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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 12 May 2015 |
| **Meeting venue:** | Novotel Ellerslie |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
|  | Confirmation of minutes of meeting of 14 April 2015. |
| 1.30pm | New applications (see over for details) |
|  | i 15/NTA/48  ii 15/NTA/49  iii 15/NTA/50  iv 15/NTA/52  v 15/NTA/53  vi 15/NTA/55  vii 15/NTA/56  viii 15/NTA/57  ix 15/NTA/58 |
| 5.45pm | General business:   * Noting section of agenda * Member portal training |
| 6.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Michele Stanton | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Present |
| Dr Christine Crooks | Non-lay (intervention studies) | 01/07/2013 | 01/07/2015 | Apologies |
| Mr Mark Smith | Non-lay (intervention studies) | 01/09/2014 | 01/09/2015 | Present |

## Welcome

The Chair opened the meeting at 1.10pm and welcomed Committee members, noting that apologies had been received from Dr Christine Crooks.

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 14 April 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTA/48** |
|  | Title: | RCT comparing diagnostic yield between R-EBUS guided cryo-biopsy Vs. CT guided biopsy for PPL. (CT-CROP) |
|  | Principal Investigator: | Dr Samantha Herath |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 April 2015 |

Dr Samantha Herath 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

* The Committee stated the study is interesting.
* The study involves comparing a new ‘cryo-biopsy’ method that is used with the Radial EBUS navigation system against the current gold standard: CT-guided biopsy.
* The CT-guided method has a diagnostic yield of 90% but it also has a high rate of complications. Roughly 30% of participants risk pneumothorax of which half require a chest drain and hospital stay.
* The Radial EBUS procedure has a diagnosis yield up to 74% with less than 1% risk of pneumothorax.The usual biopsy method involved in Radial EBUS is by forceps biopsy and cytology brush.
* This study looks at using cryo-biopsy to improve the diagnostic capability of Radila EBUS.
* The cost to administer each method is the same, at around $2,700 however this does not include the associated costs with side effects from the CT-guided method.
* The previous linked feasibility study will took one additional biopsy for participants who already need a biopsy as part of clinical care.
* The Committee commended the PIS/CF.

Summary of ethical issues (resolved)

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

* Is the cryo-biopsy method practiced anywhere else internationally? Dr Herath explained that a study had been completed in Germany with 39 patients.
* Is there a risk that a participant will go undiagnosed, noting that significant difference in diagnosis change between 74% compared to 90%? Dr Herath explained that while the cryo-biopsy is a new method it had already been studied and proven to be effective.
* The Committee asked if there is a risk due to patients who don’t get the gold standard treatment if they are randomised to the cryo-biopsy arm. Dr Herath explained that the cryo-biopsy is an extra test, on top of a standard radial EBUS biopsy. There is no withholding of standard treatment involved.
* The Committee asked what the process was when a mass was identified. Dr Herath explained that it was roughly 60% malignant 40% benign (when there is a mass). If it is malignant treatment occurs. If benign then follow up will occur with further imaging – either CT guided or a repeat test of the radial EBUS. These processes will likely be reviewed on a case by case.
* Dr Herath confirmed that Maori consultation will occur as part of the locality review process.
* The Committee asked if the researchers were going to use surveys and questionnaires. Dr Herath noted that the follow up will be an informal phone call to seek self-reported GP visits, ‘how did you feel etc.’ No use of standardised forms or Quality of Life methodology. The call is to seek information that would not be in health records.
* Dr Herath confirmed she is trained in the cryo-biopsy technique.
* Dr Herath explained that a sample size recalculation is planned for mid-way through the study.
* The Committee noted the data safety monitoring arrangements.
* Dr Herath confirmed that a feasibility study has occurred. The study was to assess tolerability of the procedure, adding that every patient who undergoes the cryo-biopsy procedure needs an endotracheal tube inserted.
* Dr Herath confirmed there will be a total of 228 participants.
* The Committee queried what funding arrangements are in place. Dr Herath explained that they had approached the Auckland Medical research Foundation and ASSER trust for this study.

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

* Please add a lay language title.
* Add lay study title under what is the purpose of the study
* The Committee noted that there is a requirement for ACC information to be included. The Committee suggests the following:

If you were injured in this study, which is unlikely, you would be eligible 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.

* Please add a separate sub-heading for ‘Risks’, within the ‘what will the study involve’ section.
* Please include Maori contact information.
* Please add more information about the post-procedural chest x-ray, as standard of care and for either procedure.
* The Committee suggested pictures could be included in the PIS to help potential participants understand the two different modalities. Particularly due to the lay association of biopsy from an external needle.
* Explain what randomisation is for participants in lay language.
* All patients have the right to have a lay language summary of results. Please offer this to participants.
* Please note the right to withdraw is possible up until the point of sedation and after this they can no longer withdraw. Please make this clear.
* Please proof read and review for jargon. Explain any jargon in lay language.
* Amend statement of approval to reflect that study was approved by the Northern A HDEC, not the Health and Disability Commission.

Decision

This application was *approved* by consensus, subject to non-standard conditions.

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| **2** | **Ethics ref:** | **15/NTA/49** |
|  | Title: | MANAGEMENT OF FEEDING DECISIONS |
|  | Principal Investigator: | Dr Anna Miles |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 April 2015 |

Dr Anna Miles 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 noted that this is not an intervention study.
* The study is observational and involves a case review audit, and interviews with staff and family members about feeding practices in ICU settings.
* The Committee noted that the application states an aim of the study is to demonstrate current practice in New Zealand. This will not be possible as it is only occurring at one site.

Summary of ethical issues (resolved)

* The researchers have noted that the staff interviews could raise sub-optimal DHB practice. The Committee felt that the researchers have recognised the potential risks relating to the staff interviews and have put in place mitigation plans. The Committee was satisfied with these measures.
* The Committee noted that there was an audit included as part of the study. The Committee were satisfied with the explanation of the audit.

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 requested clarification about the family/whanau interviews. In particular, who will be consenting; will the patient need to consent to their interview and their family also being interviewed, or will the patient and the family be consented separately. Please explain clearly how interview participants (both patients and family) will be approached and consented.
* Explain what measures are in place to ensure harm is not caused by approaching family members who have had a family member pass away eg will death status be checked prior to approaching interview participants. Similarly how will patient ability to consent be determined (eg stroke with cognitive deficits, palliative care, worsening health status) prior to approaching patients. Explain what the plan is for determining whether it is appropriate to approach potential participants, and whether there are conditions that would be study exclusions
* Explain what form of consent occurs, oral or written, in the family/whanau interviews.
* Please have a management plan for potential issues and risks that may be raised during these focus groups or interviews, noting the sensitive subject matter.
* The Committee recommends family members are contacted to determine whether the participant is able to participate.
* Add new section on recruitment in the protocol.
* Clarify who is consenting, particularly in relation to who the participant is in the family/whanau interviews. There should be separate PIS/CF for family, or the patient.
* Explain the recruitment process in detail.
* The Committee noted there could be children who are participants as there is no age range for this study – please explain if children may participate and if so appropriate study documentation should be supplied to facilitate informed consent.

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

* The Committee noted that the PIS must to explain what the study is about much earlier than it currently does.
* Remove the names and roles of the researchers at the beginning.
* Consider including a statement that participating will not affect the patient’s current or future care in any way.
* Please include information on whether interviews are taped or transcribed.
* Include the potential identifiably of staff in the PIS as identified in the application..
* Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html). Currently it states 6 years in the consent form.
* Review the wording right throughout the study documentation. For example on the advertising it states ‘you and your family have had swallowing difficulties’ which is misleading.
* Please review and include usual participant rights – withdrawal (up to a specified date), not to answer all questions, to have tape recorder turned off, to review transcript (if applicable), to have a summary of results.

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).
* Please outline in the protocol the processes in place for recruitment of the family members of sick patients. Provide detail on how the interviews work, whether they are individual or group sessions, who consents and to what and a plan for managing any stress or harm caused by the sensitive nature of the topics discussed. (Ethical Guidelines for Observation Studies para 5.11).

This following information will be reviewed, and a final decision made on the application, by Dr Karen Bartholomew and Ms Michele Stanton.

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| **3** | **Ethics ref:** | **15/NTA/50** |
|  | Title: | Oral Antiviral treatment for HCV/HIV coinfected patients: TURQUOISE-I |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 April 2015 |

Ms Angelle Lockie 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 asked if the study is phase II or phase III? Ms Lockie clarified that New Zealand will participate in the part 2 of the study, which is phase III.
* The study is approved in US. Aims to recruit 10 participants in New Zealand. 320 total participants worldwide.
* Committee noted there were no major ethical issues with study but required refinement on the PIS.

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 anyone would participate in this study. Ms Lockie explained that oral treatment for hep c is not funded in New Zealand. The study has a curative aim which has some preliminary evidence for a high success rate.
* Ms Lockie explained that current standard of care in New Zealand involves weekly injections or IV treatment. These methods have substantial negative side effects. The oral treatment has much fewer side effects.
* Ms Lockie explained that phase I and II study results have come back with 93% effectiveness with the patient population. Ms Lockie explained that this is encouraging.
* Ms Lockie explained that Part 2 is the worldwide expansion of part 1, which occurred in the United States.
* Ms Lockie confirmed that this study will not be the first time this treatment is used for co-infected patients.

Summary of ethical issues (outstanding)

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

* (R.1.4) and (R.1.5) please provide more information on how the real time data safety monitoring works and how this compares to a standard DSMC. Ms Lockie explained that researchers enter all study data into electronic data capture system, including all laboratory results. The data is sent to a medical monitor. The monitor will review for trends which may emerge, real time. This review includes adverse event reports.
* What level of protection does this have for participants? Is it better than DSMC? Ms Lockie explained that real time monitoring is better because, as the study is going along, the monitor can get the information as it happens. Traditional DSMCs reviewed data periodically.
* In most studies does information go directly to the sponsor and or medical monitor? Ms Lockie explained it is common.
* The Committee requested clarification from the sponsor as to how real time monitoring works in practice and a justification on how it meets the same level of protection as a DSMC, noting that it was a phase III study which would ordinarily require DSMC, as outlined in the NEAC ethical guidelines for intervention studies.
* Committee queried whether the study was being submitted to SCOTT. Ms Lockie will clarify.

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

* The Committee requests a comprehensive review of the PIS. Please attempt to reduce length of PIS.
* There are American emergency numbers. Pg.21 – 000 for example.
* Review explanation of cirrhosis – this does not appear well explained before table 4.
* Page 24 of PIS reads-“However, to ensure the valid results of the study, you agree that you may not be able to review or make a copy of some of your records related to the study until after the study has been completed.“ In keeping with Rule 6 of The Health Information Privacy Code please advise participants that insistence on accessing personal health information while the trial is still continuing may be treated as a withdrawal from the study. Alongside this statement you may wish to reconfirm that participants can access a summary of the results of the study at its conclusion .
* Remove statement about HDEC reviewing all research in New Zealand. This is misleading.
* Please explain current treatment and explain how oral is different, at the beginning of the document, to help participants understand what the study is about and whether they would want to participate.
* Amend compensation to clearly state participants ‘won’t’ be eligible for ACC.
* The optional sub study requires a separate future unspecified research document which must cover the below requirements. (text from the current PIS page 5 onwards can be removed and included in the optional biobanking PIS).

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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*).
* Provide information on the data safety monitoring arrangements. (*Ethical Guidelines for Intervention Studies para 6.50)*

This following information will be reviewed, and a final decision made on the application, by Dr Brian Fergus and Mr Mark Smith.

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| **4** | **Ethics ref:** | **15/NTA/52** |
|  | Title: | Comparison of the blood levels of four forms of isotretinoin 40 mg capsules in healthy male volunteers |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas America Ltd |
|  | Clock Start Date: | 30 April 2015 |

Dr Noelyn Hung (CI), Dr Tak Hung (Managing Director) and 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

* Commended the peer review, commend the amended standard generic PIS.
* Please review any cut and paste text for future applications as some mistakes were noted.

Decision

This application was *approved* by consensus.

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| **5** | **Ethics ref:** | **15/NTA/53** |
|  | Title: | Comparison of the blood levels of two forms of tibolone tablet in healthy female volunteers |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 30 April 2015 |

Dr Noelyn Hung (CI), Dr Tak Hung (Managing Director) and 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

* Commended the peer review, commend the amended standard generic PIS.
* Please review any cut and paste text for future applications as some mistakes were noted.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **15/NTA/55** |
|  | Title: | The PAMILA Study |
|  | Principal Investigator: | Professor Richard Troughton |
|  | Sponsor: |  |
|  | Clock Start Date: | 30 April 2015 |

Professor Richard Troughton 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 study is a multicentre collaborative project between Christchurch Heart Institute and Singapore Cardiovascular Research Institute (CVRI).
* This study will test samples specifically for PAMILA (New Zealand and Signapore) and then bank leftover samples for future unspecified research. The samples will be banked in an established tissue bank which has an HDEC approved generic PIS.

Summary of ethical issues (resolved)

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

* The Committee queried whether the patient population was potentially vulnerable as they were being approached 72 hours after acute myocardial infarction. Are there any issues for the informed consent process? Professor Troughton explained that 72 hours post event is actually quite different from other studies where we often approach patients in an acute phase. The research team are very conscious of the potential vulnerability of those in an acute phase and their consenting process takes that into account. However 72 hours is a fair amount of time to have passed from that acute setting, and the researchers don’t expect issues with consent.
* The Committee asked whether the optional biomarker research would involve reporting all incidental findings or only those that were clinically significant. Professor Troughton explained that it was incidental findings, but only if they were clinically important. The Committee noted the PIS is unclear currently. Please make it explicit what kinds of things would be referred back to clinicians or patients.
* Professor Troughton confirmed that the sample stored in New Zealand are stored with an established, HDEC approved, bank.
* (R.4.1.1) Regarding clinically significant findings and incidental findings. The Committee noted it refers to these being ‘managed according to clinical guidelines’. Which guidelines? Professor Troughton clarified that the research team have a lot of experience with these kinds of studies. Occasionally a patient comes back for an echo scan that may not be done for clinical reasons. It is possible to find something for example a new or previously unidentified clot. The study team will notify the relevant clinical team if identified.

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 why the main study samples will be stored for 10 years. Professor Troughton explained that it was to validate initial findings or to re-run assays if there is a problem. Singapore may bank some samples for period of time for the same reason
* The Committee asked what the future tests might be for the stored samples. Professor Troughton explained that sometimes halfway through a study a new biomarker may be identified. The PIS asks if participants can have their tissue used in new biomarker tests.
* Please explain the peer review process that is undertaken by the NMRC.
* Please clarify the expiry date of the study.
* The Committee requested the terms of reference relating to the bio-bank. (approval conditions under Section 13 of the HDEC SOPs).
* The Committee requested clarification about what tissues samples were being taken, where they are going and the various lengths of storage. Professor Troughton explained that they will be taking samples for specific analyses – these will be done in Singapore as they have the specialised laboratory. Other assays will be run here in Christchurch for similar reasons.
* The Committee noted that the main PIS involves storing tissue for 10 years. Is this mandatory?
* The Committee noted that the PIS/CF was currently confusing as it suggested that the main study involved banking of tissue for purposes unrelated to the current ethics application. Please clarify.
* What will happen to samples if they don’t participate in the separate, optional, sub study? It is currently unclear what the difference is between the main study and the sub study. Both require banking tissue. Make this clear in the main PIS.

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

* Please explain where samples are going, particularly when they are going overseas.
* Bottom of page 2 of the main PIS – please clarify for participants what tests and analysis be conducted on their tissue samples.
* The Committee noted that the study requires both retrospective and prospective access to hospital records. Professor Troughton stated it would be for 2-3 years. Please provide a time frame for follow up for participants.
* Consider removing pregnancy option from main PIS as there are no treatments in this study.
* Please review the PIS and ensure it reflects what you aim to do. Currently unclear.
* Please review and explain jargon (eg page 2 assays, validation, replication).
* Note samples may be not be stored indefinitely the researchers must supply specified time period.
* Please review both PIS (as involving biobanking) for the information required according to the Guidelines for Future Unspecified Use (eg no NZ ethical review for overseas samples, cultural issues, intellectual property).

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*).
* Clarify what will happen to participant’s samples in a covering letter to HDEC. Currently confusing due to some ‘main study’ samples being stored for 10 years.

This following information will be reviewed, and a final decision made on the application, by Mr Mark Smith and Ms Susan Buckland.

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| **7** | **Ethics ref:** | **15/NTA/56** |
|  | Title: | Investigating the effect of Carbon Dioxide and Humidity on Human Peritoneum. |
|  | Principal Investigator: | Dr Tinte Itinteang |
|  | Sponsor: | Gillies McIndoe Research Institute |
|  | Clock Start Date: | 30 April 2015 |

Dr Tinte Itinteang and a research nurse were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (outstanding)

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

* Dr Itinteang explained that they wanted to take tissue from patients, put it in the GMRI tissue bank, and then use that tissue to study the varied levels of carbon dioxide and humidity on the tissue. The researchers confirmed that no tissue will be banked after the study.
* The Committee noted that the tissue is prospectively collected and the tests are already known. This means that the participants have a right to be fully informed about participation. The Committee requests a study specific PIS. Please ensure that the PIS is clear that there will be no benefit to participants, and outlines what risks (if any) there are.
* Please use lay language.
* Please remove ambiguity about storage of tissue, adding there is no planned future unspecified research or continued storage beyond the specific study.

Decision

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

* Please create an information sheet and consent form that is study specific (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please outline in the protocol the processes in place for recruitment of participants (Ethical Guidelines for Observation Studies para 5.11).

This following information will be reviewed, and a final decision made on the application, by Mr Mark Smith and Ms Susan Buckland.

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| **8** | **Ethics ref:** | **15/NTA/57** |
|  | Title: | INS-212 - Study of Liposomal Amikacin in Adults with Nontuberculous Mycobacterial Lung Infections |
|  | Principal Investigator: | Dr Amanda McNaughton |
|  | Sponsor: | Insmed |
|  | Clock Start Date: | 30 April 2015 |

Dr Amanda McNaughton and Dr Robert McLachlan 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

* Multicentre international study phase III. Study objectives are efficacy and safety of nebulised liposomal amikacin, an antibiotic treatment for lung infections.
* Standard delivery of this class of antibiotic is through an IV. IV delivery systems run into problems with the patient population due to long term IV use (kidney, hearing issues). Nebuliser goes directly to the lungs which should be more effective (reduced systemic dose) with fewer side effects.
* Mycobacterium avium complex is a cousin of TB and requires extended antibiotic treatment.
* The Committee commended the protocol, stating it was easy to read, clear. The same comments apply to the PIS.

Summary of ethical issues (resolved)

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

* Is there a risk of use of nebulisers passing on disease or illness? Researchers explained nebulisers are standard care in Cystic fibrosis patients. They are chosen for this study specifically as it is a short delivery system and is less time consuming for the patients. Infection has not been identified as a risk using these nebulisers.
* The Committee queried the need to continue using nebulisers for 12 months even if septum test shows clearance of the infection. The researchers stated that prolonged treatment is required, international guidelines often require 1 year of continued treatment post infection clear septum result. The Committee was satisfied that continued treatment is standard practice.
* Conflict of interest (r.5.4). The Committee noted the researcher may also be usual care provider for some patients. What mitigation plans are in place for this? Researchers explained that it is common to have discussions about what treatments patients are prepared to try. Treatment is often a negotiated process with the patients. The patients will be given all of the potential options. It will be offered with all other options available, and patients are free to choose to participate or not.
* The researchers explained the verbal discussions that occur between clinician and patient. The Committee was satisfied with the recruitment discussions with clinician and patient, and that consent will be free of coercion.
* The Committee was satisfied with the recruitment discussions with clinician and patient.
* The Committee asked about the percentage of patients treated with prolonged IV antibiotics that have kidney damage or hearing problems. Somewhere between 20-30% with renal impairment via IV. The researchers explained more common in women than men and also more common in the elderly.
* Are the quality of life questionnaires standardised. The researchers confirmed they were.
* The researchers confirmed there were no additional CT scans resulting from study participation.

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 why the future unspecified research related to 24 months of storage, adding tissue was ordinarily stored for longer. The researchers explained that the tests would likely relate to biomarker analysis and there was no specific stipulation for these tests. The Committee requested more information on the likely tests, explaining that blanket consent was not appropriate for only 24 months - patients should be able to be informed about tests that would occur during a 2 year period.

Decision

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

* Clarify the future unspecified research and tissue banking component of the application in a cover letter to HDEC.
* Please justify the plan to use a future unspecified research PIS for storage which is limited to 24 months (*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 Dr Karen Bartholomew and Ms Susan Buckland.

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| --- | --- | --- |
| **9** | **Ethics ref:** | **15/NTA/58** |
|  | Title: | Study of GS-6615 in People with Chronic Stable Angina and Coronary Artery Disease |
|  | Principal Investigator: | Dr Jocelyne Benatar |
|  | Sponsor: | Gilead Sciences, Australia and New Zealand |
|  | Clock Start Date: | 30 April 2015 |

Dr Jocelyne Benatar 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

* Randomized, double-blind, placebo-controlled, parallel-group study to evaluate the effect of GS6615 in participants with chronic stable angina and coronary artery disease (CAD) receiving a stable daily dose of anti-anginal medications.
* 6 New Zealand participants.
* Application includes a pharmaco-genetic sub study.

Summary of ethical issues (resolved)

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

* Please explain how participants are protected from a safety perspective, particularly those on the placebo arm. Dr Benatar explained the eligibility criteria required participants to have stable angina that have ongoing symptoms and positive exercise tests. Currently anti-anginals do not treat the cause, they only lessen the symptoms, and rescue therapy is available.
* Confirmed study is submitted to SCOTT.

Summary of ethical issues (outstanding)

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

* Please provide the conditions resulting from the South African review process, and has the protocol changed since this review? Dr Benatar stated that there was no South African review and explained that the sponsor informed her that all changes made to protocol were because of FDA changes. New Zealand will be first country where protocol will be implemented, and will be first site activated. The submitted protocol is up to date.
* Please confirm, as A.6.3.1 states ethics review has been received in Israel and South Afria.
* Please provide more information on safety aspects of stopping standard treatments, noting the maximum of two anti-anginal medications. Dr Benatar stated she refuses to reduce anti-anginals. The Committee agreed this was appropriate and requested that study documentation including PIS/protocolis updated to reflect this.
* Please provide information on consultation with other cardiologists within ADHB including Harvey white and the Research Committee at ADHB which has a cardiologist on its board. They will review prior to commencing study. The study will be presented to the cardiologist group before study starts. The Committee requested a letter of support from the cardiologists. Suggested HDEC peer review template as an option – see quick links at <http://ethics.health.govt.nz/home>
* The Committee noted that the main study PIS and the optional sub study PIS must be standalone documents. Please remove all information in the main PIS that refers to the optional sub study and transfer to the sub-study PIS. Make sure both documents are complete in their own right.

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

* Please clarify discrepancies between the optional separate PIS and the main PIS (as it relates to tissue banking).
* The optional PIS – please add where samples are going.
* The main PIS – remove all information relating to the unspecified research and put into the separate, optional, PIS.
* Pregnancy sub study. Please correct compensation information with ACC clause. See HDEC template for guidance.
* Add Maori support contacts in optional PIS.
* Please explain risks to foetus resulting from drug interaction.
* Add information regarding sharing health information and contacting participant’s GP.
* Please reword the ACC information in the main PIS.
* Add information on how incidental or clinically significant findings will be managed.
* Pg.3 optional – less compensation cover is provided compared to the main PIS. Please explain.
* Pg.13 – reword clause relating to HDEC and the role of Medsafe.
* Include some basic inclusion and exclusion criteria on PIS.

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*).
* Confirm New Zealand is the first country to undergo ethical review.
* Update all study documentation outlining the CI’s intention to not withhold any anti-anginal medications.

This following information will be reviewed, and a final decision made on the application, by Ms Michele Stanton and Mr Mark Smith.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 09 June 2015, 08:00 AM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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 4.15pm