The Researcher explained that she does have supervisors but is not a student.
2. The Committee noted that the Māori cultural consultation suggested a study age range of over 45 and queried why this was not adopted. The Researcher explained that they considered this but decided to include younger participants as they may be in better health and the study is suitable for any asthmatics as long as they are stable and well.
3. The Committee queried the risks of giving beta blockers to people who do not need them. The Researcher explained that although there is a risk, the study requires giving beta blockers to people who are not already on them and everyone who needs them should already be on beta blockers.
4. The Committee queried if this study has been done before, noting similarities to other published studies. The Researcher explained that this specific study has not been done before and will be more relevant to New Zealand as the study drug is more widely used in New Zealand than the drugs that were used in previous studies.
5. The Committee queried the importance of the control arm of the study. The Researcher explained that similar studies found this to be essential as simply the act of being on the study can alter participants’ behaviour and outcomes.
6. The Committee questioned the justification for the high dose arm. The Researcher explained that they are aware this is unusual and it is because cardio selective beta blockers at high doses can become not cardio selective, and the researchers believe it is important to go to the maximum dose that can be clinically used in New Zealand to ensure the study results are as useful as possibly for New Zealanders. Not all participants will receive the higher dose as the side effects can be unpleasant and would be likely to break blinding. The Researcher further explained that some participants will better tolerate high doses than others, and participants will only be increased to a dose they are able to tolerate.
7. The Committee questioned whether participants would be able to take their own heart rate at home. The Researcher explained that at the first screening visit they would teach participants how to take their heart rate and check that they are doing so accurately. If participants are unable to take their own heart rate they will have the option to come in to the clinic to have it measured. The Committee suggested that some heart rate smart phone applications are free and may be able to help participants.

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 questioned the current data safety monitoring group guidelines. The Researchers explained the current structure. The Committee requested that the makeup of the group is revised to include the CI; and that all members of the DSMC have adequate expertise to assess medical events and determine their impact on the risk: benefit ratio of the study. The Committee requested that that safety guidelines are revised as are currently inadequate. The DSMC should review any SAE or AE of CTAE grade 3+ thought to be at least possibly related to study conduct. A list of AEs of Special Interest should also be developed and specific management guidance be given, including when such AEs would trigger DSMC review. Provide updated details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies* paragraph *6.50).*
2. The MPS certificate provided is a poor quality scan that cannot be read. Please provide updated evidence of CI indemnity.

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

1. Please clearly state in the Participant Information Sheet that exercise capacity will be significantly reduced while participants are on the study.
2. Please revise the Participant Information Sheet to remove typographical errors.
3. Please clarify the information about the challenge in the Participant Information Sheet, including stating where it will be done and that there will be clinical supervision.
4. Please clarify in the Participant Information Sheet that data will be de-identified rather than anonymous.

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.

This following information will be reviewed, and a final decision made on the application, by Dr Sarah Gunningham and Dr Fiona McCrimmon.

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| **5** | **Ethics ref:** | **18/STH/116** |
|  | Title: | Open-Label Extension Study of Relugolix for the Treatment of Endometriosis-Associated Pain |
|  | Principal Investigator: | Dr Bradley Chittenden |
|  | Sponsor: | Pharmaceutical Research Associates Ltd (NZ) |
|  | Clock Start Date: | 31 May 2018 |

Charlie Stratton, Allison Heard & another investigator 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 24 week open label extension study for Relugolix for the treatment of endometriosis associated pain. No other oral treatment is available.
2. The Committee commended the overall quality of the application, noting that it was good to see a LGBTQ+ friendly approach to the study and participant facing information.

Summary of resolved ethical issues

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

1. The Committee questioned how many participants will be in the study. The Researcher clarified that there will be 800 participants worldwide and 24 in New Zealand.
2. The Committee noted that some answers in the application form had been copy/pasted and refer to different drugs. Please ensure the application is more carefully completed in future.

Summary of outstanding ethical issues

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

1. The Committee queried the data safety monitoring arrangements for this study. The Researcher explained that the current plan is for the CI from each location to notify the sponsor of any safety issues. The Committee expressed their view that this is not appropriate for this study, as significant safety concerns could be found in the extension study and some participants will be receiving the study drug for the first time. Formal data safety monitoring arrangements for the study must be implemented. Provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies* paragraph *6.50).*
2. The Committee stated that the question in the application form about equipoise is not well answered. Please provide further information on how the study arms meet the requirement of equipoise. An intervention study meets the equipoise standard if the evidence is ‘equally poised’ as to the overall balance of risks and benefits of each of the interventions offered in the study, so that it cannot be determined in advance which of the groups in a proposed study will be better off (Ethical Guidelines for Intervention Studies paragraph 5.18).

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

1. The possible side effects of the study drug have not been well explained in the Participant Information Sheet. Please state the most common and likely side effects first and ensure that New Zealand terms are used rather than international terms.
2. Please put information on similar or related risks together in the Participant Information Sheet.
3. Please clarify the information in the Participant Information Sheet about menopausal symptoms.
4. Please adjust the reproductive risks section in the Participant Information Sheet to emphasise the importance of not becoming pregnant on the study. The Committee noted that a template is available at ethics.health.govt.nz that can be used as a guide for updating this information.
5. The Participant Information Sheet contains significant repetition, please revise to remove this.
6. The Committee noted that the cultural statement in the Participant Information Sheet is not reflective of the current study, as it appears to focus on genetic testing. The Committee noted that this should be updated and the cultural reviewers should specifically be asked to comment on cultural issues of inducing a menopausal state.

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.

This following information will be reviewed, and a final decision made on the application, by Assc Prof Mira Harrison-Woolrych and Ms Raewyn Idoine.

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| **6** | **Ethics ref:** | **18/STH/119** |
|  | Title: | Assessment of single doses of the trial drug AK111 in healthy adults. |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | IQVIA RDS |
|  | Clock Start Date: | 31 May 2018 |

No member of the research team was present 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 Devonie Waaka declared a potential conflict of interest and the Committee decided to allow her to remain in the room but not participate in the consideration of the application.

Summary of resolved ethical issues

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

1. The Committee queried the level of identification of study samples being sent overseas, noting that study documentation was inconsistent. The Committee stated that study samples should only retain the participant’s subject number, year of birth, and gender. The Committee requested that all study documentation is updated to reflect this.
2. Please ensure references to tissue collected in the study being stored as part of a tissue bank are not included future applications if they do not apply to the specific application.

Summary of outstanding ethical issues

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

1. The Committee noted that the Participant Information Sheet contains typographical errors, please ensure these are revised.
2. Please ensure the study title is accurate and consistent between the Participant Information Sheet and Consent Form.

Decision

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

* 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 ensure the identifiability of study samples being sent overseas is restricted as detailed above.

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| **7** | **Ethics ref:** | **18/STH/107** |
|  | Title: | (duplicate) Severe anemia risk prediction in Jehovah's Witnesses |
|  | Principal Investigator: | Prof. Colleen Bergin |
|  | Sponsor: |  |
|  | Clock Start Date: | 31 May 2018 |

Prof. Colleen Bergin 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 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 they have received a letter from representatives of the target population disapproving of this study and this letter, as well as the researcher’s response to this, must be considered alongside this application.
2. The Committee noted that researchers must do their best to understand, respect and make due allowance for diversity among participants and their communities (Ethical Guidelines for Observational Studies paragraph 4.16). The Researcher explained that they had met with concerned members of the Jehovah’s Witness community, however they had been unable to find a solution that worked for both sides.
3. The Committee raised concerns about the study’s focus on a particular religious group, noting that the ethics guidelines state that a researcher must not discriminate in the selection and recruitment of participants by including or excluding them on the grounds of religious or spiritual beliefs, except when such exclusion or inclusion is essential to the purpose of the study (Ethical Guidelines for Observational Studies paragraph 4.7-4.8). The Committee queried if these grounds are essential to the purpose of the study, or if the study could be broadened to include any eligible patient who refused, or was unable to have, a blood transfusion. The Researcher agreed that this would also be a suitable inclusion criteria. The Committee noted that this would be a different study, and the search function to identify suitable patients, the study protocol, and analysis/publication of study results cannot use Jehovah’s Witness as a selection or analysis criteria.
4. The Committee noted that strict requirements exist for the use of identifiable information without consent and stated that any future applications must clearly explain how these requirements (detailed in paragraph 6.43 of the Ethical Guidelines for Observational Studies) are met.
5. The Committee noted that the co-ordinating investigator in the application differs from that in the study protocol. Please ensure these details match in any future applications.
6. The Committee noted that as a general rule, Māori cultural consultation should take place if Māori are to be involved as participants in a project or the project relates to a health issue of importance to Māori. Evidence of consultation does not need to be submitted before HDEC reviews an application. However, HDEC does need to know the planned consultation process for the main study sites. Please ensure any future applications explain the consultation process, that is, who, what, where, when and how, and include names or institutions of those you will consult with.

Decision

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

* Researchers must not discriminate in the selection and recruitment of participants by including or excluding them on the grounds of religious or spiritual beliefs, except when such exclusion or inclusion is essential to the purpose of the study (Ethical Guidelines for Observational Studies paragraph 4.7-4.8).

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| **8** | **Ethics ref:** | **18/STH/109** |
|  | Title: | MindKiwi for ADHD: Family Group Therapy Pilot Study |
|  | Principal Investigator: | Dr Mairin Taylor |
|  | Sponsor: |  |
|  | Clock Start Date: | 31 May 2018 |

Dr. Julia Rucklidge 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 resolved ethical issues

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

1. The Committee noted that the study protocol does not include information on the process if a participant discloses risky or concerning information, such as about abuse or mental health issues. The Researcher agreed to add this information, apologising for the oversight.
2. The Committee questioned whether it was intended to make claims about the potential benefits of the study intervention from this study, noting the small sample size and lack of control group. The Researcher clarified that this is a feasibility pilot study and it is not intended to get results about the potential benefits of the intervention, instead the study would be used to inform a future larger study.
3. The Committee queried how teachers are approached. The Researcher explained that the parents will give the questionnaire to the teachers and ask them to complete it. The Committee requested that the teachers are provided with written information on the study to help inform their decision to complete the questionnaires.
4. The Committee questioned what would happen if a teacher refused to participate in the study. The Researcher explained that this is an important part of their feasibility study as teacher participation is important.
5. The Committee noted that the flow chart indicates that the questionnaires will be sent to the teachers before the first meeting between the participant family and the researchers. The Researcher explained this was a mistake and it would be after the first meeting and after consent is obtained.
6. The Committee queried if any information is available on rates of ADHD in Māori. The Researcher clarified that they are not aware of any data on rates.

Summary of outstanding ethical issues

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

1. Please add a section on possible risks to the Participant Information Sheet, as there are some potential risks (such as depersonalisation or poor decision making) and the form currently states that there are no risks.
2. Please provide a suitable information sheet for teachers, to explain why they are being asked to complete the questionnaires, what the information is for, and that the completion of these questionnaires is optional. Teachers consent will be implied by their completion of the questionnaires, no written consent needs to be obtained.
3. Please remove the statement from the start of the Child Participant Information Sheet about the participant’s parents saying they will be in the study, as the child does not have to agree to be in the study and this statement could be seen as coercive.
4. The Participant Information Sheet currently implies a potential benefit from study participation, by indicating that the study is looking at if the intervention is helpful. Please revise this to clarify that the study is looking at if the study is feasible.
5. Please clarify in the Participant Information Sheet the potential risks of confidentiality being breached.
6. Please state in the child information sheet that the child’s teacher will be asked some questions.
7. Please give a more informative study title to the participant facing documents.
8. Please state clearly in the Child Participant Information Sheet that they are able to say no to the study, even if their parents say yes.
9. Please State in the Parent Participant Information Sheet that their child will be able to dissent to study participation and the family will only be able to participate if the child agrees.
10. Please consider the HDEC template when revising the Participant Information Sheets and Consent Forms as many of the standard wordings required are already contained in these documents.
11. Please add a suitable header and footer to the Participant Information Sheets, this should include page numbers.
12. Please change the Participant Information Sheet for parents to reflect that it is for parents and/or caregivers/legal guardians.
13. Please add more information on the study to the Participant Information Sheet for 8-12 year old participants.
14. Please remove references from the Participant Information Sheet to the study being published in academic journals to help everyone. This is a feasibility study and statements about ‘helping everyone’ are inaccurate.
15. Please add information to the Child Participant Information Sheet on a contact person they can talk to if they have any questions.
16. Please add information to the Participant Information Sheets about the ability to withdraw from the study, including information on until what point participants can withdraw their data from 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* paragraph *6.22*).

## This following information will be reviewed, and a final decision made on the application, by Assc Prof Mira Harrison-Woolrych and Ms Raewyn Idoine.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:

|  |  |
| --- | --- |
| **Meeting date:** | 10 July 2018, 08:00 AM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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 3:10pm.