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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 03 February 2015 |
| **Meeting venue:** | Novotel Ellerslie |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 2 December 2014. |
|  | New applications (see over for details) |
| 12.30pm  5.05pm | i 15/NTB/1  ii 14/NTB/208  iii 15/NTB/2  iv 15/NTB/5  v 15/NTB/7  vi 15/NTB/11  vii 15/NTB/14  viii 15/NTB/19  ix 15/NTB/20  x 15/NTB/21  xi 15/NTB/22 |
| 5.30pm | General business:   * Noting section of agenda |
| 5.45pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Raewyn Sporle | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Kate O'Connor | Non-lay (other) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Paul Tanser | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Ms Kerin Thompson | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Phyllis Huitema | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |

## Welcome

The Chair opened the meeting at 12.25pm and welcomed Committee members, noting that apologies had been received from the Chairperson, Ms Raewyn Sporle. Ms Stephanie Pollard will act as Chair 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 02 December 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTB/1** |
|  | Title: | Regulation of the diabetic heart |
|  | Principal Investigator: | PhD James Baldi |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 January 2015 |

James Baldi was not 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.

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

Summary of Study

* The Committee commended the advertising.

Summary of ethical issues (resolved)

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

* (A.2.2) The Committee noted that endocrinology should be included as a field of research in future applications that are in a patient population who have diabetes.
* The Committee noted the data safety monitoring arrangements are internal. The Committee suggests having an external member included to strengthen the power of the data safety monitoring. The Committee notes this is a suggestion, not a requirement.

Summary of ethical issues (outstanding)

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

* The Committee queried whether the chart review was a formal audit of diabetic patients in the hospital, and if not, would this be done with patient consent? Please provide more information regarding process to conduct the chart review, noting this was a confidentiality issue.
* Please explain the mechanisms to protect confidentiality by the co-investigators.
* The Committee noted that exercise tests are usually safe for healthy participants due to the pain being transmitted when the body is overstressed, resulting in cessation. However participants who have diabetes will not have this safety measure and they may over exert themselves and cause damage, increasing risk. Please explain what measures are in place to identify silent ischemia. Provide more information on the staff, qualifications and training of those administering and monitoring the exercise procedures.
* Please explain the decision to have the GP be primarily responsible to communicate study results?
* The Committee queried who was planning the training regime, noting this information is not in the patient information sheet.
* Please explain where the tissue will be stored – is this in an established tissue bank?
* Please provide information (qualifications) on who peer reviewed the HDEC application.
* Committee noted there are cultural issues relevant for Maori that should have been identified in the application – for example participation issues and the use of human tissue.
* Please provide more information on what reimbursement will be provided.
* The Committee queried whether the Research Office would be considered the sponsor?
* Data more likely to be potentially identifiable rather than anonymous. Please see (*Ethical Guidelines for Intervention Studies para 7.2*) for more information on levels of data confidentiality.
* (R.1.1) states that there is a DEXA scan – is this an error?
* (R.8.1) how are benefits proportional to the risks for the non-diabetics?
* (P.4.1) please revisit this question in a cover letter.
* (P.4.3.1) has this submission now gone through Ngai Tahu and what was the outcome?

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

* Regarding ACC – please amend to ‘may’ be covered by ACC to better reflect the claim process involved.
* Pg.3 Please decide whether the GP is **required** to be informed and make this clear for participants.
* Please add Maori support contact information.
* Consider reviewing the HDEC template, particularly for the opening paragraph:

You are invited to take part in a study on [*x*]. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is [*x*] pages long, including the Consent Form. Please make sure you have read and understood all the pages.

* Simplify explanations of the tests, currently they are quite technical.
* Reword ‘time’ not ‘away from work’ with respect to reimbursement.
* Add details regarding who is funding the study.
* The cultural statement - current wording can be considered disrespectful ‘to avoid problems later’. Please reword, perhaps after consulting with the Maori research office.
* Please amend the approving Ethics Committee to ‘NTB HDEC’.
* Add information on randomisation.
* Please include information on ‘what will happen to my tissue’:

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| * outline participants access to their tissue during the study |
| * what happens to tissue if a participant withdraws? |
| * is tissue going overseas? Is the location included? |
| * what tests are conducted on the tissue? |
| * who will have access to tissue? |
| * how long the tissue will be stored? |
| * how will tissue be disposed? |
| * how will unexpected results or findings be communicated / managed? |
| * are cultural considerations relating to use of tissue outlined? |

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Address outstanding ethical issues in a cover letter.

This following information will be reviewed, and a final decision made on the application, by Ms Kerin Thomson.

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| **2** | **Ethics ref:** | **14/NTB/208** |
|  | Title: | The TARGET study |
|  | Principal Investigator: | Dr paul young |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 January 2015 |

Dr Paul Young 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

* The Committee commended the insightful application, including the awareness of the issues that the researchers face in this research environment. There was good coverage of the vulnerability of the group and the Committee commended the section on New Zealand ethics in the protocol.

Summary of ethical issues (resolved)

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

* The Committee queried how the requirement for treatment to be in the best interests of the patient is met by this research project. Dr Young explained that in general terms, over the passage of time, in intensive care units – the care that patients get here (New Zealand) is better than anywhere else in the world. These units have an entrenched culture of research. The best possible outcomes are being achieved because of these research studies.
* Dr Young explained that when he talks to patients about comparative studies which compare two standard treatments, with no greater risk being in the trial compared to being not in the trial, the vast majority of patients and families recognise that there is an altruistic feature of participation.
* The Committee asked about the best interest of the particular patients. Please confirm there is no increased risk due to randomisation, or time taken to randomise. Dr Young stated there was no change in time to start feeding, and reiterated that there was no risk in randomising, stating this will take 30 seconds and will not adversely impact patient care.
* Dr Young stated that from the information we have now the treatments are equivalent. However we have some reason to believe that one of the treatments (caloric dense feeding) we are testing could be better, so there is a good reason to conduct the study.
* The Committee queried if there is ever any clinical reason to give one form of feeding over another? Dr Young stated no – not that we are aware of, however we have an exclusion criteria to only include patients who would have their best interests met by being enrolled. If there was some new clinical reason that meant there was a better treatment we would not enrol someone into the study.
* The Committee queried if there could be a case where you would switch between feeding types? Dr Young explained that it could be possible that you would want more fluid, which would result in a change – but that patient interest is always the guiding feature of decisions.
* (P.4.6) – not collecting ethnicity, please explain. Dr Young explained that ethnicity data is not stored on the ‘front sheet’ (data collection) in Australia, like it is in New Zealand. This means 80% of the data will not have any ethnicity. In New Zealand we aim to have 800 participants, of which 10% are estimated to be Maori. This will not be sufficient information to do any meaningful information analysis. The Committee stated that collection of ethnicity data is important for other reasons, such as knowing generally who is entering research studies, participation rates etc. Dr Young explained that the logistical requirements will be difficult. The Committee recommended that the ethnicity data is collected at New Zealand sites, adding that this was not a requirement.
* Committee queried who will be signing the statement that indicates that it is in the best interest of the participant on consent form. Dr Young explained that it was his responsibility, but that this could be delegated to others. In practical terms the CI can’t be the person who does that all the time, but this will require clear delegation procedures, such as a logging of delegation and training of staff to know when best interests is or isn’t met. The Committee stated that as far as responsibility goes the best interest assessment should be with the CI and co-investigators. Dr Young agreed that primary responsibility lies with CI.
* Dr Young confirmed this study was not possible in any other patient population.
* The Committee queried whether research co-ordinators, who might sign the CF, are medically trained? Dr Young explained that they are intensive care nurses with a lot of experience, and confirmed they are medically trained.
* Please explain process for treatment of weight loss or high blood sugar, and risks of over and under feeding. Dr Young explained that to optimise nutrition feeding tubes could be put in small intestine, using drugs to increase absorption, IV nutrition – all of these occur regardless of the arm the patient is randomised to. Regarding blood sugar, blood gases are routine – insulin is given to combat high blood sugar.
* The Committee noted that usually revoking of consent is not required in writing. The Committee noted documentation is important in this study however participants can still withdraw verbally. Please make this clear to participants, and if this occurs then please use the outlined processes such as logging, patient notes.
* (R.5.1) – funding. Is funding for New Zealand confirmed? Dr Young stated not exactly – HRC application is pending. Ranked highly but process is not complete. NHMRC funding is granted but is primarily for Australian sites however the cost of the feed comes out of the NHMRC budget.

Summary of ethical issues (outstanding)

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

* The Committee asked whether the DSMC arrangements were finalised. Dr Young stated the DSMC charter will be finalised tomorrow, and the first New Zealand patient will not be enrolled for at least 12 months from now. Dr Young confirmed this study will have an independent DSMC.

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

* Reformat consent form so that the family statement is followed by family signature. Consider the flow of the document.
* Remove tossing a coin analogy.
* The Committee requested a line in the PIS on who is funding the study, once confirmed.
* Please reconsider the audience for the PIS/CF (the family, and the now well participant). I.e. address the relatives – they are considering what their loved one may prefer or would want. Regarding the patient – that their whanau was consulted and that they can actually withdraw, including their data. Make this last point explicit.
* Please make it clear that there are no additional procedures by participating, that it only concerns randomisation and data collection.
* Please explain further that your doctor will decide one feed over than another, or will switch if it is in the best interests. I.e. the best interest trumps the research, for any particular case.
* Pg.1 – Committee noted that the wording of ‘we have enrolled you’ could be better worded that we have started treatment (feeding) and that the enrolment is about data and continuation of the randomised treatment. This clarifies that nothing in particular has been done except for the randomisation between standard treatments.

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*).
* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*

This following information will be reviewed, and a final decision made on the application, by Ms Stephanie Pollard.

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| **3** | **Ethics ref:** | **15/NTB/2** |
|  | Title: | Neurogenic mechanisms in asthma |
|  | Principal Investigator: | Prof Jeroen Douwes |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 03 February 2015 |

Prof Jeroen Douwes and Dr Asher Ali 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

* The Committee congratulated the researchers on their HRC funding.
* Study will have 1100 participants, aged between 12 and 17.
* Invitations will be made to these participants by writing to them. Participants were involved in prior study.
* Cohort interaction has been maintained by birthday cards, the past study did not have funding for follow up.

Summary of ethical issues (resolved)

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

* Researchers confirmed that screening questionnaire is only administered after informed consent is given.
* Committee suggested reconfirming consent as the participants’ progress through the study, depending on their eligibility. This is because people are consenting to things that the participants may not be involved in.
* (A.5.2) sponsor. Is the research office the sponsor, due to being the contract holder? Researcher confirmed he would add the research office as sponsor.
* (B.1.1 pg.13) for future applications please ensure that this is in plain English, for example talking to your neighbour over the back fence rather than your colleagues.
* (B.2.1) does not mention questionnaires. In future please include to ensure your application is complete.

Summary of ethical issues (outstanding)

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

* The Committee queried the screening questionnaire, citing that it was not uploaded. The Researchers explained it is very similar to the asthma questionnaire. The idea is to confirm eligibility (some may have gained or lost asthma which then impacts their eligibility).
* The Committee stated that there should be a letter of introduction, before the PIS goes out, which explains the purpose of the screening questionnaire.
* The Committee noted that the PIS may not actually be relevant for many of the potential participants. The Researcher explained that they felt all information should be in there to allow them to say no, knowing what may be involved, even if it turns out they were not eligible.
* The Committee explained that there must be information outlining that some people will be eligible – to better reflect the nature of the study and what would reasonably be involved for all participants.
* Please explain how often participants get 50 dollars – currently not clear. Researchers stated they were not sure and would clarify.
* The Committee noted that the participants may be 16 in which case they can consent for themselves. Under 16 year olds can also consent if considered competent, but would ordinarily provide assent. Please view the guidance material for assent at <http://ethics.health.govt.nz/guidance-materials/example-templates-assent-forms>
* The Committee noted there is a discrepancy between PIS and application regarding the age group of participants. The researcher clarified for the Committee.
* The Committee noted that adolescents questionnaires include sensitive and tough questions (such as mum or dad dying) – what mechanisms are in place to support adolescents who may be going through rough times. Researchers noted that their own numbers are there, adding they are not specialised to deal with these kinds of situations, but could refer on to the correct people. The researchers asked whether having a disclaimer, or a note, about the potential for distress and provide contact information for a help line would be a good idea. The Committee stated this would be appropriate.
* The Committee queried if response from parents and children are sent back in same envelope. Researchers confirmed they were. The Committee stated that the children may lie, due to the personal nature of the questions, and the thought that parents may look at the responses. Committee suggested giving the children / adolescents an envelope to send their own response back.
* (Parental questionnaire) Please explain how some of the personal questions are actually relevant to the study? For example questions on suicide – marriages falling apart – traumatic events etc. Researchers suggested introducing these questions, explaining they were important for the study, due to cortisol levels and stress and how these relate to the illness. The Committee considered this appropriate, stating to include statement why these questions are relevant. Add Freephone contacts. Add a statement that explains that the participants do not need to answer all questions if they don’t want to.
* The Committee noted the PIS is not age appropriate and uses jargon. Please explain jargon or remove it. Consider trialling the PIS with a 12 year old to see how much they understand. See assent form link given above for guidance.
* Regarding the compensation statement in PIS, please clarify if you have insurance, as you state that you will cover ACC if ACC doesn’t.
* Committee noted that this study is ACC covered – if you do want to provide insurance please submit insurance information to HDEC in your response.
* The Committee queried why the GP name and address is requested (parent CF). The Researchers explained that this is for contacting them if something is identified to be abnormal. This information would be relayed to the GP for follow-up.
* The Committee requested addition of tick box to CF about consenting for researchers to contact GP.

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

* Add Maori support contact details.
* Add information on who pays for the study.
* Clarify the reimbursement and koha amounts.
* Clarify that participants can withdraw from study at any time, including verbally.
* Please make it clear that the pepper oil test occurs at a different, separate, visit.
* Committee suggested a flow chart to visually represent the different steps and levels of eligibility.
* Add page and version numbers to PIS.
* PIS confuses assent, consent and questionnaire. Please review for consistent use.
* Wording in challenge section (about inhaling) can be simplified.
* Please adequately identify what questionnaires are screening questionnaires.
* Add information about notifying GP under section ‘what will happen to my information’.
* Add health and disability advocacy contact information.

If you plan to store tissue and conduct future unspecified research, please include the below:

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| * **Future Unspecified Research (FUR) and Biobanking**   **\*note these are requirements for FUR** |
| * an indication of the type and nature of the research to be carried out and its implications for the donor, where possible, and an explanation of why the potential donor is being approached for their tissue and specifically what tissue is being sought. |
| * known possible researchers or institutions that might use the tissue sample, if possible. |
| * whether the donor’s sample is going to be, or is likely to be sent overseas, and where possible, to what country or countries. |
| * acknowledgement that all future unspecified research in New Zealand will be subject to ethical review. However, when a tissue sample is sent overseas, unless it is sent in conjunction with a New Zealand research project, future research is likely to be considered by an overseas ethics Committee without New Zealand representation. |
| * whether the donor’s identity and details will remain linked with the sample or whether the sample will be de-linked. |
| * a statement that if a donor consents to a tissue sample being unidentified or de-linked, they relinquish their right to withdraw consent in the future. |
| * whether the donor may be contacted in the future regarding their tissue sample. Whether or not, and under what circumstances, information about the future unspecified research will be made available to the donor and/or (where relevant) their clinician. |
| * acknowledgement that the donor will not own any intellectual property that may arise from any future research. |
| * whether there is provision to withdraw consent for the use of human tissue samples in the future. Where there is provision to withdraw consent, only tissue samples remaining at the time of a request to withdraw and any information held for future unspecified research may practically be withdrawn. Tissue samples or information used in research before the request to withdraw is received is unlikely to be able to be returned or destroyed. |
| * acknowledgement that the donor’s decision regarding the consent for use of their tissue sample for unspecified future research will in no way affect the quality of a donor’s current or future clinical care. |
| * where and for how long a tissue sample will be stored, how it will be disposed of and whether there is a cultural protocol for its disposal. For example, information about the institution holding the tissue sample: its aims, research procedures and research governance. |
| * whether or not tissue samples could be provided to other researchers and institutions, and whether or not such provision could include sending samples to other countries |
| * whether or not collected samples will be provided to commercial biomedical companies or will be used in commercial research collaborations, if known. |
| * what provisions will be made to ensure patient confidentiality. |
| * that different cultural views may inform choice about donation of tissue; for example, for some Maori, human tissue contains genetic material that is considered to be collectively owned by whanau, hapu and iwi. |
| * that cultural concerns may arise when tissue samples are sent overseas, including how tissue samples are stored and disposed of. Processes for monitoring and tracking what happens to samples may not be acceptable to donors. |
| * that donors may want to discuss the issue of donation with those close to them, for example; family, whanau, hapu and iwi. |
| * **Note:** FUR must be listed as OPTIONAL and must be **distinct** from the main study – this can either be a separate PIS (if there is substantial information that warrants it) or it can be a separate consent area on the consent form (if the additional tests are optional but not that different from the primary study). * **HDEC has a preference for separate PIS/CF for optional sub studies, FUR or bio banking as the information required is often different to the main study.** * For more information see the Guidelines for Future Unspecified Research <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> |

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 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*).
* Please provide age appropriate information sheets and assent forms for younger participants and amend the existing information sheets and assent/consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please submit evidence of sponsor insurance. *(Ethical Guidelines for Intervention Studies para 8.4).*
* Address outstanding ethical questions with a cover letter.

This following information will be reviewed, and a final decision made on the application, by Ms Kate O Connor.

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| **4** | **Ethics ref:** | **15/NTB/5** |
|  | Title: | HIMS |
|  | Principal Investigator: | Dr Helen Petousis-Harris |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 January 2015 |

Dr Mark Thomas and Mr Adrian Ludlam were present in person for discussion of this application.

Potential conflicts of interest

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

Mrs Erik declared a potential conflict of interest. The Committee decided that Mrs Erik could stay in the room and take part in the decision of the application.

Summary of Study

* The study is a feasibility study, assessing response rate to research questions. The study results will inform a larger study.
* The study aims to generate foundational data, including prevalence data, to provide evidence based treatment for men with HPV.
* The Committee congratulated the researchers on their HRC funding.
* The Committee commended the researchers on their engagement with relevant stakeholders.
* The Committee commended the value of study.
* 150 participants total (please include this on the patient information sheet).

Summary of ethical issues (resolved)

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

* The researchers explained that there is no direct registry for sexuality which results in a slightly different data collection method. We have proposed an aggregate anonymous data collection method to inform the potential roll out of vaccinations.
* The Committee whether the HRC peer review had any common themes or questions. Researchers stated no, nothing in particular.
* The Committee noted there were no written consents and no clinical notes taken. Please explain how the consent process works. The researchers explained this was due to the desired anonymity of the patient population, adding that this patient community works best with verbal consent and no record taking. The Committee noted this has risks for researchers due to the inability to demonstrate consent, and may pose a liability for both researchers and participants.
* The researchers explained that the patient population did not want to disclose their sexual orientation. The Committee noted that a consent form doesn’t need to state anything about HIV or sexuality, which would reduce the concern from the participants in signing it.
* The Researchers explained their experiences with community work with the patient population. They stated that when they were taking swabs to test for HPV the patients may be misled, the idea being that if the person’s name was recorded it might indicate that that test results can be linked back, which could be misleading, as the researchers wanted to keep the samples anonymous. Researchers added that the community commonly uses pseudonyms which can further complicate the issue of linking results and or documenting the consent.
* The Researchers explained they were not testing for HIV, rather they were recruiting HIV patients from the HIV clinic (assuming they had HIV), as well as asking them about HIV on questionnaire.
* The Researchers confirmed there is a documented verbal informed consent written that is logged.
* The Researchers explained verbal is standard practice with this patient population. The Committee was comfortable with the justification of verbal consent.
* The Committee queried why the researchers were not collecting ethnicity data. The researchers explained that primarily sexuality was of interest, not ethnicity. The power resulting from analysis from ethnicity data would not be relevant – the researchers explained that ethnicity is a variable of interest, however it will not be utilised in this feasibility study. There is no reason for extra emphasis to recruit for particular ethnicities. The researchers confirmed they could record ethnicity.
* Committee suggested recording why participants were not eligible, as an important data point for a feasibility study (i.e. intoxicated etc.) Researchers agreed.

Summary of ethical issues (outstanding)

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

* If you plan to store tissue and conduct future unspecified research, please review the below. If you decide to store tissue for future unspecified research you must provide the Committee with a PIS/CF covering the below.

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| * **Future Unspecified Research (FUR) and Biobanking**   **\*note these are requirements for FUR** |
| * an indication of the type and nature of the research to be carried out and its implications for the donor, where possible, and an explanation of why the potential donor is being approached for their tissue and specifically what tissue is being sought. |
| * known possible researchers or institutions that might use the tissue sample, if possible. |
| * whether the donor’s sample is going to be, or is likely to be sent overseas, and where possible, to what country or countries. |
| * acknowledgement that all future unspecified research in New Zealand will be subject to ethical review. However, when a tissue sample is sent overseas, unless it is sent in conjunction with a New Zealand research project, future research is likely to be considered by an overseas ethics Committee without New Zealand representation. |
| * whether the donor’s identity and details will remain linked with the sample or whether the sample will be de-linked. |
| * a statement that if a donor consents to a tissue sample being unidentified or de-linked, they relinquish their right to withdraw consent in the future. |
| * whether the donor may be contacted in the future regarding their tissue sample. Whether or not, and under what circumstances, information about the future unspecified research will be made available to the donor and/or (where relevant) their clinician. |
| * acknowledgement that the donor will not own any intellectual property that may arise from any future research. |
| * whether there is provision to withdraw consent for the use of human tissue samples in the future. Where there is provision to withdraw consent, only tissue samples remaining at the time of a request to withdraw and any information held for future unspecified research may practically be withdrawn. Tissue samples or information used in research before the request to withdraw is received is unlikely to be able to be returned or destroyed. |
| * acknowledgement that the donor’s decision regarding the consent for use of their tissue sample for unspecified future research will in no way affect the quality of a donor’s current or future clinical care. |
| * where and for how long a tissue sample will be stored, how it will be disposed of and whether there is a cultural protocol for its disposal. For example, information about the institution holding the tissue sample: its aims, research procedures and research governance. |
| * whether or not tissue samples could be provided to other researchers and institutions, and whether or not such provision could include sending samples to other countries |
| * whether or not collected samples will be provided to commercial biomedical companies or will be used in commercial research collaborations, if known. |
| * what provisions will be made to ensure patient confidentiality. |
| * that different cultural views may inform choice about donation of tissue; for example, for some Maori, human tissue contains genetic material that is considered to be collectively owned by whanau, hapu and iwi. |
| * that cultural concerns may arise when tissue samples are sent overseas, including how tissue samples are stored and disposed of. Processes for monitoring and tracking what happens to samples may not be acceptable to donors. |
| * that donors may want to discuss the issue of donation with those close to them, for example; family, whanau, hapu and iwi. |
| * **Note:** FUR must be listed as OPTIONAL and must be **distinct** from the main study – this can either be a separate PIS (if there is substantial information that warrants it) or it can be a separate consent area on the consent form (if the additional tests are optional but not that different from the primary study). * **HDEC has a preference for separate PIS/CF for optional sub studies, FUR or bio banking as the information required is often different to the main study.** * For more information see the Guidelines for Future Unspecified Research <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> |

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

* Use lay study title – no need to state it is a feasibility study.
* Feel free to put key bullet points at the start of the PIS.
* Add that mouthwash contains small amount of alcohol.
* Provide HPV project information in paper copy if a participant didn’t have access to the website.
* Pg.3 – not medical exam, no results – good, nice and clear – perhaps bold this for emphasis. Consider re-emphasising this at the start of the PIS.
* Refer to NTB Committee.
* Include health and disability ethics advocacy contact information.

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Address outstanding ethical issues with a cover letter, and if deciding to store tissue, address below.
* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).

This following information will be reviewed, and a final decision made on the application, by Ms Stephanie Pollard.

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| **5** | **Ethics ref:** | **15/NTB/7** |
|  | Title: | A study of airway and lung microbiome in children with bronchiectasis |
|  | Principal Investigator: | DR NAVEEN PILLARISETTI |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 January 2015 |

Dr Naveen Pillarisetti and Mike Taylor were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* The Committee discussed what microbiome is with the researchers.
* The researchers explained that microbiome is well known in the human gut, but that information is lacking in the area of bronchiectasis.
* Cited the difficulty of getting samples from the lungs from children.
* The study will involve 3 groups of children. Those coming in for diagnosis that will then have a bronchoscopy, children with diagnosis of bronchiectasis who may have had bronchoscopy and healthy children. Parents sign PIS prior to all study procedures.
* Committee noted the PIS was easy to read and easily understandable.

Summary of ethical issues (resolved)

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

* Please explain what support is provided for Maori participants. The researchers explained that locality process has Maori consultation as a requirement which will inform practice to accommodate cultural support for children and whanau.
* Confirmed study summary is provided in a lay language.
* Will you have difficulty recruiting the healthy children? The researchers explained that they had not done the lung sampling before, adding that they are first meeting potential participants at Starship, for their standard treatment, which makes it harder than those who visit the clinic frequently, who may be more inclined to participate.
* Committee noted that the procedures for the healthy children have no benefit from sampling. Please justify this patient group as fundamentally required for this study. The researchers confirmed that the health children are a fundamental requirement to the study validity, adding that the study can’t go ahead without it. Committee was satisfied with the response.
* The Committee asked if age or ethnicity were factors in this study population. Researchers explained this study is very exploratory; there is little data out there it’s hard to know whether age will make a difference. The researchers expect severity to be a factor.

Summary of ethical issues (outstanding)

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

* The Committee queried the lack of DSMC, please justify this decision. The researchers explained that these procedures are routine and are only added on to those who have clinical reasons for a similar procedure. Researchers explained that in past studies we have asked an independent colleague to overview safety information, for example from someone from infectious diseases. The Committee felt this would be appropriate.
* Please view the guidance material for assent at <http://ethics.health.govt.nz/guidance-materials/example-templates-assent-forms>
* (P.4.2) states that tissue can be returned or disposed. Please explain process in place to accommodate these options.

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

* Please amend ACC ‘would’ to ‘may’…be eligible.
* Please reconsider the information at the beginning, changing it to more simple, general, information, or moving the introduction down and having a new introduction. See HDEC template for more information.
* Review PIS page numbers.
* Regarding the parent of established bronchiectasis, please reconsider the wording ‘if you choose not to take part, your treatment at the hospital’. As the treatment does not require hospitalisation this can be misleading. Refer to on-going care rather than hospital.
* Please add Maori support contacts.
* Amend to declaration by participant to by parent.
* Review ‘you’ and ‘your child’ use, with respect to who the PIS is consenting as the participant.
* Add general aesthetic on pg.1 rather than referring to the children as simply ‘sleeping’.

Decision

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

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| **6** | **Ethics ref:** | **15/NTB/11** |
|  | Title: | Fractional Flow Reserve (FFR) |
|  | Principal Investigator: | Professor Harvey White |
|  | Sponsor: | Health Research Council of New Zealand |
|  | Clock Start Date: | 22 January 2015 |

Professor Harvey White 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.

Dr Tanser declared a potential conflict of interest, and the Committee decided to allow Dr Tanser to stay in the room and take part in the discussion of the application.

Summary of Study

* The study assesses the efficacy of stenting the surrounding arteries of those that caused a heart attack.
* Usual clinical practice is clinical judgement, roughly 50-50 between the two treatments.
* Dr White explained that historically it was recommended not to touch any other arteries, however over last year there has been a large increasing of stenting. FFR is a tool that assists clinical decision making. Long term outcome is not known about preventative stenting.

Summary of ethical issues (resolved)

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

* The Committee queried if all people will be well enough to provide consent. Dr White confirmed.
* The Committee queried if some potential participants will be in an emergency type situation? Dr White explained that maybe 10% will be. About half will have fully written informed consent, half will initially provide verbal consent. Most, 90%, would have written informed consent, before they have the procedure.
* No participants who have shock, these are excluded. No participants will have no form of informed consent, verbal or written. All patients give either verbal or written consent prior to the procedure.
* Committee queried the follow up in place. Dr White explained that it was only planned as health records review for 18 months – 3 years. Please make this explicit in the PIS.
* Queried who the sponsor is, please clarify with ADHB and provide information to HDEC if the sponsor changes.
* Please explain how the study will reduce ethnic disparities. Dr White explained that by enrolling as many ethnicities you generate data that leads to evidence that can treat patients who are then better treated.
* Please include a lay language summary of results to participants.
* P.4.2 – in future applications please include more information ‘we will pay particular attention, discuss process and results with whanau’.
* Please explain lack of DSMC. Dr White explained that because the study will involve randomisation between two standard treatments there will be no DSMC. The study would not be stopped as the treatments are already standard practice. There will be efficacy endpoints. Committee suggested getting some doctors from the various sites to review safety information at regular intervals. Dr White agreed, stating that this could be done.

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

* Suggested running the PIS by some patient populations to see if it is well understood.
* Include further ACC information: *If you were injured in this study, which is unlikely, you may be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. 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.*
* Include statement ‘we discussed the study with you before your (next of family/kin/friend). Please confirm your willingness to continue to participate in ‘study related activities’.
* Please add Maori contact details
* Remove extra chest (typo).

Summary of ethical issues (outstanding)

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

* Dr White explained the reasoning why side effect information was not listed at all, due to two standard treatments being listed. The Committee understood the reasoning, but required that enough information was there to provide informed consent. Please include more information on the basic risks involved in participating, noting that this is research not standard practice, even if the procedures are standard.

Decision

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

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| **7** | **Ethics ref:** | **15/NTB/14** |
|  | Title: | ADAPT |
|  | Principal Investigator: | Dr John Beca |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 January 2015 |

Dr John Beca, Ms Claire Sherring and Ms Miriam Rea were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* The study will involve 0 to 18 year old participants. The Committee noted that the PIS should be amended to reflect this.
* The researchers explained that the study will formally monitor standard practice treatments, involving follow up phone calls, questionnaires and some cognitive function testing.

Summary of ethical issues (resolved)

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

* The Committee discussed the use of routinely collected data without consent.
* The Committee noted that there are no extra tests or medical procedures related to the study.
* The Committee queried whether there had been considerations for children who have TBI through family or other human being intervention (abuse). Researchers noted that this data is very important and it is standard practice to collect this data and follow up, adding that the children are removed from dangerous environments so interacting with the person who caused the TBI will not be an issue for research and or follow up.
* The researchers confirmed that if the over 16 year olds are able to consent before leaving they will provide consent.
* HDEC was satisfied with accessing data routinely collected without consent, but advised that retrospective consent was sought when consent was sought for the follow up.
* Assent is appropriate due to children being unconscious at the time of being in hospital.
* (P.4.4) the Committee noted that the study does not use Kura Kaupapa Maori methodologies.
* (P.4.2) for future applications please acknowledge the tapu nature of the head.
* The Committee requested that ethnicity information is collected in line with the New Zealand Census, as this best reflects the New Zealand demographics. The researchers stated they would collect it internally.
* The Committee queried why pregnancy was an exclusion criteria for the study. The Researchers were not sure, but suspected it was due to the study being an international study.

Summary of ethical issues (outstanding)

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

* The Committee queried what would happen for the participants that would be 16 or over, who were not able to provide informed consent. The Committee noted that it was an observational study, and that the procedures would need to be observational (such as access to data without consent, or parents providing information without consent of the young adult). The cognitive screening should occur with consent from the child if it is understood to be a physical research related procedure, and could only occur without consent if it met the requirements of right (7) 4 of the Code of Rights.
* The Committee noted that a case will need to be made via an amendment to your project if you do encounter adults who can’t provide informed consent, which will need to explain how the cognitive testing is in the best interests of the adult who can’t provide informed consent, that you have sought assent from family or friends and that this research can only be conducted in this particular patient population.

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

* Add info being able to stop cognitive tests if children show signs of distress.
* Remove info on medication.
* Include statements about the contact points at 3 – 6 months.
* Add Maori support contact details
* Tokelauan is spelt incorrectly.
* Include further ACC information: *If you were injured in this study, which is unlikely, you may be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. 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.*

Decision

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

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| **8** | **Ethics ref:** | **15/NTB/19** |
|  | Title: | Pharmacokinetic and safety study of lower doses of ceritinib taken with a low-fat meal versus 750 mg of ceritinib in the fasted state in adult patients with (ALK-positive) metastatic non-small cell lu |
|  | Principal Investigator: | Professor Mark McKeage |
|  | Sponsor: | Novartis Pharmaceuticals Australia Pty Limited |
|  | Clock Start Date: | 22 January 2015 |

The Study Coordinator Margaret Joppa and Co-Investigator Dr Christian Schwabe 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

* The study drug has been approved overseas. This trial is primarily to get the drug approved in NZ.

Summary of ethical issues (resolved)

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

* The Committee queried if treatment is on-going or whether it is a short single treatment. The researchers explained that the protocol allows access if needed, determined by efficacy in each individual patient.
* Note withdrawal of consent does not require written action, as it can be verbal. Researchers confirmed this was acceptable.
* For future applications please ensure plain English statement is not highly technical.
* (R.1.6) the Committee noted that a study should not be terminated for ‘any’ reason and in particular studies cannot be terminated purely for commercial reasons.
* Researchers confirmed Maori Health Research Office approval had been received from Waitemata DHB.
* (P.4.1) Committee noted that for future reference the Treaty of Waitangi statement is irrelevant and out of context.
* Committee asked about additional biopsies. The researchers explained that FISH tests for ALK status will have already been done as standard care, but study participants will still need to provide a biopsy sample to conduct tests – however this will likely be an archived sample and not a new biopsy.
* The Committee queried whether ethnicity data was collected, and if so, was it using the New Zealand Census template. Researchers stated no, they were using the sponsor data sheet. The Committee stated that collection of New Zealand ethnicity data is important for other reasons, such as knowing generally who is entering research studies, participation rates etc. The Committee recommended that the ethnicity data is collected at New Zealand sites, adding that this was not a requirement

Summary of ethical issues (outstanding)

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

* (P.3.2) potential vulnerable people. Please explain how this will be managed from the units point of view, in terms of recruiting vulnerable patients and managing their perceived ideas of how the study may benefit them. Researchers stated CI will discuss treatment and study options with the patients at the clinic. Researcher explained that the CI is best suited to answer this, and he was unable to attend the meeting today.
* The Committee noted that the DSMC is internal. The Committee suggested having an independent colleague to review the safety information. The researchers explained the internal processes include a quality assurance manager, who provides assurance that the data collected is high quality and that safety information is monitored. The Committee requested further information on the DMSC that sponsor is providing, covering composition and scope of assessment.
* (P.3.3.1) has reimbursement been explained in PIS? Please provide participants, and the Committee, information on reasonable study costs and reimbursement.

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

* Consider tabling the visit information to avoid repetition.
* Noted study title is very long, please reword in lay language.
* Pg.3 states there is evidence to keep your disease under control – is this justified? Researchers explained that she felt it was due to the FDA approving the drug, and cited anecdotal information from other trials. The Committee noted this was not sufficient to justify the statement and noted the study was to prove that it did help control disease, please remove statement.
* Please state that access to the drug beyond the trial will be available if the drug is shown to be beneficial.
* The Committee noted that the flow chart requires an option to not participate (or decide not to sign).
* pg.4 – screening assessment – please remove ‘signing consent form’ – bit presumptuous. Change to ‘discuss’.
* Pg.5 blood PK samples – please provide more information.

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*).
* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*
* Provide details on what processes are in place to accommodate the highly vulnerable context of recruitment *(Ethical Guidelines for Intervention Studies para 6.2).*
* Provide information on reimbursement *(Ethical Guidelines for Intervention Studies para 6.34).*

This following information will be reviewed, and a final decision made on the application, by Ms Kate O Connor

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| **9** | **Ethics ref:** | **15/NTB/20** |
|  | Title: | TV46017-COPD-10046 |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: | PPD |
|  | Clock Start Date: | 22 January 2015 |

Dr Dean Quinn 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

* Phase I component has been completed in Australia. The New Zealand arm is Phase 2a study.

Summary of ethical issues (resolved)

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

* The Committee queried if there have been any SAE from Australian arm. Dr Quinn stated none that he was aware of, that were not outlined in the IB.
* Confirmed SCOTT has been submitted.
* (F.1.2) The Committee noted that the last two sentences have nothing to do with reducing inequalities.
* Is alert card 24/7 contactable number? Dr Quinn confirmed it was, adding it would be a cellphone number.
* (P.4.6) will you use New Zealand Census questions to collect ethnicity? Dr Quinn was not sure what the set up was for the electronic information collection provided by the Sponsor. The Committee stated that collection of ethnicity data is important for other reasons, such as knowing generally who is entering research studies, participation rates etc. The Committee recommended that the ethnicity data is collected at New Zealand sites, adding that this was not a requirement.

Summary of ethical issues (outstanding)

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

* The Committee queried the constitution of the DSMC. Is there a New Zealand member on DSMC? Dr Quinn explained it could be an Australian, but may be a New Zealander. Please confirm once known.
* Committee noted payment should be the same across different sites as it is to reimburse for inconvenience – please explain.
* Please provide payment for participation. Dr Quinn stated he is not aware of the amount paid yet. Please provide this information once received from Sponsor.
* The Committee noted that terminating study for commercial reasons is not acceptable, and is outlined in the NEAC Guidelines for Intervention Studies. Please ensure the possibility of termination for these reasons is not stated in PIS.
* Can participants drive post treatment? Dr Quinn stated they should be able to. Currently PIS states you can’t drive or operate heavy machinery until your doctor permits. Please amend and or clarify.
* (F.2.1) are translators and or interpreters available if an exclusion criteria is speaking and reading English. Dr Quinn stated he would look into this, but assumed not.
* Please see (*Ethical Guidelines for Intervention Studies para* 7.2) for more information on levels of data confidentiality, and confirm which applies to this study.
* Please clarify that all results, including drug and alcohol results, will be sent to GP. Also make this clear in PIS.
* Please explain the alcohol restrictions in the study. Dr Quinn explained that this was to ensure that the participants who have frequent or heavy alcohol use are excluded. Dr Quinn confirmed that if a positive alcohol result would exempt inclusion in the study. Please make this explicit in PIS.
* (P.4.1) please readdress this question in cover letter.

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

* Consider target population with regard to the language used.
* ‘you have agreed’ in PIS needs to be removed.
* The Committee discussed the participants being told to not use their rescue medication 6-12 hours prior to spirometry test. Please explain what their options are, if not rescue medicine, to ensure they are able to stay comfortable while following the study rules.
* Reword ‘discharge the subject’
* Reword ‘early termination’.
* Pg.15 - please include Maori health contact details.
* The Committee queried if GP is required to be informed of participation. Dr Quinn confirmed. Please include this in PIS.
* Pg.6 - health authorities. Please remove as this is not required in New Zealand.
* Committee found it difficult to make sense of the side effect profiles. Please use 1 in 10, 1 in 100 for example – the likelihood of them occurring. Or most common, least common 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* *para 6.22*).
* Provide information on reimbursement *(Ethical Guidelines for Intervention Studies para 6.34).*
* Respond to any questions in the outstanding ethical issues with a cover letter.

This following information will be reviewed, and a final decision made on the application, by Ms Kerin Thomspon.

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| **10** | **Ethics ref:** | **15/NTB/21** |
|  | Title: | Gliclazide 30 mg bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 22 January 2015 |

Dr Noelyn Hung, Dr Tak Hung and Ms Linda Folland 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

* Committee commended peer review.

Summary of ethical issues (resolved)

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

* The Committee queried why initial each page of the PIS. Researchers explained due to ensuring proper informed consent. Committee was satisfied with response.
* Is patient alert card 24/7? Researchers confirmed.
* (P.4.1) The Committee noted that if there is no benefit then don’t feel afraid to say so.
* The Committee queried why Zenith Technologies was listed as a contact for Maori support. Researchers explained that they would actually pass on to the other organisations. Please make this clear in the PIS.
* (F.1.2) The Committee noted that cheaper drugs benefit everyone, not only Maori.
* Committee noted that MPS out of date – Researchers explained they are updating at the moment.

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

* Page 8 – blood samples collection - hours as a unit written after number 72.

Decision

This application was *approved* by consensus.

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| **11** | **Ethics ref:** | **15/NTB/22** |
|  | Title: | Why do Australian women have better breast cancer survival ratios than NZ women? |
|  | Principal Investigator: | Dr Rachael Flanagan |
|  | Sponsor: | The NZ Breast Cancer Foundation |
|  | Clock Start Date: | 22 January 2015 |

Dr Rachael Flanagan 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

* Dr Flanagan explained that the NZ Breast Cancer Register has roughly 800 women diagnosed within Auckland each year, varies year to year but is increasing each year. There will probably be more than 2.5 thousand women to contact over the 5 year sample (2009-2013)
* Study aims for 60% completion rate for questionnaires.

Summary of ethical issues (outstanding)

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

* The Committee asked if there is funding covering the large amount of data analysis and contact? Please provide funding arrangement information.
* Committee asked about the potentially very unwell participants, would they be included? Dr Flanagan explained yes, if they wanted to – they would be given information the decision would be up to them. The Committee suggested Dr Flanagan provides a process to identify how to choose participants and avoid undue stress.
* Dr Flanagan confirmed the researchers would identify mortality before initiating any contact. The Committee suggested looking at the cost and potential time lag of identifying mortality and advised Dr Flanagan consults with the breast cancer registry.
* Dr Flanagan explained that this study is considered a snapshot to compare between New Zealand and Australia. The Committee noted it was better understood as the difference between Auckland and Brisbane rather than New Zealand and Australia.
* The Committee queried how generalizable the data will be, due to the specific patient population, noting there will not be any deceased peoples data and no data on those lost to follow up people. Furthermore there will be quite strict geographical limits.
* The study will not seek to analyse any information from deceased patients. Dr Flanagan explained that high risk groups (that are lost by death not included) will be analysed by following recent diagnoses to track survival over 5 years.
* Committee queried whether it was feasible to expect people to remember what people were eating in 2009. The Committee suggested trialling this to see if collecting this data was feasible.
* The Committee recommended getting biostatistician now rather than after the data had been collected. This will inform what data to collect and how to collect it.
* The Committee asked Dr Flanagan what data analysis would be conducted. Dr Flanagan explained they wanted to describe risk factors, lifestyle, and treatment, follow up. A strong focus on lifestyle, then subset analysis on indigenous population.
* (P.3.2) please explain the vulnerable patient group. Dr Flanagan stated those recently diagnosed with breast cancer need to be treated sensitively.
* The Committee asked if those with diminished competency would be approached. Dr Flanagan stated no, will be excluded. The Committee noted may add to non-generalizability of population.
* How will participants be approached and invited to participate? Dr Flanagan explained there was a planned registry meeting to release the information to researchers, who will recruit medical students to assist in contacting potential participants. Following the initial mortality data analysis we will call every person, discuss with them over the phone, and then send the PIS and questionnaire either online or via post.
* The Committee queried if it’s possible to be approached in clinics by people who they are engaged with. Researcher stated possibly but this was not currently an avenue of recruitment.
* Committee queried what considerations are in place regarding consent and access to health information. Committee noted accessing registry to contact participants is reasonable, but not clear that access to GP and health records without consent is justifiable, if seeking consent to complete questionnaire. Dr Flanagan stated that there isn’t much data required from GP notes. Committee queried if possible to seek consent to access health information at same time as seeking consent for questionnaire.
* The Committee suggests reworking questionnaire and pilot usability with people to see what people can remember.
* Expand PIS/CF. Explain the data collection information. Describe type of questions that will be in questionnaire.
* Committee queried the peer review noting that there was a conflict in that a peer reviewer is also a co-investigator. Please provide independent peer review, and consult a biostatistician. This includes peer review of feasibility and funding.
* Committee asked whether the registry database was able to record and manage the new information.
* Committee suggested involving patient advocacy group to confirm that breast cancer patients would want to be part of such a study.
* Review answers to p.4.1 and p.4.3.1 on application when resubmitting to HDEC.

Decision

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

* Additional independent peer review perhaps from breast oncologist plus biostatistician input (use HDEC template) is needed.
* Design issues which led to doubts over feasibility of study achieving its aims included lack of detail in protocol regarding clear endpoints, objectives and analysis plan.
* Needs more detail regarding funding for large data collection
* Access to stated records/databases/Brisbane data needs plan.
* Potential bias in population to be included, time frame proposed and issues with retrospective recall.

5.7 Scientific inadequacies in a study proposal have ethical implications. The scientific quality of a proposal should be such that the proposal’s objectives can reasonably be expected to be achieved. For example, a questionnaire unlikely to achieve an adequate response rate will be scientifically inadequate. It is important that studies that include Māori participants and aim to generate conclusions relevant to Māori engage sufficient numbers of Māori participants to produce useful data and avoid imposing an unethical burden on Māori. Projects without scientific merit waste resources and needlessly use participants’ donated time.

5.9 Studies must be conducted or supervised only by investigators with the necessary skills and resources to conduct the study and deal with any contingencies that may affect participants. Necessary skills may include competence in understanding different cultural understandings of knowledge and of how such understandings might impact on the analysis and results of a study.

5.11 All observational studies should be conducted according to written protocols that state the aims of the study, the data needed and how the data will be collected, used and protected. A principle of proportionality applies here: the amount of detail in the written protocol and the extent of protocol review processes should be related to the level of risk the study presents to participants.

5.12 When relevant, the protocol should include a statistical plan indicating the rationale for the number of participants involved.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. Please contact Dayle at Otago to query the information cited in Otago university applications regarding ‘cultural statements’ (15/NTB/1).
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 03 March 2015, 08:00 AM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

The following members tendered apologies for this meeting.

1. Mrs Phyllis Huitema for April
2. Mrs Phyllis Huitema tentative for March

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

The meeting closed at 5.45pm