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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 26 June 2018 |
| **Meeting venue:** | Room 1S.5, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 22 May 2018 |
| 12:30pm | New applications (see over for details) |
|  | i 18/CEN/112  ii 18/CEN/98  iii 18/CEN/101  iv 18/CEN/102  v 18/CEN/103  vi 18/CEN/104  vii 18/CEN/96  viii 18/CEN/113  ix 18/CEN/107  x 18/CEN/111 – CLOSED Meeting  xi 18/CEN/105  xii 18/CEN/108 |
| 5:30pm | General business:   * Noting section of agenda |
| 5:35pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Apologies |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | 30/07/2015 | 30/07/2018 | Apologies |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |
| Ms Rochelle Style | Ethical and Moral Reasoning (Lay) | Co-opted NTA | Co-opted NTA | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Mrs Sandy Gill and Dr Melissa Cragg.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Rochelle Style confirmed her eligibility, and was co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 22 May 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/CEN/112** |
|  | Title: | APOLLO-1 |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | CBT Pharmaceuticals, Inc. |
|  | Clock Start Date: | 14 June 2018 |

Professor Ed Gane and a co-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 resolved ethical issues

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

1. The Committee queried the suitability of the starting dose. The Researcher explained the rational for this dose.
2. The Committee requested that a safety summary is submitted to HDEC after phase 1 finishes before phase 2 begins.
3. The Committee noted that excess identifiers should be removed before any data or tissue is sent outside New Zealand, year-of-birth, gender, and a unique study number should be the only identifiers to remain on tissue or data sent overseas.
4. The Committee noted that the cultural questions in the application have been poorly answered. The Committee stated that they are especially disappointed about this as they have raised it in relation to a number of the researchers past applications. The Committee referred the researcher to the guidance available at [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz) that can be used to inform future answers in the application form.
5. 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.
6. The Committee and the Researcher discussed the insurance and compensation arrangements for the study.

Summary of outstanding ethical issues

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

1. Please adjust the Participant Information Sheet to reflect that HIV is a notifiable disease.
2. Please adjust the side effect profile information in the Participant Information Sheet at page 11 where the statement in relation to CBT-501 which refers to ‘the following side effects below may occur in humans” has not been completed.
3. Please ensure the Participant Information Sheet is up to date for the trial data of CBT501 which is in the protocol as at 13 February 2018
4. Please ensure that everything in the Consent Form is explained in the Participant Information Sheet (for example, explain significant abnormal results).
5. Please note in the Participant Information Sheet that when data or samples are sent overseas different confidentiality rules may apply. The Committee suggested that the following wording could be used to guide an update to the Participant Information Sheet: *“Some of the organisations that will have your data/samples will be located outside NZ, including countries where data protection may be different or less restrictive than in NZ. However, [we] will take reasonable measures to keep your personal health information confidential. However, absolute confidentiality cannot be guaranteed. By signing this document, you agree to the transfer of your personal health information to such countries. If the results of the study are published they will not be published in a form that could reasonably be expected to identify you”.*
6. If it is intended to collect information on babies born to study participants, or their partners, consent for this must be obtained after the baby is born and cannot be obtained from the parents before birth. Please update the relevant forms to allow for this.
7. The Risks of radiation in the Participant Information Sheet are poorly explained and will not be understood by a lay participant. Please revise this information.
8. The Committee queried whether the Future Unspecified Use of Tissue Participant Information Sheet is correct in stating that samples would only be retained for 2 years. Please adjust this if it is not correct.
9. Please state more clearly in the Participant Information Sheet that this is an investigational/experimental treatment with no guaranteed long term benefit.
10. Please add a table to the Participant Information Sheet to better express the schedule of events.
11. Please ensure only information relevant to this study is included in the Participant Information Sheet, for example references to octreotide does not seem to apply in this study.
12. Please remove the following statement from the optional Participant Information Sheet ‘scientists never seek exploration for new discoveries’.
13. Please revise the Participant Information Sheet for continuing treatment beyond disease progression to remove unnecessary repetition from the main Participant Information Sheet. Please consider whether it would be better to provide a copy of the Participant Information Sheet that the participant originally signed instead, to help clarify for the participant what information has changed since their original consent.
14. The Committee requested the compensation wording reflects the HDEC template wording, 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, [x], 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.”*
15. Please amend the consent form so it is consistent with the amendments made to the Participant Information Sheet.
16. Please use the template for the pregnancy consent form. The current one is missing a number of key matters, The templates is available at [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz)

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 Mrs Helen Walker and Dr Dean Quinn

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| **2** | **Ethics ref:** | **18/CEN/98** |
|  | Title: | Atopy & Allergies following Paediatric Solid Organ Transplantation |
|  | Principal Investigator: | Dr Amin Sheikh |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 June 2018 |

Dr Amin Sheikh 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 resolved ethical issues

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

1. The original study involved posting questionnaires to participants. This applications proposes to increase the study sample size and to conduct the questionnaires by phone, which is less time consuming and is expected to achieve a higher response rate.
2. The Committee queried how the researchers would identify potential participants. The Researcher explained that they have an internal spreadsheet of patients who have received transplants and they will use this to identify and recruit participants. The Researcher noted that as they have less paediatric transplant patients and need to match these with adult patients they intend to recruit all eligible paediatric patients and selection of adult participants based on how closely their transplant times were in relation to the paediatric patients.

Summary of outstanding ethical issues

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

1. The Committee noted that the cultural questions in the application form have been poorly answered. The Committee would like to see if there is any information about the incidence of transplantation and allergies in different ethnicities. Please consider the guidance available at [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz) before providing an updated response.
2. The Committee noted that the Participant Information Sheet for the original study did not make reference to participant’s being called and this would need to be updated.
3. The Committee stated that it would be preferable for the researcher to initially approach potential participants by post, with an invitation letter, Participant Information Sheet, and potentially a copy of the questionnaire. The invitation letter should state that a phone call would follow the letter, and give details of how the participants could opt-out of this follow up phone call. When approaches to participants identified through health records involve visiting or telephoning them at their home, it is generally desirable that some advance notice be given (for example, through a letter) (Ethical Guidelines for Observational Studies paragraph 6.8).
4. The Committee noted that this re-submission does not include a Participant Information Sheet. A number of different documents provided to the patients must be provided, including:
   * An invitation letter, outlining the study, how participants were identified, and how participants can opt-out of the follow up phone call if they are not interested in participating.
   * an information sheet for parents of participants <16 years of age,
   * an information sheet for participants able to provide their own informed consent (this includes all participants aged 16 years or older)
   * an information sheet for children (aged 11-16), and
   * a very simple information sheet for young children (aged 7-11) that should very simply explain their participation in the study.
   * Guidance on consent and assent can be found at [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz)
5. Please adjust the questionnaires to not collect participants’ names, a unique study number should be used instead.
6. The Committee queried whether the questionnaires have been validated.
7. Please use the Health and Disability Ethnicity Data Protocols standard ethnicity collection question the when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These options are: New Zealand European, Māori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan), Please state.
8. Please adjust the protocol to include further information about exactly which data are being collected for the study.
9. Please provide details of how participants who were children in the original study and are now adults will be approached and consented.
10. The Committee noted that verbal consent is acceptable, as long as it is suitably recorded. Please provide details of how this will be recorded.
11. Please ensure details are provide on how it will be determined when it is appropriate to obtain information and consent from parents, and when this should be obtained from the patient themselves.

Decision

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

* When approaches to participants identified through health records involve visiting or telephoning them at their home, it is generally desirable that some advance notice be given (for example, through a letter) (*Ethical Guidelines for Observational Studies* paragraph 6.8).
* Please amend the information sheet and consent forms, taking into account the suggestions made by the Committee *(Ethical Guidelines for Observational Studies* paragraph6.10).

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| **3** | **Ethics ref:** | **18/CEN/101** |
|  | Title: | A pilot study for improving cognition after stroke study (PiCaSSo) |
|  | Principal Investigator: | Ms Susan Mahon |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 June 2018 |

Ms Susan Mahon 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 resolved ethical issues

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

1. The Committee queried if the study question has already been answered by other studies. The Researcher explained that there is not information on the specific programme in a New Zealand context.
2. The Committee queried if participants will have ongoing access to the programme after the study. The Researcher explained that they will have something similar to provide free after the study ends.
3. The Committee queried if this would be available for control participants too. The Researcher confirmed that control participants would also be able to try the study programme after the study.
4. The Committee noted that health information collected in this study must be retained for 10 years.
5. The Committee queried if a Westfield voucher will be suitable for participants. The Researcher explained that it will be suitable in their experience.
6. The Committee queried who will be doing the cognitive assessments. The Researcher explained that it will probably be the occupational therapist.

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 whether all cognitive assessments are part of standard care or study specific. Please provide details of the identification and screening process for participants, including what aspects are study specific and which parts are standard care.
2. Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).

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

1. Please add study contact numbers to the Participant Information Sheet, including details of a suitable person to provide Māori cultural support, as per the HDEC template.
2. The Committee requested the compensation wording is updated 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.”*
3. Please state in the Participant Information Sheet what happens after the study, including mentioning focus groups. If these focus groups will be open to all participants it may be suitable to obtain consent for this at the initial consent stage, alternatively they can be mentioned and a separate Participant Information Sheet and Consent Form provided at a suitable time for the focus groups.
4. The Participant Information Sheet indicates that the participant’s doctor will be informed if harmful effects occur, please clarify which doctor this is intended to refer to.
5. The Participant Information Sheet refers to the National Health and Disability Commission. Please clarify if this is intended to refer to the Health and Disability Ethics Committee
6. Please add information on the kinds of questions that participants will be asked in the questionnaires. This should include clarifying that there are three questionnaires and one of them is a capacity assessment (MoCA)
7. Please add a place to record participants’ email addresses in the Consent Form if they indicate they wish to receive a copy of the study results.
8. Please indicate in the Participant Information Sheet that a risk of the study is that participants could find the questions in the questionnaire, or an inability to complete study tasks, upsetting. Please also state that participants could stop at any time and that they could be referred to someone (such as a counsellor) if that were the case.
9. Please clarify the study screening process in the Participant Information Sheet, including adding details on who would be involved.
10. Please explain all assessments involved in the study in the Participant Information Sheet.
11. Please add information on the weekly phone calls to the Participant Information Sheet.
12. Please add information on exclusion criteria, such as not having a home computer or being unable to speak English, to the Participant Information Sheet.
13. Please ensure that lay language is used throughout the Participant Information Sheet, terms such as ‘cognitive rehabilitation’ are unlikely to be understood by lay participants.
14. Please ensure that font/formatting is consistent throughout the Participant Information Sheet.
15. Please revise the Participant Information Sheet to remove all typographical errors.

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 Cordelia Thomas and Dr Peter Gallagher.

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| **4** | **Ethics ref:** | **18/CEN/102** |
|  | Title: | FIRE Trial |
|  | Principal Investigator: | Mr Mark Fraundorfer |
|  | Sponsor: | St Vincent's Private Hospital |
|  | Clock Start Date: | 14 June 2018 |

Mr Mark Fraundorfer and Ms Rana Reuther were 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 resolved ethical issues

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

1. The Committee queried if participants will need to pay to be in the study. The Researcher explained that the study treatment is not publically funded and to receive this treatment patients, or their insurance company, must pay. The Researcher further explained that if patients agree to be in the study the cost will be about half of what it would be to pay for the treatment outside the study. The Committee considered this and agreed it is not an unacceptable inducement to participate, and the savings will often go directly to the participant’s insurance company.
2. The Committee queried if the device manufacturer has any access to study data or influence over study publication. The Researcher confirmed that they would not.

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 justification for study data being retained indefinitely, as indicated in the application. The Researcher explained that their understanding was that the data was to be de-identified and stored indefinitely. The Committee stated that as the site retains the information to link data to participants that the data is not fully de-identified and must not be stored indefinitely. The Researcher agreed to not store study data indefinitely, it will be stored for a maximum of 15 years (for New Zealand participants). Please adjust all study documents to reflect this.
2. The Committee queried if the peer reviewer is involved in the study, noting that their independence from the study is unclear. If they are not fully independent from the study please obtain peer review from someone else, if they are independent please ask them to provide more information on what was considered during their peer review. The Committee noted that the HDEC Peer Review template may be useful regardless of who provides further peer review. Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).

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

1. Remove references in the Participant Information Sheet to the St Vincent’s primary treatment outcomes because this study is about salvage treatment and participants may be misled about the chances of successful outcomes.
2. Please add a simple explanation of the study procedure to the Participant Information Sheet.
3. The Committee suggested that a lay friendly study title could be added to the Participant Information Sheet, for example ‘nano-knife surgery for radioresistant prostate cancer’.
4. Please consider adding a diagram to the Participant Information Sheet to help explain the study procedure.
5. Please clarify in the Participant Information Sheet how many general anaesthetics are involved in the study and how this compares to standard care.
6. Please add further information to the Participant Information Sheet on alternative treatment options and that insurance may not cover the study treatment. Explain any additional costs that participants may incur through participation in the study, for example GP costs in having PSA levels monitored.
7. Please state in the Participant Information Sheet that some the EPIC questionnaire is quite involved and participants can choose to not answer all questions if they are uncomfortable providing the information.
8. Please revise the information on how confidentiality will be maintained to reduce repetition.
9. Please remove the reference to participants becoming pregnant from the Consent Form.
10. Please remove the information about the risks if the participant’s partner becomes pregnant as study participation should not introduce any additional risks.
11. Please include a statement in the Participant Information Sheet that data will be sent overseas and list the countries. Please also include a statement advising participants that data protection in those countries may be different or less restrictive than in NZ.
12. Please explain in more detail what the severity and likelihood of the side effects are – the term ‘temporary’ does not provide sufficient information for participants.
13. Please confirm the operation of the data safety and monitoring board and that it has two independent observers as noted in the protocol.
14. Please do not use a patient’s name of Date of Birth on the questionnaires, only the unique patient study number should be used (year of birth and gender can also be used if necessary).

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 below.

This following information will be reviewed, and a final decision made on the application, by Mrs Helen Walker and Dr Dean Quinn.

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| **5** | **Ethics ref:** | **18/CEN/103** |
|  | Title: | MK3475-775 |
|  | Principal Investigator: | DR Michelle Wilson |
|  | Sponsor: | MSD |
|  | Clock Start Date: | 14 June 2018 |

Dr Michelle Wilson and Ms Pallavi Wyawahare 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 resolved ethical issues

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

1. The Committee commended the high quality of response to the cultural questions in the application form.
2. The Committee queried if the study involves Future Unspecified Use of Tissue or Biobanking. The Researcher confirmed that it does not.
3. The Committee noted that the list of people able to access study data is very broad. The Researcher clarified that this is only for de-identified data.
4. The Committee noted that excess identifiers should be removed before any data or tissue is sent outside New Zealand, year-of-birth, gender, and a unique study number should be the only identifiers to remain on tissue or data sent overseas.
5. 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’s preference is 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.
6. The Committee and the Researcher discussed the insurance and compensation arrangements for the study.

Summary of outstanding ethical issues

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

1. Please include in the Participant Information Sheet the risks to participants from the combination of pembrolizuam and lenvatinib As this is a Phase 3 trial, there is some data about the risks of the combination of the two drugs in addition to the risk for each of them separately (which have been properly addressed in the Participant Information Sheet)
2. Please state in the Participant Information Sheet how long questionnaires take to respond to and how often they need to be filled in.
3. Please include in the Consent Form an option for a participant to consent to continued contact with a participant’s GP or health care provider if the participant withdraws from the study, for any reason and to take steps to locate my whereabouts
4. Please revise the wording in the Participant Information Sheet about ‘chasing people up’, this terminology should be changed, and it should be adjusted to reflect that at some point the researchers must stop attempting to follow up with participants.
5. Please adjust the information in the Participant Information Sheet to reflect whether participants will receive home blood pressure monitors, of if they will need to come in to have this checked.
6. Please add information to the Participant Information Sheet about how potential incidental findings would be managed and include this in the Consent form.
7. The Committee queried if participants would be able to have their samples returned or destroyed if requested. The Researcher explained that although participants can request this it may not be able to happen. Please clarify this in the Participant Information Sheet and the consent form.
8. The Committee noted that participants must be able to access and request correction of data collected about them at any point in the study, although this may require them to be withdrawn from the study if it breaks study blinding. Please clarify this in the Participant Information Sheet.
9. The participant alert card is incorrect, please revise this for accuracy.
10. Please add a short flow chart to the Participant Information Sheet to better represent what will happen to the participant.
11. Please alter the information in the Participant Information Sheet relating to the risks of pregnancy as the chances of a participant becoming pregnant are very low and the Participant Information Sheet should reflect this.
12. Please amend the consent form to be consistent with the amended PIS and check against the template to ensure all sections have been included (for example, include in the consent form that the participant understands the compensation provisions, consents to data and samples being sent overseas, HDEC audit etc).

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 Mrs Helen Walker and Dr Patries Herst.

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| **6** | **Ethics ref:** | **18/CEN/104** |
|  | Title: | DBT at Korowai Manaaki: A Process Evaluation |
|  | Principal Investigator: | Dr Clare-Ann Fortune |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 14 June 2018 |

Miss Molly Weenink 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. In September 2017 Korowai Manaaki started running a Dialectical Behaviour Therapy programme. This project aims to evaluate this programme it to see how well it is working.
2. The evaluation will involve conducting semi-structured interviews with current participants, past participants, parents/legal guardians of participants, and others involved in the programme or with participants (such as teachers).
3. The evaluation focuses on the process and how people feel about how the programme was run, rather than evaluating the programme for efficacy.

Summary of resolved ethical issues

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

1. The Committee queried if the researcher who would be conducting the interviews has suitable experience working with this population group. The Researcher explained that they are experienced working with an adult prison population and will be well supported by those running the programme to ensure they can successfully conduct the interviews.
2. The Committee queried if participants will feel free to decline participation, especially considering that the study population includes people in the youth justice system who may feel participation is not truly optional. The Researcher explained that they will do their best to ensure participation is free, including obtaining written consent in advance and then obtaining verbal consent before each interview.
3. The Committee queried the independence of the peer reviewer, noting that the submitted peer review does not include the name (or other details) of who conducted the review. The Researcher apologised for this oversight and confirmed that the reviewer was independent.
4. The Committee queried how graduates would be contacted. The Researcher clarified that the initial approach would be made by one of the programme facilitators who will know the individual.
5. The Committee queried the plan if a participant becomes distressed. The Researcher explained that they are not intending to talk about anything potentially upsetting or distressing, but that if someone was to become upset this can easily be discussed with the staff managing them.
6. The Committee queried if it will be practical to contact parents/guardians. The Researcher explained that from their past experience they feel it will be practical.

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 what questions will be asked. The Researcher explained that they are still working this out. The Committee noted that any questionnaires, or guides for semi-structured interviews, must be submitted for HDEC review.

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

1. The Committee noted that the pamphlets provided are not suitable for Participant Information Sheets and Consent Forms were not provided. 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), an information sheet and assent form for children, and an information sheet and consent form for other adult participants (e.g. teachers). Guidance on consent and assent can be found at [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz)
2. Please include in the Participant Information Sheet that the interviews will be audio recorded and transcribed.
3. Please remove the reference from the pamphlet to participants helping to find other participants.
4. Please state in the Participant Information Sheets, where appropriate, that participants’ personal and medical records will be accessed and ensure the consent forms include a section reflecting that consent. Please also indicate the type of information that will be collected.
5. The Committee noted that any health information collected in the study should be stored for a minimum of 10 years, or 10 years after the participant turns 16 for younger participants.

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 concern detailed above.

This following information will be reviewed, and a final decision made on the application, by Mrs Helen Walker and Dr Peter Gallagher.

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| **7** | **Ethics ref:** | **18/CEN/96** |
|  | Title: | BIOMEDE |
|  | Principal Investigator: | Dr Karen Tsui |
|  | Sponsor: | ANZCHOG / ACCT |
|  | Clock Start Date: | 31 May 2018 |

Dr Karen Tsui 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 study investigates if three medicines: erlotinib, everolimus and dasatinib will help treat Diffuse Intrinsic Pontine Glioma (DIPG) when given at the same time as radiotherapy.
2. 16 participants will be recruited in New Zealand.

Summary of resolved ethical issues

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

1. The Committee noted the high quality of the application
2. The Committee noted that the information sheet for continued participation implies participants will have finished treatment and asked if this is correct. The Researcher explained that this was correct and the form will only be used in this participant group. Otherwise the main information sheet and consent form would be used.
3. The Committee queried how many participants would be recruited in New Zealand as the numbers given in the application differed. The Researcher explained 16 is accurate as on average they have 4 patients a year so will meet this number.
4. The Committee noted that there is a per-case reimbursement per recruitment of two thousand Australian dollars to cover costs of enrolment.
5. The Committee and the Researcher discussed the insurance and compensation arrangements for the study

Summary of outstanding ethical issues

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

1. Please amend the information sheet, assent form, and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. Please provide an updated and translated insurance certificate. (*Ethical Guidelines for Intervention Studies section 8*).
3. Please clarify the requirement for patient DOB + initials to be sent overseas. Please clarify if it is possible to use the code only and year of birth. (*Ethical Guidelines for Intervention Studies* *para 7.1 – 7.6*).

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

1. Please include that there is a risk to fertility in the 11 – 15 year old information sheet.
2. The Committee requested the compensation wording is updated for accuracy in all information sheets, 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.*
3. Amend references to ‘Health and disability’ advocate in all information sheets.
4. Please add a table of study procedures, to the appropriate information sheets; this includes what happens each visit, how long the visit might last, where it will occur, etc.
5. Please explain in the benefits section that if the study medicines do not work for DIPG then there will be no benefit to participation.
6. Please replace “rate of curing DIPG” with “better management of DIPG”.
7. Please move the contact details to the end of the information sheet.
8. Remove the paragraph in the future unspecified research Participant Information Sheet which relates to incidental findings form genetic testing and that it may be upsetting because the participants will not receive any genetic results and it may be confusing for participants to read this. .
9. Please offer a summary of results of the study rather than requiring to ask.
10. Please include a statement in the relevant PIS that data and samples will be sent overseas and list the countries. Please also include a statement advising participants that data protection in those countries may be different or less restrictive than in NZ.

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*).
* Please provide an updated and translated insurance certificate. (*Ethical Guidelines for Intervention Studies section 8*).
* Please clarify the requirement for patient DOB + initials to be sent overseas. Please clarify if it is possible to use the code only and year of birth. (*Ethical Guidelines for Intervention Studies* *para 7.1 – 7.6*).

This following information will be reviewed, and a final decision made on the application, by Dr Cordelia Thomas and Dr Dean Quinn.

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| **8** | **Ethics ref:** | **18/CEN/113** |
|  | Title: | Aging, older people and mental illness |
|  | Principal Investigator: | Dr Debbie Peterson |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 June 2018 |

Dr Debbie Peterson 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. This study aims to better understand the changing needs of New Zealanders with experience of mental illness as they grow older.
2. People aged 55 and over who use specialist mental health services will be given the opportunity to complete a survey about their experience of aging and plans for the future.

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 recruitment process. The Researcher explained that the study will be advertised amongst consumer networks and mental health services. The Researcher explained that the survey will also be online on the Otago university website.
2. The Committee asked how the Researchers would be able to tell if the participants are under 55. The Researcher explained that based on prior experience running surveys they can tell and they are not looking at making statistical claims.
3. The Committee asked if there are any ways to identify participants. The Researcher explained the online survey is anonymous.
4. The Committee were satisfied with the peer review as suitably independent.

Summary of outstanding ethical issues

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

1. Please provide the poster and any other advertisements that will be patient-facing. (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. 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*).

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

1. Remove ‘older’ from people aged 55 or over. Just say people aged over 55.
2. The Committee suggested saying it may take it a bit more than 20 minutes to complete. E.g. 25 – 30.
3. Please add a Māori cultural support contact to the end of the information section.
4. Please add contact details for mental health services at the end of the online survey.

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*).
* Please provide the advertising materials associated with the study. (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Mrs Helen Walker and Dr Peter Gallagher.

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| **9** | **Ethics ref:** | **18/CEN/107** |
|  | Title: | Gestational Diabetes and the microbiome |
|  | Principal Investigator: | Dr Lynne Chepulis |
|  | Sponsor: | University of Waikato |
|  | Clock Start Date: | 14 June 2018 |

Dr Lynne Chepulis and Dr Greg Jacobson 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 study investigates what changes occur (if any) in the gut microflora (bacteria) populations in healthy pregnant women as compared to pregnant women with gestational diabetes (GDM).
2. The study also investigates the gut microflora populations present in the newborn babies born to these mothers to determine whether the gut microflora pattern of diabetic mothers is also present in the neonatal gut populations.

Summary of resolved ethical issues

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

1. The Researchers confirmed that they are only interested in the bacterial DNA and not human DNA.
2. The Committee asked if there will be return of individual results. The Researcher stated that they will only do so if participants specifically request.
3. The Committee asked if the Researchers will be informing participant’s GPs about the study. The Researchers stated they would not as the participants will be under the care of diabetes staff and their midwife so this will not be necessary.
4. The Committee queried the food consumption questionnaire. The Researcher explained that it is a validated questionnaire produced by Otago University.

Summary of outstanding ethical issues

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

1. Add a section to the ICF that obtains consent for collection of samples from the child after they are born. Please note that this can only be completed post-birth Please add a bullet point to the Consent Form for participants to agree to be contacted after birth to collect information on their child.
2. Please amend the section “at least the second motion” for clarity.
3. 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.”*
4. Please include a statement in the relevant Participant Information Sheet that data and samples will be sent overseas and list the countries. Please also include a statement advising participants that data protection in those countries may be different or less restrictive than in NZ.
5. Please include in the Participant Information Sheet a section about the return of individual results and include a section in the consent form
6. Please also include a section in the Participant Information Sheet if any abnormal results might be expected and how they will be managed. Please also include a section in the consent form
7. Please remove tick boxes from the consent form except for items where ticking “no" would not exclude someone from participating.
8. Please be more specific about what health records will be sent overseas and where they will be held.
9. Please note that health information storage has to be ten years after the child turns sixteen, not from date of study completion.

Decision

This application was *approved with non-standard conditions* by consensus. The non-standard conditions are:

* 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*).
* Please only use the unique participants ID and year of birth for samples. Not exact date and initials.

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| **10** | **Ethics ref:** | **18/CEN/111** **(CLOSED)** |
|  | Title: | KEYNOTE-756 |
|  | Principal Investigator: | Dr Sarah Barton |
|  | Sponsor: | Merck Sharp & Dohme (Australia) Pty Ltd |
|  | Clock Start Date: | 14 June 2018 |

Dr Sarah Barton and Ms Maureen Blakemore 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.

Decision

This application was *provisionally approved* by consensus.

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| **11** | **Ethics ref:** | **18/CEN/105** |
|  | Title: | A novel trans-anal tube and absolute pressure catheter for monitoring across colorectal anastomoses |
|  | Principal Investigator: | A/Prof Greg O'Grady |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 14 June 2018 |

A/Prof Greg O'Grady and Ms Charlotte Dumble 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 investigates the feasibility of trialling, and comfort of, a new trans-anal tube in patients undergoing colorectal surgery.

Summary of resolved ethical issues

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

1. The Committee queried how any randomisation process would work. The Researchers stated it’s a feasibility study so there will be no randomisation. Currently they are aiming to validate the trial design and ensure participants and clinicians are happy.
2. The Committee noted that the responses to cultural questions in the application form were excellent.
3. The Committee asked who is making the initial study approach? The Researcher explained that it will either be an honours student or a research nurse.
4. The Committee asked what the honours student’s role is? The Researchers explained that they help design the tube, have conducted a systematic review, and are now helping the feasibility study. Later they will assist with the data analysis.
5. The Committee asked if MEDSAFE will be notified of adverse events. The Researcher explained these will be notified to ADHB.

Summary of outstanding ethical issues

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

1. Please provide suitable information sheets and consent forms for surgeons. (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. 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*).

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

1. Please add page numbers.
2. Remove the double up on p1 para 2. The “if you decide not to take” part is repeated.
3. P3 – refer to correct approving committee
4. Add researcher contact details to the end of the form with all others.
5. Please add Māori cultural support contact details.
6. Please remove side effects bullet point in the consent form.
7. Please remove the GP tick box
8. Amend references to the study being purely observational as it is an intervention design.
9. Please make sure both the consent form and information sheet have the same title.
10. Clarify the lay explanation of the study in the ICF.
11. Explain what risks are rather than just relating them to the risks of a foley tube as lay participants may not know these.
12. Please clarify what is meant by psychological stress.

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*).
* Please provide an information sheet and consent form for surgeons. (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Dr Cordelia Thomas and Dr Patries Herst

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| **12** | **Ethics ref:** | **18/CEN/108** |
|  | Title: | Evaluation of a novel retractor |
|  | Principal Investigator: | A/Prof Greg O'Grady |
|  | Sponsor: | University of Auckland, New Zealand |
|  | Clock Start Date: | 14 June 2018 |

A/Prof Greg O'Grady and Ms Charlotte Dumble 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 aims to develop a novel retractor that solves problems with current instruments such as length or suitability for operations in the low rectum.

Summary of resolved ethical issues

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

1. The Committee queried if the honours student would have any direct interaction with participants. The Researchers explained that they will only talking to them about the study and assist with data analysis.
2. The Committee noted that Māori consultation will be done as part of locality approval.

Summary of outstanding ethical issues

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

1. 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*).
2. Please provide an information sheet and consent form for surgeons. (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

1. Please bold study title and have less emphasis on CI.
2. Please clarify the honours student’s role and that they will not be enrolling patients.
3. Include information from b.1.1 in the application form that helps explain why the new retractor is better.
4. The Committee requested the compensation wording is updated 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. Explain that there will be no benefit beyond normal care.
6. Please clarify in the Participant Information Sheet that participants are “Free to withdraw at any point until surgery begins”.
7. Please make sure there is no new information introduced in the consent form.
8. Please mention that photos maybe be taken in the ICF. The Committee was happy with this aspect being optional and that the Researchers have an example on hand.
9. Remove references to retaining study data as this is not relevant.
10. Check Participant Information Sheet for typos
11. Please explain what a group surgeon is.
12. Please explain the questionnaires will assess comfort of use for the surgeons.
13. “Consent form will be required” – Please explain that this means that the form must be signed.
14. Amend the reference to study team having anonymous access to health records to more clearly explain what this means.
15. Clarify that the retractor will not be used in the event that it looks to be harming patients.
16. Please include the risks of the new device even if it is identical to the new retractor.
17. Please explain that the participants will not be eligible to benefit from any intellectual property generated as a result of their participation.

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*).
* Please provide an information sheet and consent form for surgeons. (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Dr Cordelia Thomas and Dr Patries Herst

## General business

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

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| --- | --- |
| **Meeting date:** | 24 July 2018, 08:00 AM |
| **Meeting venue:** | Room GC.1, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington, 6011 |

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 5:35pm