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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 26 May 2015 |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 28 April 2015 |
| 12.30pm | New applications (see over for details) |
| 12.30-12.55  12.55-1.20  1.20-1.45  1.45-2.10  2.10-2.35  2.35-3.00 | i 15/CEN/61  ii 15/CEN/62  iii 15/CEN/63  iv 15/CEN/64  v 15/CEN/66  vi 15/CEN/67 |
| 3.05pm | General business:   * Noting section of agenda |
| 3.15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Gael Donoghue | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Apologies |
| Dr Dean Quinn | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Apologies |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Stephanie Pollard | Non-Lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Dr Dean Quinn and Dr Patries Herst.

The Chair noted that fewer than two appointed non-lay members of the Committee were present, and that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Mrs Stephanie Pollard confirmed her eligibility, and was co-opted by the Chair as member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 28 April 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/CEN/61** |
|  | Title: | Play and Anxiety in Hospitalised Children |
|  | Principal Investigator: | Ms Esther Leauanae |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 14 May 2015 |

Ms Esther Leauanae 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

* This study will look at the impact of therapeutic play is on the anxiety levels of children in hospital to see if it is beneficial.

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 the researcher what the age group/s of the children she wishes to recruit to the study will be. The researcher advised that it would be somewhat open as she does not know how old the children who present at hospital will be at this stage but the age range will be primary age school children (5-11 years).
* The committee advised that the researcher the forms that the researcher is currently asking it to approve are not appropriate for understanding at a 5 year old level. The committee advised that the accepted age group split for assent forms for children are 5-7 years old and 7-12 years old and that it would like to see an assent form for each age group. The committee would expect to see the same information given in a different way for these age groups and would expect that the assent form for 5-7 year olds has limited wording and pictures (e.g cartoon picture of a worried person crying). The committee suggested that the researcher may wish to contact ex-colleagues at Starship Hospital for some examples of information sheets and assent forms for children. The researcher may also wish to refer to examples of information sheets on the HDEC website: <http://ethics.health.govt.nz/home>.
* The committee queried why there are two consent forms for parents? The researcher explained that parents will also be participants in the play session and she is seeking their consent to participate as well as their consent for their child to participate. It was thought that combining the two into one might be confusing for the parents. The committee suggested that the researcher combine the two into one but have two distinct sections – one for the parent and one for the child.
* The committee noted that the researcher is looking to recruit 10 participants to the study and the researcher confirmed this – 2 children, their parents and 2 play specialists. The committee queried whether the researcher expected to get reasonable data with that number of participants? The researcher explained that the study design is a single case study that will look at minute changes of anxiety behaviour throughout admission. The single case study design is typically used for such studies because it is hard to do larger group studies for something this specific.
* The committee noted that the peer review included with the application was completed by the researcher’s supervisor and asked that the researcher seek independent peer review from someone not participating in the research.
* The committee noted the answer given on the application form at question r.1.3 that standard treatment will be withheld from participants and asked whether participation will mean intentional delay for having the play intervention? The researcher advised that it would be delayed for two days to test baseline (no play), and that this can fit with natural circumstances such as a child being admitted to hospital on a Friday and not receiving the play therapy until the Monday (because play specialists do not work on the weekend). If a child is admitted on a weekday standard treatment is that they wouldn’t have to wait for two days to receive the play therapy. The committee was concerned that a child who was admitted to hospital and was feeling anxious would need to wait for two days. The committee queried whether ‘no play’ for two days could give a true baseline as anxiety levels may alter on admission to hospital and be heightened anyway. The committee asked that the researcher flag this with the independent peer reviewer as it would not be happy if the baseline test was found to not add anything to the study given that standard treatment will be withheld.
* The committee noted the answer given at question a.1.6 on page 5 of the application form the researcher is professionally and personally acquainted with hospital staff as she previously worked as Kidz First Children’s hospital. The committee asked whether the researcher has a plan in place to deal with any conflict of interest that may arise as a result. The committee suggested ways in which the researcher may wish to manage this including having her supervisor listen to the recorded discussion to assess that any conflict of interest is managed.
* The committee requested viewing the questionnaires that will be administered by the play specialist in this study.
* The committee queried whether the statement in the participant information sheet that participation in in the study will not affect the play specialist’s employment can be guaranteed by the researcher? The committee thought that this is an assurance that the employer can give rather than the researcher and asked that this statement be removed from the information sheet.
* Please explain that you will outline the study with parents.
* Please make clear that you will be there at all play sessions unless there is good reason not to be. For example, during the weekend
* Please make clear to participants that they can change their minds about being in the study and can withdraw at any stage.
* Please include in the information sheets that an adequate understanding of English is necessary for participation in this study and the reason why.

Summary of ethical issues (resolved)

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

* The committee noted the answers given at questions p.4.1 and p.4.2 of the application form that are about benefit to and cultural considerations for Māori. The committee advised that consultation with Māori is required unless the researcher intends to exclude Māori from the study, and suggested that the researcher may wish to refer to the Health Research Council’s *Guidelines for Researchers on Health Research Involving Māori.* For future reference, the committee noted that the answers in this question need to be made specific to Māori some of the main cultural issues for Māori could include that the head is considered Tapu, knowledge is Taonga and that the researchers will be dealing with whanau.
* For future reference, question f.1.2 on the application form is intended for populations other than Māori and it would be helpful if you are able to note any known statistics about these groups and how your study might help reduce any inequalities.
* The answer given at question r.1.2.1 on page 14 of the application form gave the impression that a participant’s health practitioner need not be informed that their patient is taking part in the study. The researcher thought that this referred to GPs and advised that other health practitioners will be aware that of an individual’s participation in this study.
* The committee noted that the play specialists may be involved in the study for a month, will administer fear scale and that this may take some time out of their working day. The committee queried whether the employer knows how much time this will take? The researcher advised that the fear assessment will take about 30 seconds to 1 minute after a procedure. Generally in practice, the play specialist will be with a child after the procedure as part of standard practice.
* The committee noted that the intended recruitment process is that participants will we identified by the play specialist as being at risk and then their information given to the researcher. The committee noted that this is a breach of privacy and suggested that the researcher give the information sheets to the play specialists who then distribute to potential participants and ask them to contact the researcher if they are interested in taking part.
* The committee noted the answer given at question r.8.1 on page18 of the application form that the findings of the study will have “considerable implications for paediatric services and subsequently for paediatric patients”. The committee agreed that this is pre-emptive statement and while it did not wish to undermine the value of the study suggested that more appropriate wording might be along the lines of this research possibly leading to further research in the area.

Decision

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

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| *6.10* | The committee advised that the researcher the forms that the researcher is currently asking it to approve are not appropriate for understanding for children who may participate in this study.  *Verbal information provided should be tailored to the individual, taking into account the participant’s level of knowledge and understanding and the amount of detail they desire. Written information provided should be tailored to the study population (for example, it should be culturally appropriate for that study population), and should have a reading age appropriate to that population.*  *When inviting children to participate in any research, the investigator much ensure that the children, and where appropriate, the children’s parents, guardians or caregivers have been fully informed about the research in a manner best suited to their needs. Each child must be given full information about the research in a form that he or she can readily understand.*  *Children must be advised of their right to decline participation and their right to withdraw from the research at any time without giving a reason.*  *Investigators must give the children an opportunity to ask questions and to have those questions answered to the children’s satisfaction.*  *If proxy consent is required, the proxy must also be given full information about the research and be advised of the child’s right to decline participation or withdraw from the research at any time. (Appendix 2)*  The committee noted that the peer review included with the application was completed by the researcher’s supervisor and asked that the researcher seek independent peer review from someone not participating in the research.  *Peer review delivers an objective opinion: Those acting in the capacity of reviewers are charged with delivering a balanced and considered analysis of the research. Generally, the success of the peer review process is determined by the extent to which these evaluations can be considered free of bias, equitable and fair. Objectivity can be compromised if peer reviewers have conflicts of interest, and so appropriate peer reviewers typically will not be materially connected to the researcher(s) in a way that might undermine objectivity, and be free from either positive or negative inducements. (Appendix 1)* |

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| **2** | **Ethics ref:** | **15/CEN/62** |
|  | Title: | The study of Fulranumab as Adjunctive Therapy in Subjects with Signs and Symptoms of Osteoarthritis of the Hip or Knee |
|  | Principal Investigator: | Dr Paul Noonan |
|  | Sponsor: | Janssen - Cilag NZ Ltd |
|  | Clock Start Date: | 14 May 2015 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* The study drug is a monoclonal biological antibody that targets human nerve growth factor as it prevents and modulates pain.

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 noted that the FDA has placed a full clinical hold on all ongoing studies of the drug conducted in a US application due to concerns that that class may be associated either rapidly progressive osteoarthritis or osteonecrosis. The hold has since been lifted.
* The committee noted that participants on the placebo arm of the study will receive standard of care for OA pain therapy in the double-blind phase and that paracetamol will be offered in the wash out and double-blind phase. The committee agreed that a statement be included in the participant information sheet that advises individuals that should their pain become unmanageable that they need to go back to the researcher/contact the study doctor should they need more pain relief.
* The committee noted that ionising radiation not needed for normal clinical management will be administered. The committee noted that the researchers have stated that a medical physics expert has not verified that accurate effective doses have been calculated for this ionising radiation when this is a requirement. (question r.1.13.3 on page 19 of the application form). Please clarify for the committee why this has not been done.
* The committee noted that the researchers have stated that participant recruitment will be via data bases and advertisements. Please submit copies of the advertisements that you will use.
* Please follow the MHRA advice relating to questions 8,9 and 10 as they are about safety and also note page 15 of the CBG advice regarding long term administration.

The committee requested the following changes to the participant information sheet and consent form:

* Please include a lay title.
* Please revise the sheet and check the drug names are relevant to New Zealand and a New Zealand audience.
* In the interests of informed consent, please state the following exclusion criteria that may not be evident from an individual’s medical records: viral infection, stroke or seizures, cardiac events, allergies, chronic steroid use and history of or current use 3G paracetamol per day.
* Page 3: please revise the information given under the headings ‘May we contact your other doctors? and ‘Agreement to allow the study doctor to obtain information from your other doctors’ as information is repeated here.
* Page 22: please remove the information about future research and genetic research and include it on the optional information sheet only.
* Page 24 of the main sheet and page 6 of the optional sheet: please check the layout and separate the information starting at the heading ‘If you consent, please read and then sign below’ from the information sheet and include it on the consent form.
* Please state that ethical approval is from the Central Health and Disability Ethics Committee.
* Page 14, side effects: please revise the information and remove any duplication. The committee noted that the rare effects such as osteonecrosis are not listed. Please clarify for the committee why you have not included these.
* Page 26: at the first set of tick boxes please include “or no” as it currently reads “please check yes” – tick boxes – please tick yes! Please remove the repeat reference to the paragraph beginning: “I have been informed that if I have a joint replacement surgery…” as it appears twice.
* The committee noted that the researchers answered ‘yes’ to question r.4.1 on the application form that the study might produce findings that may be both unexpected and clinically significant. Please state this in the participant information sheet and state how this will be managed. You may wish to use the detail given in your answer to question r.4.1.1.

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 clarify why you have not had a medical physics expert verify that accurate effective doses have been calculated for this ionising radiation when this is a requirement.
* Please submit copies of the advertisements that you will use to recruit participants.

This information will be reviewed, and a final decision made on the application, by the Chair, Mrs Gael Donoghue and Dr Cordelia Thomas.

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| **3** | **Ethics ref:** | **15/CEN/63** |
|  | Title: | Edoxaban in Venous Thromboembolism (VTE)Associated with Cancer (Hokusai VTE Cancer) |
|  | Principal Investigator: | Dr Gordon Royle |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 14 May 2015 |

Dr Gordon Royle and Mrs Catherine Howie 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

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

* The committee complemented the researchers on a well put together application and information sheet. The committee noted that it did not have any major ethical concerns about this study.
* The committee queried whether there is any risk to the partners of male participants becoming pregnant. The researchers noted that they did not think that there were any cautions in previous trials in this regard but that they would double check and confirm this for the committee.
* The researchers brought the committee’s attention to the answer stated at question b.4.4 on page 15 of the application form. They have stated that data generated in the study will be made available for use in future research. They advised that the raw data will not be made available but the findings will be and could not envisage a scenario that would require this unless a larger study or meta-analysis is needed. One possible scenario could be that the sponsor may want to use the raw data as they use meta-data but they would still be answering the same questions that the data was collected for. The committee stated that it was useful to hear clarification of the intentions of use of the data. The committee noted that it was useful for future reference as the application form itself cannot be changed once accepted for review.
* For future reference by way of providing clarification at the meeting the committee asked why it was stated that researchers will retain records for a period of 2 years at question r.2.5 on page 20 of the application form as the statutory requirement is 10 years. The researchers advised that their policy is that health information be kept for up to 15 years and that the 2 year timeframe looked to have been entered in error.
* The committee sought clarification on how long blood samples would be stored for. The researchers confirmed that the samples will be held at QLAB for the duration of the study.
* For future reference, the committee noted that some statistics on the overall population would have been helpful at question f.2.1 given that they had stated at question f.1.1 that the study might contribute to reducing inequalities in health outcomes between different populations.
* The committee complemented the researchers on their recognition of cultural issues for Māori and also the fact that they had reiterated the importance of participants making known to researchers any over the counter meds being taken.

The committee requested the following changes to the participant information sheet and consent form:

* The committee queried whether there is a possibility that study title might be simplified? The researchers advised that it cannot be changed in anyway as it comes from the study protocol. The committee asked that a lay title be included before that main title and made prominent.
* Please provide up front a statement confirming that personal information is held in confidence as a reassurance for anyone starting to read through the document.
* The committee requested that the researchers proof-read the document to check for typos.
* Page 2: the committee requested that the flow chart be adapted to be more user-friendly and that lay terminology be used so that participants understand what is being shown to them.
* Please include in lay terms the following exclusion criteria from question f.2.1 on page 28: 2,3,9,13 and 15 and also the inclusion number 3.

Decision

This application was *approved* by consensus.

Non-standard conditions of approval are:

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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| **4** | **Ethics ref:** | **15/CEN/64** |
|  | Title: | Ki67 and Mitotic count in endocrine sensitive early breast cancer |
|  | Principal Investigator: | Dr Sarah Barton |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 May 2015 |

Dr Sarah Barton 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 researchers plan to used archived tissue samples from 2000-2009 and correlate test scores with clinical data to determine prognostics and potentially spare people from having any unnecessary chemotherapy. The committee agreed that this is an important study.
* The committee noted the answer given at question p.4.2 on page 18 of the application form that donors have all agreed that their tissue can be stored and used for research purposes. The committee queried whether consent was either written or verbal? Dr Barton advised that consent where given is written consent and that there will be some individuals from the period 2000-2002 who have not signed the form.
* The committee queried whether the research team could exclude samples and data taken from patients prior to 2002 and reach the numbers required to do the study without running the risk of biasing the results? If this is doable it would protect the important right of participant consent and that would be preferable. The committee noted however that if Dr Barton did find that there might be bias when embarking on reaching the numbers required that she could submit an amendment to the study to use samples and data from 2000-2002.
* The committee queried whether the research team have access to mortality data about the individuals whose samples and data they would like to use. Dr Barton advised that this population has a reasonably good prognosis so it is likely that many will still be alive.
* The committee agreed to approve the study for patients who have given consent only.
* The committee noted that for future reference question p.4.1 on the application form asks about how the study might benefit Māori and advised that any known statistics about breast cancer in Māori women would have been useful here. The committee noted that the Health Research Council Guidelines for Researchers on Health Research Involving Māori is a helpful reference document when it comes to answering these questions. The committee also advised that known statistics about pacific island and other NZ populations would have been useful at question f.1.2 on page 19 of the application form.

Decision

This application was *approved* by consensus.

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| **5** | **Ethics ref:** | **15/CEN/66** |
|  | Title: | The effect of lifestyle interventions on non-disabling Stroke and TIA patients. |
|  | Principal Investigator: | Mr Vishal Nagar |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 14 May 2015 |

Mr Vishal Nagar and Dr Jeremy Lanford 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.

Dr Cordelia Thomas declared a potential conflict of interest. The committee decided that it was not substantial enough to require that Dr Thomas to leave the room and not take part in the discussion.

Summary of ethical issues (resolved)

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

* The committee asked whether participants in the control arm of this study will receive care. The researchers confirmed that participants in the control group will receive standard care as per the New Zealand guideline recommendations for post-stroke care.
* The committee noted that one of the main ethical issues the researchers identified was that only patients recommended by a stroke physician will take part in the study and the committee noted that it was satisfied with this from a safety perspective.
* For future reference when completing the application form, the committee noted that the taking of blood is a cultural issue for some Māori.
* The committee advised that known statistics about pacific island and other NZ populations would have been useful at question f.1.2 on page 25 of the application form.
* The researchers confirmed that they will go through the information sheet with participants so that the information is given both verbally and in writing.

Summary of ethical issues (outstanding)

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

* Peer review: the committee noted that there is no endorsement from the peer review group about whether or not the study should go ahead. The researchers confirmed that the study has been discussed thoroughly joint venture from James Faulkner.
* The committee noted that one of the peer reviewers was also a researcher and agreed that it would like to see peer review from a third party who can provide an objective opinion without a perceived conflict of interest. The committee asked whether this is possible and the researchers agreed that they would seek peer review from someone independent of the study. The researchers may wish to use the HDEC peer review template, which is on the HDEC website homepage under the ‘Quick Links’ section: <http://ethics.health.govt.nz/>.

The committee requested the following changes to the participant information sheet and consent form:

* Please review the documents for typos.
* Please insert footers so that version numbers can be tracked in future.
* Page 2: Please state that the Central Health and Disability Ethics Committee has given ethical approval for the study.
* Page 2: last paragraph. Please state that people are invited to sign the consent form if they choose to participate. The wording as it stands appears presumptive.
* Page 3: second paragraph. Please state that the standard procedures are not “expected” to cause any discomfort or harm.
* Page 4: please include more information in the intervention descriptions. For example, give examples of exercises and what the dietary changes might be.
* Page 5: under the heading possible benefits and risks to you of participating. Please state that the usual parking fee will apply at Wellington Hospital.
* Page 5: under the heading possible risks and benefits: please state that participants may not receive any benefit from being in this study.
* Please inform participants that they will be eligible to apply for compensation through ACC. The following is taken from the HDEC PIS/CF pro forma:
  + *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 state on the consent form that any information about participants will be held in confidence.
* Please simplify some of the descriptions around inclusion/exclusion criteria so that they are understandable for a lay audience. Please include Atrial Fibrillation in the exclusion criteria.
* Please state that the taking of blood is a cultural issue for some Māori.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide evidence of scientific peer review for this study from a third party that can provide an objective opinion without there being any perceived conflict of interest.

This information will be reviewed, and a final decision made on the application, by Mrs Gael Donoghue and Mr Paul Barnett.

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| **6** | **Ethics ref:** | **15/CEN/67** |
|  | Title: | Splenic Flexure Lymph Node (SFLN) Study |
|  | Principal Investigator: | Dr Carolyn Vasey |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 May 2015 |

Dr Carolyn Vasey 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

This study will examine lymph node drainage of the Splenic Flexure in the hope that it will help inform surgeons whether the left or right side of the transverse colon is responsible for lymphatic draining. The knowledge gained from this study may help stop secondary cancers and improve secondary outcomes. The committee noted that the idea is commendable.

Summary of ethical issues

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

* The committee commend the researcher on the use of visuals in the participant information sheet and consent form.
* For future reference please note that the details to be stated at question a.4.1 on the application form are those of the primary contact person.
* Application form p.1.1 page 16. The committee was concerned that the information sheet would be given to potential participants on the morning of their operation and this would not give them enough time to consider and discuss. Dr Vasey explained that when patients are diagnosed they go through a work up period of up to a month and are seen by surgeons in outpatient clinics where families also come. The information sheet will be extended to patients at that point, which is 2-3 weeks prior to surgery. A research nurse will then contact patients to ask if they wish to be involved. Consent for surgery will be on the day but preparation and education is done 2-3 weeks prior. Participants will be taken through the information verbally and the researchers will use visuals – in this way the written information will supplement the conversation. Patients will have time to consider the information. The committee noted that having a research nurse follow up removes the hierarchy.
* The committee noted that usually an investigator will go through the sheet with the participant. In this case it does not appear that it will be the case and the committee would like to see the opportunity for participants to go through and ask questions.
* The committee discussed whether further inclusion/exclusion criteria is needed in the information sheet and agreed that only that which is not in patient medical records will need to be included. Dr Vasey confirmed that surgeons will only invite participants who meet the criteria to the study and that this information will be in their medical notes.
* Dr Vasey confirmed for the committee that an in house consultation with Māori has taken place. They anticipate no or low numbers of Māori in this particular study. For future reference the committee noted that this is the kind of information, along with any known statistics, that is useful at question p.4.1 on page 19 of the application form.
* Question p.4.2. on the application form asks what cultural issues may arise for Māori. A cultural issue for Māori A product made from human blood and is an issue for some Māori and this should be stated in the application form. The committee suggested that this information be passed on to person who completed the application form.
* The committee queried how long the procedure might take and Dr Vasey advised that it could take up to 15 minutes in total which includes standard pre-operative prep time.

The committee requested the following changes to the participant information sheet and consent forms:

* The committee noted that some information in the consent form is not included in the information sheet (e.g study will be stopped if it appears harmful), and asked that the researchers review both documents and include the information in the information sheet as it is useful for people to have the information in one document rather than having to find it across two different documents.
* Please state upfront why people are being invited to the study. Question b.2.1 on page 10 of the application form states this and the researchers may wish to use this information.
* Page 3 and page 5: please combine the information about confidentiality under one heading.
* Page 4: please clarify that information about the study will be discussed and decided with researchers prior to signing the consent form which is done on the day of the procedure.
* Page 4: please review this page for typos.
* Page 5 under the heading ‘Safety’: the committee noted that the statement “Allergic reactions to radiopharmaceuticals may occur but are extremely rare and are usually mild” seemed a bit loose when compared with the consent form which states that they are mild to serious. Please review both documents and make sure that this information is consistent.
* The committee queried whether the researchers will feedback any technical aspects to the participant and whether there would be any benefit to them or impact on their standard care in any way. Dr Vasey confirmed that participants would get the same standard of care regardless. She will let patients know how the procedure has gone and then explain what part removed. The committee asked that the following be made clear to patients: that participation will have no benefit to participants/that this research is not about them receiving any benefit or altering standard care in any way.
* Please be clear about whether Mr Hulme-Moir has expertise using the technique with bowel cancer or melanoma patients.
* Please remove reference to “treatment” being stopped and replace it with “procedure”.
* The committee noted that information sheets usually have a statement about what compensation participants may be eligible for in the event of medical misadventure. Dr Vasey advised that this is included in the pre-operative consent that includes a statement about the risks involved. The committee agreed that there was no harm if that was the case but noted that the information sheet could state that the surgery is being conducted as research and include the following statement:
  + *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.*

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*).

This information will be reviewed, and a final decision made on the application, by Mrs Gael Donoghue and Mrs Sandy Gill.

## 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:** | 23 June 2015, 08:00 AM |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington , 6011 |

No members tendered apologies for this meeting.

The meeting closed at 3.15pm.