Health and Disability Ethics Committees

Minutes

Committee:	Northern A Health and Disability Ethics Committee
Meeting date:	11 March 2014
Meeting venue:	Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland

Time	**Item of business**
12.00pm	Welcome
12.05pm	Confirmation of minutes of meeting of 11 February 2014
12.30pm	New applications (see over for details) i 14/NTA/22 ii 14/NTA/25 iii 14/NTA/26 iv 14/NTA/31 v 14/NTA/32 vi 14/NTA/33 vii 14/NTA/34
4.30pm	viii 14/NTA/36
4.35-4.50pm	General business: Noting section of agenda
4.55pm	Meeting ends

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	01/07/2014	Present
Mr Kerry Hiini	Lay (consumer/community perspectives)	01/07/2012	01/07/2014	Present
Dr Etuate Saafi	Non-lay (intervention studies)	01/07/2012	01/07/2014	Apologies
Ms Michele Stanton	Lay (the law)	01/07/2012	01/07/2014	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	Present

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Welcome

The Chair opened the meeting at 1.16pm and welcomed Committee members, noting that apologies had been received from Dr Etuate Saafi.

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 11 February 2014 were confirmed.

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New applications

1	**Ethics ref:**	**14/NTA/22**
	Title:	PHYSACTO™
	Principal Investigator:	Dr Andrew G. Veale
	Sponsor:	Boehringer Ingelheim Pty Limited
	Clock Start Date:	27 February 2014

Dr Andrew G. Veale (Co-ordinating Investigator) and Mrs Carol Veale (Study Co-ordinator) were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- The Committee noted the programme was worthwhile and the researchers had been very thorough in their application.
- The researchers explained their study to the Committee. The researchers noted this study is different than other clinical drug trials, in that it involves exercise and behavioural modification as well as a study drug. The combination gives the study a unique ability to assess the study drug more accurately. The researchers explained, other studies can result in a placebo effect because participants feel better for reasons unrelated to the study drug. This study controls for these features, providing a package treatment.
- The Committee noted the PIS was long and wordy and queried if the researchers felt it would be appropriate to reduce the length. The researchers explained that the sponsor had a lot of mandatory information, and in particular felt it necessary to describe each clinic visit in detail. The researcher acknowledged there was a chance of getting 'lost' in the detail. The Committee requested the length is reduced. The researchers confirmed they would go back to the sponsor with an edited version.
- The researchers queried if they were able to provide an executive summary. The Committee felt this was a good idea. The researchers confirmed they would create one and submit it as a post approval item to HDEC. The Committee noted the researchers should still address the PIS length.

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- The Committee noted the limited number of participants. The researchers explained the logistical challenges of administering the exercise intervention. The Committee acknowledged this.
- The Committee queried whether the focus was on any particular component of the study, or if it was approached as a package treatment. The researcher stated the sponsor was interested in all aspects, including the pro-active tool evaluation and the study drug. The researchers explained that all data generated from the study would be useful and incorporated.
- The Committee confirmed the recruitment and treatment was through private institutions.
- The Committee noted the Maori contact details on the PIS were for the DHB, though the recruitment and treatment was from private practices. The researchers explained they don't have many avenues of Maori consultation and support outside of DHB. The Committee queried if they would seek consultation for this study. The researchers confirmed they had applied but not received word back.
- The Committee queried why participants would be interested in this fairly intensive research project. The researchers explained that participants are interested in using the study drug delivery mechanism (Respimat inhaler).
- The Committee queried if New Zealand was the first country that ethics had been sought, noting the study was to be conducted in 12 countries (predominantly European).
- The researchers explained that Australia has applied for ethics, though were unsure about other countries. The researchers stated there was no reason New Zealand was one of the first countries to have ethics applied for, citing a pragmatic approach to 'get started as soon as possible' as the justification.
- The Committee confirmed there is no cost for patients.
- The Committee queried the recruitment mechanism in place, and who approaches potential participants. The researchers explained they have access to a database which has patients who have been asked about being contacted for research. The Committee queried how this was set up. The researchers explained that participants with various forms of respiratory diseases and issues were initially emailed asking if they wanted to be part of a research registry (roughly 17,000 people). Of the 17,000 roughly 500-700 consented to be contacted for research. There is a condition that states that they will only be approached for ethically approved protocols. The other avenue of recruitment is when one study is finishing the participants may ask if there are any other studies they could join up on. The researcher would inform them of other similar studies.
- The Committee queried how the doctor patient relationship is managed with recruiting to database or for the study. The researchers explained it is explicit that being on the database does not mean they have to take part, adding that the researcher is not always the treating doctor for the potential participants.

- The Committee confirmed SCOTT approval was applied for and pending.

– The Committee queried how researchers will know when to remove a patient from the trial. The researchers explained the QCG parameter is the more frequent sign, though there have been cases of cardiac arrest in past trials. The second most common reason for people pulling out is when people don't tolerate the treatment. This is identified through the patient diary which is an objective measure. This is an important outcome measure, and there are criteria for withdrawing participation. The Committee requested that this information is included in the PIS.

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

– Please review the length of the PIS. Remove any repetition.

– Please provide an executive summary as a post approval item before recruiting.

– Please review technical terminology and express in lay language for participants.

– Please indicate briefly at the start of the PIS the substantial time commitment that would be required Make it explicit that the study medication will not be available after the study has concluded.

– Please further explain the conditions for participants to be taken off the study drug, for instance if the medication is identified as not being effective for an individual participant.

– The Committee queried why there was no adverse effect listed relating to the liver in the protocol, noting there was a statement about testing for baseline liver levels in PIS. The researchers stated baseline liver function for all studies, regardless of prior risk or adverse effect is now a mandatory FDA requirement. The Committee requested that If liver damage is a real possibility in this study it should be made clearer for the participant

– Please review and ensure all contact numbers are New Zealand rather than US.

– Remove US references (public health plan etc).

Decision

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

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2	**Ethics ref:**	**14/NTA/25**
	Title:	TOBA - BTK
	Principal Investigator:	Associate Professor Andrew Holden
	Sponsor:	Intact Vascular
	Clock Start Date:	27 February 2014

Associate Professor Andrew Holden, Ms Donna Katae and Miss Helen Knight were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- The Committee was appreciative of the readability of the concise PIS.
- The Committee queried the trial goal of bio-equivalence rather than superiority. The researcher explained the study is statistically designed to show non-inferiority. The researcher explained in order to show superiority you need a lot more cases. As a first in man study it is to show it is non-inferior, rather than superior, adding that if the trial showed the treatment to be inferior you would not want to test it on a larger patient population.
- The researcher explained the relationship between the current study and prior studies, noting that this study aims to show whether tacks are a viable method of keeping arteries open without using a stent as stents narrow the artery while keeping it open. The placement of the tack is First-in-Man, though tacks have been used in other studies.
- The Committee confirmed that in terms of procedures this study does not have any additional procedures from standard practice, apart from the use of tacks instead of stents.
- The Committee queried a comment from the peer review. A prior study had a 12 month follow up, asking whether it was appropriate to wait to see the study results and if there had been any adverse effects. The researcher stated that there was no need to wait as the advantage and effect of the procedure/device is short term (over 6 months). There is no evidence that complication would occur at a later stage.
- The Committee noted that participants are only confirmed to be eligible once surgery had begun and the patients were unconscious. The Committee queried

whether the option to revert to standard practice was available up until the surgery. The researcher confirmed participants were able to withdraw and would have the chance to talk to study team, adding that once the procedure started they would be sedated and they must follow through with the surgery and are either in the study or not.

- The Committee requested that more wording is included on PIS so participants know A) this is a treatment for dissection, not narrowing of the arteries (which is being treated either inside or outside study participation) and that B) once the procedure starts they are not able to stop, so study involvement and consent is valid before the operation.
- The Committee requested that it is clear to participants that they are only found to be eligible after they start the surgery.
- The Committee queried the peer review noting it is provided by the sponsor (internal).
- The researcher explained that there is data to show the device has been used in different areas successfully.
- The Committee queried whether the CI was confident in the DSMC to monitor safety information. CI stated he was confident.
- The researchers confirmed the study had started in other countries.

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

– Pg 2. Standard treatment described as an ‘x-ray procedure’. Committee queried if this is the best way to explain standard practice, noting it could imply that treatment is just an x-ray. The researchers explained it was a surgery performed under x-ray, but acknowledged that it could be re-worded.
– The Committee queried the heading ‘possible risk and complaints’ and suggested shortening it to risks.
– Please include further information on the additional angioplasty, noting that while it is clinically driven, it is not different from care outside of the trial.
– Please include a lay summary of results for participants, as well as the journal article.

Decision

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

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3	**Ethics ref:**	**14/NTA/26**
	Title:	Safety and Performance Study of the Shockwave Lithoplasty System
	Principal Investigator:	Associate Professor Andrew Holden
	Sponsor:	Shockwave Medical Inc
	Clock Start Date:	27 February 2014

Associate Professor Andrew Holden 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 ethical issues

The main ethical issues considered by the Committee were as follows.

- The researcher explained how the study device addresses the shortcomings of current standard practice.
- The earlier First-in-Man study proved that the concept works. This used a 2cm balloon which was found to be not long enough for the cases of more extensive calcium build-up. The new device is longer at 6 cm but the same in all other aspects.
- A CT scan of participant's target artery is required for this study which is an additional procedure from standard practice. This scan is required as it will help identify which participants are likely to be treatable or not, resulting in much a higher rate of entry criteria confirmation prior to surgery.
- The researcher explained that parachutes will be used as a safety measure for this study, adding that this measure had been useful in preventing complications in past studies.
- The Committee noted there is a sub study in the trial overall, which will be a mandatory requirement (so is not a separate consent for this particular study). Please make this explicit in the PIS.
- The Committee noted that the peer review is by the sponsor' internal review board. The Committee queried if the review board is paid by the sponsor. The CI responded that the advisory board are paid for travel but not paid for their time and are not financially linked to any investigational product.

- The Committee requested the following changes to the Participant Information Sheet and Consent Form:
- The Committee requested that it is clear to participants that they are only found to be eligible after they start the surgery.
- Standard treatment described as an 'x-ray procedure'. Committee queried if this is the best way to explain standard practice, noting it could imply that treatment is just an x-ray. The researchers explained it was a surgery performed under x-ray, but acknowledged that it could be re-worded.

Decision

This application was *approved* with nonstandard conditions by consensus.

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4	**Ethics ref:**	**14/NTA/31**
	Title:	ASPECT - A double-blind study to assess the safety and efficacy of intravenous Ceftolozane/Tazobactam with that of Meropenem in Ventilated Nosocomial Pneumonia
	Principal Investigator:	Dr Shay McGuinness
	Sponsor:	Cubist Pharmaceuticals, Inc.
	Clock Start Date:	27 February 2014

Dr Shay McGuinness (Co-ordinating Investigator) and Rachael Parke (Co-investigator) were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

Committee considered the application in two sections – with and without consent:

Regarding consenting participants:

- The Committee noted that the study was a phase III. The Committee asked the researcher to explain the results of the past studies. The researcher explained that this study is for new antibiotic treatments tested against an existing antibiotic. It is a non-inferiority trial, so there is no power in the study to prove the experimental antibiotic is better, and no prior evidence to suggest, that this antibiotic is superior to standard treatment.
- The researcher clarified that the FDA has ruled that studies can design for non-inferiority rather than superiority for antibiotics. This is a recent development and is a means to fast track approval of new antibiotics (because of the resistance evolving nature of these infections).
- Committee queried standard treatment antibiotic (Meropenem) success rate. The researcher responded it is roughly 60%.
- The phase II testing shows that the experimental antibiotic is safe. Some early results show it is at least as good at the specific target organism, but the researcher could not definitely predict there would be any benefit in this trial.
- The researcher explained the benefit of new antibiotics, noting the study antibiotic could be more effective as a treatment as it is targeted.

- The Committee requested information on the consent process during prior studies.
- The researcher explained that in 2005 he discussed legal issues of consent with crown law.

The discussion then turned to question of obtaining consent

- Because of the nature and severity of the infection, the researcher was of the view that none of the potential participants would be capable or in a position to give informed before the trial started.
- As per previous applications previously approved by HDECs in the past, the researcher proposed obtaining assent from relatives and then retrospective consent form the patients when they had recovered.
- The researcher explained he and colleagues were operating on the basis of previous discussions with Crown Law dating back to around 2005.
- The researcher described the internal process that he and colleagues had followed in the past and up to the future. The Committee heard a detailed explanation of this process and would be interested if the researcher and fellow workers had ever documented this process (the process of study enrolment without prior consent for critically ill people in the hospital).
- The researcher was of the view that this process dated back to the 1990's and several thousand people had gone through the process.
- There was then considerable discussion between the Committee and the researcher about advice from Crown Law. Namely, while critically ill patients can be treated clarification is required such critically ill people can be enrolled in a trial without prior consent.
- Until final advice is received from Crown Law on this issue, the Committee has no option but to defer the application in the meantime.
- Should this application eventually proceed the Committee will still need to review the application from the point of view design, peer review, assessed risk/benefits, PIS content.

Decision

This application was *deferred* by consensus, as the Committee while it seeks further information.

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5	**Ethics ref:**	**14/NTA/32**
	Title:	LEE011X2106
	Principal Investigator:	Dr Rita Sasidharan
	Sponsor:	Novartis
	Clock Start Date:	27 February 2014

Dr Rita Sasidharan and Mr Ashish Joshi were present by teleconference for discussion of this application.

Potential conflicts of interest

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

Dr Christine Crooks declared a potential conflict of interest, and the Committee decided to have Christine will abstain from discussion and decision.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- The study is a Phase II, randomized, three arm, open label study to assess the clinical efficacy, safety and tolerability of LEE011 + everolimus + exemestane compared with LEE011 + exemestane compared with everolimus + exemestane (this arm is the standard treatment) in the treatment of postmenopausal women with estrogen receptor positive, Her2 negative locally advanced or metastatic breast cancer.
- The subjects will be randomized 2:2:1 to one of the three arms of the study. Study is looking at standard therapy and an experimental therapy.
- The Committee requested that the randomisation process is made clear (in the PIS), including the chance to get standard treatment or some form of the study drug.
- The need for a study biopsy will be very minimal, but not zero chance.
- Please clarify how many procedures are additional to standard treatment for participants. CT scans will be required
- The Committee queried why the PK tests will look at DNA as well as bio-markers and why the DNA testing was not in the bio-banking optional PIS.
- The researchers agreed further information on tissue storage was required on the PK test and optional bio-banking PIS.
- Please clarify the term ‘nonstandard visit’. The researcher clarified that any additional visits that are related to the study will be paid for. Please clarify this for participants to ensure they understand their compensation.

- Committee queried whether phase I trial results were available. The researcher explained that they did not have this information, as they are only taking part in the phase II trial. The Committee noted that the study commencement at the DHB was conditional receiving results from the phase 1 trial results.
- The Committee asked whether the PIS would include a dose range.
- Committee requested that any comments from the Maori consultation are sent to HDEC, particularly relating to bio-banking.

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

– The PIS is very difficult to read. Please review the use of technical language and make the PIS more readable to the lay person.

- The Committee requested the following changes to the OPTIONAL tissue banking Participant Information Sheet and Consent Form:

– The bio-banking form will need a large amount of revision, for instance where the tissue is being stored.
– Include the word ‘optional’ in the bio banking study PIS and CF.
– The Committee is not inclined to approve indefinite storage. Please state a finite time , e.g. 15 years
– Be explicit with regard to the patient information that will accompany the human samples, in particular for those samples going overseas.
– Please be explicit when covering incidental findings, the risks and the referral follow up processes in place for any incidental findings.
– Please add a section on ‘what happens to my samples’, such as in the case of death.

Decision

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

- Please amend the separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research taking into account the Committee’s suggestions (*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*).

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

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6	**Ethics ref:**	**14/NTA/33**
	Title:	Dunedin Colorectal Cohort
	Principal Investigator:	Professor John McCall
	Sponsor:	University of Otago
	Clock Start Date:	27 February 2014

Professor John McCall 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 ethical issues

The main ethical issues considered by the Committee were as follows.

- The Committee queried if there are two aspects of the application.
- The first aspect is to amalgamate the historical tissue samples into a consistent ethical approval to store beyond initial consented duration.
- The second aspect relates to prospective collection and 'use' of tissue.
- The Committee acknowledged the value of the tissue.
- These tissue studies and that the value of the cohort study outweighs the risk not obtaining re-consent.
- The Committee suggests using the New Zealand Census question in the place of the ethnicity question on the PIS provided.
- Could the researcher clarify whether historical samples have been overseas and if there were any plans to send historical samples overseas?
- The Committee requested more information about the protocol, noting it was version 1. The Committee was unsure whether the version 1 protocol supplied was an amended protocol building on prior practice. Please clarify. Copies of any prior documents would be appreciated
- The Committee would be interested in details of any publications related to the historical samples
- Could you please confirm the intention of the attached PIS, the Committee was not confident that the PIS relates to the historical studies or is the new PIS for ongoing collection.
- The Committee felt that the retrospective component could be approved but wanted further review of the PIS for prospective consent.

- The Committee requested the following changes to the Participant Information Sheet and Consent Form:
  - Describe the processes that will be followed where there adverse findings from the new testing
  - The Committee suggests the researchers read the storage of future MOH guidelines for guidance on the requirements to bio-bank human tissue (http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0)
  - Please clarify if patient is consenting to unspecified use of tissue? Or are there specific tests and it is just the new technology for analysis that is to be used?
  - If unspecified use who will be approving future research?
  - Needs to be clear in PIS
  - Please clarify in PIS re tissue and blood being sent overseas
  - Will sample be de-identified or delinked
  - Will patient be able to get tissue back?
  - Will patient be informed of any results?
  - What process is followed with incidental findings?
  - What if patient dies will family be informed of any incidental findings?
  - Will sending samples overseas be optional? E.g. if some groups want to participate in study but do not want samples to go overseas?
  - How will samples be stored and managed?

Decision

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

- Please amend the separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research taking into account the Committee's suggestions (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
- A tracked changes version of the exiting protocol and PIS and the changes made as requested by the Committee.

This following information will be reviewed, and a final decision made on the application, by Dr Christine Crooks, Dr Brian Fergus and Mr Kerry Hiini.

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7	**Ethics ref:**	**14/NTA/34**
	Title:	Phase 3 randomised, double blind, placebo-controlled study to demonstrate the efficacy and long term safety of DUPILUMAB in adult patients with moderate-to-severe Atopic Dermatitis
	Principal Investigator:	Dr. Gordon Dean Millar-Coote
	Sponsor:	PAREXEL International Pty Ltd
	Clock Start Date:	27 February 2014

Dr. Gordon Dean Millar-Coote 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 ethical issues

The main ethical issues considered by the Committee were as follows.

- The study involves study drug administered for patient population with atopic dermatitis.
- The Committee noted the sponsor or researchers cannot restrict access to personal health information, even during the time the study is active. Please remove this statement from PIS.
- No insurance certificate for cover of participants. Please submit.
- Please include information about access to medication after study has closed. Is the study drug available after the trial as closed? Are there side effects related to coming off the study drug? If so, please include in PIS.
- The Committee requested a reasoned justification for the placebo arm noting that having the control group inject themselves each week for a year is a substantial commitment. Why not just monitor the placebo participants?
- The PIS is unnecessarily long. Please reduce length layman friendly (after all participants are volunteering for a lengthy trial).
- The fact there are multiple sites does remove the need for Maori consultation. Please be specific as to which organisation is being consulted at which site. If consultation is impractical, please explain why.
- Committee suggests on-going consultation with Maori to ensure future research on the samples is managed appropriately.

- Please explain the term use of 'health information has no expiration date'. The Committee requests a time frame for retention of health information.
- B.1.1 – 'immunogenicity', please explain the level of risk this poses for participants.
- P.3.1 please explain the planned use of recruitment clinics.
- Committee requests that questionnaires do not have areas for participants to record their name as this poses confidentiality risks.
- Please remove references to US law.
- Please clarify the status of ethical approval in other countries.
- The Committee suggests the researchers read the storage of future MOH guidelines for guidance on the requirements to bio-bank human tissue (http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0)

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

- Please include duration samples will be kept.
- Please include information on how incidental findings will be managed.
- Include information on disposal of tissue.
- Include purpose of future research.
- Add a section 'Who will access my samples'.

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

– Please include information on confidentiality, for instance that information will be de-identified. (pg. 11)
– Please explain reasoning behind the study and what is involved (Injection every week for a year – what is required for participants).
– Include information upfront about why the participant has been approached to participate.
– The Committee suggests moving the purpose of the study to the top of the 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*).
- Please amend 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*).
- Justify use of Placebo *(Ethical Guidelines for Intervention Studies para 5.22)*
- Provide further information on the recruitment process (*Ethical Guidelines for Intervention Studies para 6.2)*

This following information will be reviewed, and a final decision made on the application, by Ms Shamim Chagani, Dr Brian Fergus and Ms Susan Buckland.

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8	**Ethics ref:**	**14/NTA/36**
	Title:	p16 as a surrogate biomarker for the presence of Human Papillomavirus (HPV) infections in oropharyngeal squamous cell carcinoma
	Principal Investigator:	Mr Peter Ou
	Sponsor:	University of Auckland
	Clock Start Date:	27 February 2014

Mr Peter Ou 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 ethical issues

The main ethical issues considered by the Committee were as follows.

- Mr Ou explained that the study aims to verify the accuracy of the p16 by using a different, standard, diagnostic test on the samples that have already been tested with p16.
- Mr Ou added there is a second component of the study that aims to assess whether the rate of cancer has decrease or increased over a period of time by linking patient information and drawing links between public health initiatives and HPV.
- Mr Ou stated the ADHB uses the P16 test due to its affordability and this test is the standard practice diagnostic tool.
- The Committee clarified that the research is presented for an University of Auckland honours project, not as ADHB research.
- The Committee noted the purpose of the research was confused between the ethics application and the protocol. Various aspects, such as diagnostic testing and HPV prevalence and health statistics, were not part of a structured project goal or study question, and were found in various parts of the applications.
- Mr Ou clarified that the primary aim is to determine accuracy of the p16 test, which is current standard practice.
- The Committee noted that test cohorts could be described but cautioned that extrapolating this information to a New Zealand population is not possible due to the sample size.

- The Committee queried why the researcher was looking back at past tests. The researcher explained that they wanted to also review the prevalence of HPV over the last 30 years. The Committee stated this would not be considered in the scope of this application and would require further HDEC application. This application related to comparing diagnostic testing.
- The Committee explained that any re-testing is unconsented and the standard surgical consent does not cover future unspecified use, in this case for research. The consent only covers diagnostic testing relating to participants samples relating to their health and internal quality assurance.
- The Committee and would be willing to accept an Expedited application for this second part of the study
- The Committee felt the justification for not seeking consent was only acceptable in cases when the samples had prior P16 tests where Mr Ou is only seeking to validate the test. The database creation and the health information relating to risk factors are required to validate the test and should be considered in a separate ethics application.
- The Committee confirmed they would only consider approving the application with regards to the P16 re-testing and not the patient data linking or risk factor analysis.
- The Committee queried how many samples are to be tested. Mr Ou clarified the pilot was 20 but aim to do all 200 if it turns out to be feasible.

In summary:

- The Committee suggests splitting the project into two applications. The first is to run the diagnostic testing which it is prepared to approve.
- Mr Ou can then submit an expedited application to link the health information and risk factors once testing has completed.
- The Committee requests a new protocol is submitted with the limited scope involving only re-testing the tissue samples in a de-identified format. The Committee expects the tissue to be de-identified by the laboratory and then given to Mr Ou to re-test.

Decision

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

- A new protocol that clearly states what testing will occur, how samples will be managed and how many samples will be tested (*Ethical Guidelines for Observational Studies para* 5.11).

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This following information will be reviewed, and a final decision made on the application, by Mrs Karen Bartholomew, Dr Brian Fergus and Ms Susan Buckland.

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General business

1. The Committee noted the content of the "noting section" of the agenda.

   - The Committee discussed 14/NTA/10 and considered the legal advice given. The Committee reached a consensus and agreed to decline the application.

   - The Committee discussed how New Zealand was considered a viable place to start research, noting that New Zealand is often the first country to be approached for ethics approval.

2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

Meeting date:	08 April 2014, 01:00 PM
Meeting venue:	Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland

The following members tendered apologies for this meeting.

1. Mrs Karen Bartholomew is tentative.

3. **Problem with Last Minutes**

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

4. **Matters Arising**

   - The Committee discussed length and density of PIS and talked about methods to address this, including using some examples from researchers to show how a PIS can make complex information accessible.
   - The Committee discussed the changes that need to be made for the template PIS/CF – including more information on compensation and more white space formatting.

The meeting closed at 5.15pm