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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 08 March 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1:00pm | Welcome |
| 1:05pm | Confirmation of minutes of meeting of 09 February 2016 |
| 1:30pm | New applications (see over for details) |
|  | i 16/NTA/22  ii 16/NTA/18  iii 16/NTA/24  iv 16/NTA/23  v 16/NTA/21  vi 16/NTA/50 |
| 3:50pm | General business:   * Noting section |
| 4:00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 11/11/2015 | 11/11/2018 | Present |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 11/11/2015 | 11/11/2016 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Present |
| Dr Christine Crooks | Non-lay (intervention studies) | 11/11/2015 | 11/11/2018 | Present |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 11/11/2015 | 11/11/2016 | Present |
| Dr Kate Parker | Lay (consumer/community perspectives) | 11/11/2015 | 11/11/2018 | Present |
| Dr Charis Brown | Non-lay (intervention studies) | 11/11/2015 | 11/11/2018 | Apologies |

## Welcome

The Chair opened the meeting at 1:00pm and welcomed Committee members, noting that apologies had been received from Dr Charis Brown.

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 09 February 2016 were confirmed.

## New applications

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| 1. | **Ethics ref:** | **16/NTA/22** |
|  | Title: | Prognostic models for women with breast cancer in New Zealand |
|  | Principal Investigator: | Professor Mark Elwood |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 February 2016 |

Professor Mark Elwood and Dr Sandar Tin Tin were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study follows a number of previous HDEC approved studies using data from breast cancer registries.
2. This study involves secondary data analysis to validate and develop a prognostic model for patients diagnosed with breast cancer in a New Zealand context. Six international models will be tested with New Zealand data.
3. New Zealand has four large breast cancer registries that contain data on patients with breast cancer. An HRC funded study based in the Waikato has already analysed the Auckland and Waikato registries together, and linked this data with a range of datasets relevant to diagnosis, treatment and outcomes. The researchers intend to use this pre-linked data and augment it with a small amount of data required to test the prognostic algorithms (as outlined in the application).
4. These registries have approval to operate based on automatic enrolment of women (a consent form is not signed). For example prior to 2012 the Auckland breast cancer registry operated with informed consent, however a study found that this produced misleading and biased information. The Researcher indicated that patients from a higher socio-economic background were more likely to give consent, thus the samples were skewed. When the registries operated on the basis of consent the results found a significant overestimate of survival. Because of this bias produced by obtaining informed consent, with HDEC approval the registries transitioned to a non-consensual recruitment model and now all patients with breast cancer in New Zealand have their data included.
5. This study requires the use of identifiable health information as the researchers need to link the information from the registry with other health information through participants NHI number. However, once the data is linked and pulled into the study all identifiers, including NHI, will be removed.
6. The purpose of this study is to combine data from the National Cancer Registry, the Auckland and Waikato Breast Cancer Registries, and Hospitals to determine whether predictive models used overseas are accurate within New Zealand, and, ultimately, to develop a more accurate predictive model for New Zealand patients diagnosed with breast cancer.
7. The Researcher stated that they want to work with clinicians to ensure that any prognostic tool developed is useful.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether participants or their doctors would be contacted at any point for this study. The Researcher explained that they did not intend to contact participants or their doctors at any point this is prognostic model validation only.
2. The Committee noted that accessing participants NHI number would provide the researchers with quite a lot of private information about these participants. The Researcher acknowledged this and stated that this was essential as they want to look widely at factors that may contribute to breast cancer patient’s prognosis. The Researcher also indicated that once data was collected, the identifying information would be removed so that the analysis was conducted on de-identified data.
3. The Committee questioned whether individual participants could be identified through the results of this study. For example, if the results described one participant of a minority group living in a specific area and of a certain age then this may identify the individual to those that know them. The Researcher stated that the results would identify groups, and they would expect that these groups would contain at least 100 participants so no individual participants could be identified.
4. The Committee questioned whether HRC funding would be sought for this study as the application indicated that it may be. The Researcher explained that although they could apply for HRC funding they are unlikely to as although the study involves a lot of work it shouldn’t require a lot of funding and they are more likely to apply for smaller local funding.
5. The Committee questioned whether all patients in the registry would be included in the study. The Researcher explained that they intended to include most patients, however, some patients with limited follow up or other subgroups may be excluded.
6. The Committee questioned whether data collected prior to 2012 would be included as they had previously stated that this data was bias due to the requirement for consent. The Researcher explained that this data had retrospectively been expanded to include information from patients who did not provide consent and that this allowed the reliable use of this data. The Researcher stated that they expected to include information going back to about 2006.
7. The Committee noted that the application spoke of an advisory group that would be set up, and questioned whether this has started. The Researcher clarified that they are currently looking in to this and that they know that this group will include Maori and Pacific Island representation and clinicians and will likely meet 3 times per year to consider whether the project is leading to a useful outcome. The Committee requested that when this advisory committee is set up that they are advised of the arrangements for this and the makeup of the committee.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **16/NTA/18** |
|  | Title: | Evaluating the addition of Regional Analgesia to reduce post-operative delirium in patients having Hip Fracture surgery. (RASAPOD) |
|  | Principal Investigator: | Dr Tin Chiu |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 February 2016 |

Ellen Waymouth and Dr Timothy Short were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study considers whether the use of a local nerve block in patients having surgery for a fractured hip has an impact on their level of delirium.
2. The goal is to reduce delirium without compromising pain management in these patients.
3. All participants in this study will receive standard of care anaesthetic and will be randomised to two study arms, one group will receive a nerve block and another arm that will not receive this.
4. Nerve blocks are part of usual practice (i.e. general anaesthetic with or without nerve block can be considered part of standard care) in some locations for post-operative pain management, but this study is looking at delirium specifically.

Summary of ethical issues (resolved)

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

1. The Committee questioned the follow up arrangements as a twice daily cognitive testing follow up seemed quite burdensome. The Researcher explained that twice daily follow up was ideal to assess delirium, however if this was deemed to be too burdensome at the time for the participant they would not need to complete all follow up activities every day and may be withdrawn from the study. This is part of the feasibility assessment.
2. The Committee noted that this is a pilot study and questioned whether 50 participants was suitable for a pilot. The Researcher stated that they were comfortable with the recruitment size.
3. The Committee questioned how long the researchers expected to take to recruit 50 participants. The Researchers stated that they expect recruitment to take 6 – 12 months.

Summary of ethical issues (outstanding)

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

1. The Committee noted that participants in this study are potentially vulnerable as they may include frail elderly and will include patients in pain and potentially confused from a recent fall and fractured hip. The committee request an assurance from the researchers around the process for consent to this study in that context. The Researcher acknowledged this concern and stated that most patients will be operated on 12-24 hours after admission and that this should provide sufficient time for the consent process and for participants to consult with their family and whanau regarding the study before deciding to be involved.
2. The Researcher explained that most patients would have a family member or carer present and that if concerns were raised about the participant’s understanding of the study or ability to consent family could be consulted. The Committee noted that although it is good to discuss the project with these family members they cannot provide consent on the participant’s behalf and the participant must be deemed competent to consent for themselves.
3. The Researcher confirmed that they would not approach participants deemed unable to consent for themselves for this study, however, they noted that previous studies have included non-consenting participants who have family available to provide consent. The Committee stated that this application only covered participants who are able to consent for themselves and that proxy consent is not acceptable.
4. The Committee questioned whether patients who failed the MOCA completed at baseline would be considered competent to give consent. Also whether pre-existing alcohol or drug use may have a bearing on competency or study outcome. The Researcher explained that they had not considered this scenario yet but they would consider this and inform the Committee. The committee noted Geriatrician involvement with the study and requested their view on competency for consent. The committee requested a written statement of the consenting process.

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

1. The Committee questioned whether the 90 day follow up was done by phone. The Researcher confirmed that this is done by a phone call. The Committee requested that this is clarified in the Participant Information Sheet and that this section is rephrased in appropriate lay language as a calling it a 90 day mortality follow up may cause unnecessary concern for participants.
2. The Committee noted that the Participant Information Sheet contains a lot of jargon and needs to be simplified, including rephrasing words like delirium.
3. Please add the risks of the nerve block to the Participant Information Sheet, although this is a small risk it must still be stated.
4. The Committee stated that some of the sections in the Participant Information Sheet may not be necessary for this study and although they are included in the HDEC template they are more suitable for clinical trials and unnecessary for this study. The Committee suggested that removing or reducing these sections may improve readability.
5. Please add a statement to the Participant Information Sheet in the compensation section to inform participants that if they have private health insurance they should check with their insurer whether their participation may impact their cover.
6. Please add to the consent form a statement about access to participants health information to ensure it is clear that they are consenting to this being accessed.
7. Please add the researchers contact details to the Participant Information Sheet.
8. Please state in the Participant Information Sheet that participants’ GPs will be contacted as this should not be optional for this study.
9. Please add information considering drug and alcohol use in terms of determining competency or outcome.
10. The Participant Information Sheet refers to cancer in some parts, please ensure this is amended for accuracy and clarity.

Decision

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

1. The Committee asked the researcher to confirm the consent and recruitment arrangements for this project, including how it will be determined whether participants are competent to provide informed consent. Please explain these processes more fully.
2. Please clarify the data safety monitoring arrangements for this study as the application states that this study has independent data safety monitoring and the Committee questioned whether this is accurate.
3. The Committee noted that the participant questionnaires had not been uploaded with the application, please provide these for our records.
4. Please amend the information sheet and consent forms, 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, by Dr Christine Crooks and Ms Susan Buckland.

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| **3** | **Ethics ref:** | **16/NTA/24** |
|  | Title: | Testing the combination of an experimental agent Enzalutamide Plus AndrogenDeprivation Therapy (ADT) Versus Placebo Plus ADT in Patients with Metastatic Hormone Sensitive Prostate Cancer (mHSPC) |
|  | Principal Investigator: | Dr Peter Gilling |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 25 February 2016 |

Dr Peter Gilling and Rana Reuther were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study involves 1100 participants over 250 study sites worldwide.
2. SCOTT approval is currently being applied for.
3. The Researcher explained that they believe this study will provide important clarification regarding the role of the study drug in this patient group.

Summary of ethical issues (resolved)

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

1. The Committee questioned the use of a placebo in this study. The Researchers clarified that the placebo arm in this study is essential for scientific validity and involves standard of care only and the study arm is standard of care plus the study treatment. The Researcher explained that standard of care involves a treatment provided 3 monthly to control the patient testosterone levels. The study arm involves the addition of an oral drug taken daily, participants in the placebo arm will take an oral placebo to maintain study blinding.
2. The Committee questioned whether other study sites had received ethics approval yet. The Researcher explained that other sites were in various stages of applying for ethics approval and the New Zealand site expect to be the first to get ethics approval.
3. The Committee noted that the Participant Information Sheet contains a lot of information about confidentiality but after reading this it was still unclear how much information would be shared with the study sponsor. The Researcher explained that all information provided to the sponsor would not contain identifying information, just a study number, and only the researchers at the New Zealand site would be able to access identifiable information. To clarify this on the Participant Information Sheet.
4. The Consent Form refers to information being shared with other countries and companies. The Committee questioned whether this is optional. The Researcher explained that this is a compulsory part of study participation, however only deidentified information will be shared.
5. The Researcher noted that Maori consultation would be obtained through the DHB, however, this study also involved private clinics and they questioned whether this Maori consultation from the DHB would cover the private clinics too. The Committee confirmed that this is suitable.
6. The Committee questioned whether participants would be given a study contact card. The Researcher confirmed that they would be provided with one that included the research nurse’s contact number.

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

1. Please simplify the confidentiality information in the Participant Information Sheet.
2. The Committee noted that currently the Participant Information Sheet reads like it exists to protect the rights of the sponsor, however, it exists to inform participants about the study not to protect the sponsor. Please ensure this is reflected in the Participant Information Sheet as it could be significantly simplified and still fully inform participants about the study.
3. The section about unblinding of participants in the information sheet is currently contrary to the Health Information Privacy code, please revise this. Participants can access and correct any information about them at any time, although this may mean that they must be withdrawn from the study.
4. The Participant Information Sheet states that the study drug has not been approved by Medsafe. The Committee suggests that it may be better, and more accurate, to state that it has not *yet* been approved by Medsafe.
5. Early in the information sheet it states that ‘procedures will be performed’ but these aren’t explained further until later in the form. Please either explain these procedures earlier in the form or state that they are listed on a later page (please include the page number).
6. Please clarify in the Participant Information Sheet who pays for standard of care.
7. The Participant Information Sheet states that the sponsor can stop the study without consent of the participants. The Committee agreed that this may be the case, however they cannot stop for commercial reasons in New Zealand. Please ensure this is clear in the Participant Information Sheet.
8. The Committee noted that the Participant Information Sheet states that 160mg is well tolerated, however it does not state the dosage for this study. The Researcher confirmed that the study dosage is 160mg, 4 x 40mg tablets a day. Please clarify this in the information sheet.
9. Please ensure it is clearer in the Participant Information sheet that participants will receive the study drug until they relapse.
10. Page 2 of the Participant Information Sheet mentions the risk of seizures, however this is not well explained. Please give more information regarding this risk when it is first mentioned. The Committee noted that participants cannot drive or operate machinery throughout the study according to the Participant Information Sheet. The Researcher explained that they believe this only applies to the beginning of the study due to the small risk of seizures. Please clarify this in the information sheet.
11. Please ensure that all health information is stored for a minimum period of 10 years for adult participants and for 10 years after infant participants turn 16 years old (Health (Retention of Health Information) Regulations 1996).
12. The Committee questioned whether this study involves additional testing beyond that of standard care. Please clarify in the Participant Information Sheet whether the risks of standard test, such as MRI, are greater due to more testing in the study or just standard risks from non-study-specific testing.
13. Please ensure that the Future Unspecified Use of Tissue form includes all of the necessary information. The Committee requests that it is compared against the HDEC template to ensure it contains all of the same information.
14. The information regarding GCP and the Declaration of Helsinki is not relevant to the Future Unspecified Use of Tissue form and should be removed to improve clarity.
15. The Committee notes that unless the samples are completely de-linked that participants should be able to withdraw from the future use of their tissue. Please clarify in the information sheet whether this is possible in this study.

Decision

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

1. Please amend the information sheets and consent forms, 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, by Ms Shamim Chagani and Ms Susan Buckland.

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| **4** | **Ethics ref:** | **16/NTA/23** |
|  | Title: | A RANDOMISED, DOUBLE BLIND, PLACEBO CONTROLLED STUDY OF DYSPORT INTRADETRUSOR TREATMENTS FOR URINARY INCONTINENCE IN NEUROGENIC DETRUSOR OVERACTIVITY DUE TO SPINAL CORD INJURY OR MULTIPLE SCLEROSIS |
|  | Principal Investigator: | Dr Peter Gilling |
|  | Sponsor: | Covance New Zealand Ltd |
|  | Clock Start Date: | 25 February 2016 |

Dr Peter Gilling and Rana Reuther were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Botulinum toxin injections are commonly used to treat urinary incontinence due to either spinal cord injury or multiple sclerosis, although this is an inexact science that is not standardised. The use of botulinum toxin treatment in neurogenic detrusor over activity patients can improve urinary incontinence by relaxing the bladder muscle and reducing the incidence of involuntary urination.
2. This study involves testing an alternative brand of botulinum toxin treatment. Botox, which is made by Allergan, is the current market leader. This study involves trialling a different brand of botulinum toxin, Dysport, which is made by Ipsen.
3. The Researcher explained that currently Botox is an alternative to surgery and this study will consider whether there is phase III evidence to support Dysport’s efficacy in this setting. .
4. This study will also compare two dosages of the study drug.
5. Currently patients receive a Dysport treatment as their symptoms require.
6. This study has a 6 week follow up visit that will determine whether the study drug has been effective as it can take 3-4 weeks for the drug to work.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether this study will receive SCOTT approval. The Researchers explained that the study drug is currently registered with Medsafe for use in other parts of the body (this study will therefore be off-licence use or use for a new indication) and the researchers have been told by SCOTT that they do not require SCOTT approval. The Committee noted that this means that they will not receive peer review through SCOTT and requested further evidence of independent peer review.
2. The Committee questioned whether participants would have more catheter insertions because of their participation in the study. The Researchers confirmed that they will be getting the same number of catheter insertions as standard of care.
3. The Committee questioned whether any information was available on the prevalence of this condition in Maori. The Researcher explained that because this condition is caused by a spinal cord injury they do not believe that there is a higher incidence in Maori.
4. The Researcher confirmed that they are currently obtaining Maori consultation.
5. The Committee questioned the data safety monitoring arrangements of the study. The Researchers confirmed that they data safety will be reviewed by an independent committee.
6. The Committee noted that although they currently do not intend to use advertising to recruit that if this changed they would need to submit any advertising for HDEC approval.
7. The Committee questioned what would happen if abnormal results were found. The Researchers explained that they would tell the participant of any abnormal results, but that they would not normally inform their GP.
8. The Committee questioned how the possible conflict of interest would be mitigated if participants were also patients of the researchers. The Researcher explained that participants would be recruited by the research nurse rather than the clinician to reduce the conflict of interest.
9. The Committee questioned how many participants would be recruited in New Zealand. The Researchers stated that it would be around 8, as this is a relatively rare condition and it may be difficult to recruit.
10. The Committee asked whether ethics approval had been granted in any other countries yet. The researcher stated that New Zealand would be the first site to get ethics approval.

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

1. The Committee noted that the possible benefits stated in the Participant Information Sheet may be overstated as they do not know yet if participants will obtain a benefit. Please rephrase this to ensure that it does not appear that the researchers are claiming that the study drug is superior to Botox as this is not yet known.
2. The Participant Information Sheet states that the study can be terminated early for the commercial interest of the sponsor, however, in New Zealand this not acceptable. Please take note of this and revise the information sheet for accuracy.
3. Please state more clearly in the Participant Information Sheet that the study drug will not continue to be provided beyond the end of the study.
4. The Committee noted that in New Zealand all health information must be stored for a minimum period of 10 years (Health (Retention of Health Information) Regulations 1996), please adjust the information sheet to reflect this.
5. Please remove the tick boxes from the consent form unless they are truly optional, meaning that a participant could select ‘no’ and still participate in the study.

Decision

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies para 6.22).*
2. Please provide further evidence of independent scientific peer review for this study.

This following information will be reviewed, and a final decision made on the application, by Dr Christine Crooks and Dr Kate Parker.

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| **5** | **Ethics ref:** | **16/NTA/21** |
|  | Title: | Development of the COMFORT Cohort |
|  | Principal Investigator: | Prof. Richard Gearry |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 February 2016 |

Prof. Richard Gearry was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee considered 16/NTA/21 and 16/NTA/50 together as they are related in the sense that 16/NTA/21 is the application for the COMFORT study and 16/NTA/50 is for the establishment of the COMFORT Tissue Bank that involves tissue exclusively obtained through the COMFORT study.
2. Potential participants will be invited to the study by their gastroenterologist and given a copy of the Participant Information Sheet, if they are interested they will be contacted by the research nurse to go through the informed consent process.
3. Participants will be patients with IBS and a control group of patients without IBS symptoms, selected from a group of patients attending for colonoscopy
4. Participants will complete a questionnaire, a food diary, and provide a range of samples, including giving blood at the clinic, faecal and breath samples. Participants will then do bowel prep for the colonoscopy that will be performed as standard and samples will be taken during the colonoscopy. Some participants would not have samples taken during their colonoscopy if they were not involved in the study, however all participants will have samples taken for the study.
5. Some participants may have a diagnosis from their colonoscopy of a condition that would exclude them from the study.

Summary of ethical issues (resolved)

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

1. The Committee questioned the makeup of the research team, specifically they asked whether the research team included a nutritionist and a biostatistician. The Researcher confirmed that the COMFORT study includes a nutritional epidemiologist and that studies using samples from the tissue bank would include appropriately qualified researchers as part of the governance and scientific advisory function. The Committee requested further information about all researchers involved in the COMFORT study.
2. The Committee questioned the appropriateness of the recruitment process and inclusion criteria. Specifically, the Committee noted that the control group are those without IBS having a colonoscopy, they questioned whether people already having a colonoscopy are a suitable comparator group as they may not accurately reflect the general population. In particular the Committee noted that this is a High Value Nutrition science challenge project, and that product development was a likely outcome from this work therefore there are ethical implications of ensuring scientifically robust comparator groups and also implications for the health claims of resulting products. The Researcher explained that although they would like to have samples from the general population they cannot do so for practical reasons. The Researcher explained that they will need to factor this in to their results as they are unable to justify participants getting a colonoscopy only for study purposes. The researchers commented on the inflammatory basis for some of the investigations and outlined their mitigation to try and exclude cases where this was likely to confound results for example exclusion of cancers, Inflammatory Bowel Disease, inflammatory polyps etc. The researchers stated that they were satisfied that these criteria meant that the comparator group was scientifically robust.
3. The Committee noted that this project is funded from the High Value Nutrition funding from MBIE. The purpose of this study is to improve understanding of the causes of IBS as this will allow the development of targeted food products for people with IBS.
4. The Committee questioned whether the rates of IBS in Maori are known. The Researcher explained that they are not aware of any studies on this and that IBS may be reportedly lower in Maori, however it is not clear whether the rates are actually lower in Maori.
5. The Committee questioned whether extra information would be collected for the tissue bank. The Researcher stated that the same information is being collected for the tissue bank and the main study. This is cross-sectional rather than longitudinal research.
6. The Committee noted that the Tissue Bank application appeared to be for indefinite storage of samples and that the consent for stated that samples would be kept for 25 years. The Committee explained that they can only approve the Tissue Bank for 10 years. Consequently, the Committee requests that in 10 years the researchers apply to extend the tissue storage and that they retain the information sheet’s statement that samples will be stored for 25 years as they will consider approval of an extension of the Tissue Bank beyond an initial 10 years.

Summary of ethical issues (outstanding)

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

1. The Committee questioned who owned the data, given that this project is funded by MBIE. The Committee raised concerns about industry officials requesting access to study data or samples from the tissue bank. The Researcher assured the Committee that although MBIE are the study funders that control of the data and samples remains with the research team and any requests for access would need to come through the regular tissue bank process. The Committee requested that the researchers clarify and confirm who owns the intellectual property and the study data.

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

1. Please ensure all terms are clearly explained in the Participant Information Sheet.
2. Please ensure it is clear in the Participant Information Sheet what information people are consenting to be included in the study and the tissue bank.
3. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement if it is relevant for the study: *“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
4. Please remove the yes/no boxes from the Consent Form unless they are truly optional, meaning that participants could select ‘no’ and still be involved in the study.
5. Please add information on withdrawing from the study and the tissue bank (parameters on withdrawing samples and data) to the Participant Information Sheet, including whether family can withdraw the participant’s information and samples from the study if the participant dies.
6. Please make it clearer in the Participant Information Sheet that participants’ GPs will be informed of their participation in the study.
7. Please ensure that information regarding Tissue Banking and Future Unspecified Use of Tissue is separate from the main study consent form.
8. Please make it clearer that participants’ samples are potentially identifiable.
9. Please ensure it is clear in the Future Unspecific Use of Tissue Information Sheet that participation in this aspect of the study does not involve collecting additional samples, but rather continued storage and access to samples collected for the main study.
10. Please consider rephrasing the information about intellectual property to make it more lay and easily understandable.
11. Please ensure it is clear what is meant by ‘you are eligible to be a control’ as lay participants may not understand what it means to be a control.
12. The Future Unspecified Use of Tissue Information Sheet states that this future research could be of any type, however it will only be for IBS research. Please rephrase this for accuracy.
13. Please add analysis of genetic markers and DNA to the list of things participants agree to.
14. Please add a statement to the forms to inform participants that if they change their mind they may withdraw from the study at any time.
15. Please explain in the Future Unspecified Use information sheet that a governance group will manage data and determine who has access to this.
16. Please add a suitable ACC statement to the Participant Information Sheet.

Decision

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

1. Please confirm the data and sample access arrangements in relation to the study funder.
2. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (Ethical Guidelines for Observational Studies para 6.10).

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

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| **6** | **Ethics ref:** | **16/NTA/50** |
|  | Title: | COMFORT Cohort Tissue Bank |
|  | Principal Investigator: | Prof. Richard Gearry |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 February 2016 |

Prof. Richard Gearry was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee considered 16/NTA/21 and 16/NTA/50 together as they are related in the sense that 16/NTA/21 is the application for the COMFORT study and 16/NTA/50 is for the establishment of the COMFORT Tissue Bank that involves tissue exclusively obtained through the COMFORT study.
2. Potential participants will be invited to the study by their gastroenterologist and given a copy of the Participant Information Sheet, if they are interested they will be contacted by the research nurse to go through the informed consent process.
3. Participants will be patients with IBS and a control group of patients without IBS symptoms.
4. Participants will complete a questionnaire, a food diary, and provide a range of samples, including giving blood at the clinic. Participants will then do bowel prep for the colonoscopy that will be performed as standard and samples will be taken during the colonoscopy. Some participants would not have samples taken during their colonoscopy if they were not involved in the study, however all participants will have samples taken for the study.
5. Some participants may have a diagnosis from their colonoscopy of a condition that would exclude them from the study.

Summary of ethical issues (resolved)

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

1. The Committee questioned the makeup of the research team, specifically they asked whether the research team included a nutritionist and a biostatistician. The Researcher confirmed that the COMFORT study includes a nutritional epidemiologist and that studies using samples from the tissue bank would include appropriately qualified researchers. The Committee requested further information about the researchers involved in the COMFORT study.
2. The Committee questioned the appropriateness of the recruitment process and inclusion criteria. Specifically, the Committee noted that the control group are those without IBS having a colonoscopy, they questioned whether people already having a colonoscopy are a suitable comparator group as they may not accurately reflect the general population. The Researcher explained that although they would like to have samples from the general population they cannot do so for practical reasons. The Researcher explained that they will need to factor this in to their results as they are unable to justify participants getting a colonoscopy only for study purposes.
3. The Committee noted that this project is funded from the High Value Nutrition funding from MBIE. The purpose of this study is to improve understanding of the causes of IBS as this will allow the development of targeted food products for people with IBS.
4. The Committee questioned whether the rates of IBS in Maori are known. The Researcher explained that they are not aware of any studies on this and that IBS may be reportedly lower in Maori, however it is not clear whether the rates are actually lower in Maori.
5. The Committee questioned whether extra information would be collected for the tissue bank. The Researcher stated that the same information is being collected for the tissue bank and the main study.
6. The Committee noted that the Tissue Bank application appeared to be for indefinite storage of samples and that the consent for stated that samples would be kept for 25 years. The Committee explained that they can only approve the Tissue Bank for 10 years. Consequently, the Committee requests that in 10 years the researchers apply to extend the tissue storage and that they retain the information sheet’s statement that samples will be stored for 25 years as they are likely to approve an extension of the Tissue Bank beyond an initial 10 years.

Summary of ethical issues (outstanding)

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

1. The Committee questioned who owned the data, given that this project is funded by MBIE. The Committee raised concerns about industry officials requesting access to study data or samples from the tissue bank. The Researcher assured the Committee that although MBIE are the study funders that control of the data and samples remains with the research team and any requests for access would need to come through the regular tissue bank process.

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

1. Please ensure all terms are clearly explained in the Participant Information Sheet.
2. Please ensure it is clear in the Participant Information Sheet what information people are consenting to be included in the study and the tissue bank.
3. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: *“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
4. Please remove the yes/no boxes from the Consent Form unless they are truly optional, meaning that participants could select ‘no’ and still be involved in the study.
5. Please add information on withdrawing from the study and the tissue bank to the Participant Information Sheet, including whether family can withdraw the participant’s information and samples from the study if the participant dies.
6. Please make it clearer in the Participant Information Sheet that participants’ GPs will be informed of their participation in the study.
7. Please ensure that information regarding Tissue Banking and Future Unspecified Use of Tissue is separate from the main study consent form.
8. Please make it clearer that participants’ samples are potentially identifiable.
9. Please ensure it is clear in the Future Unspecific Use of Tissue Information Sheet that participation in this aspect of the study does not involve collecting additional samples, but rather continued access to samples collected for the main study.
10. Please consider rephrasing the information about intellectual property to make it more lay and easily understandable.
11. Please ensure it is clear what is meant by ‘you are eligible to be a control’ as lay participants may not understand what it means to be a control.
12. The Future Unspecified Use of Tissue Information Sheet states that this future research could be of any type, however it will only be for IBS research. Please rephrase this for accuracy.
13. Please add analysis of genetic markers and DNA to the list of things participants agree to.
14. Please add a statement to the forms to inform participants that if they change their mind they may withdraw from the study at any time.
15. Please explain that a governance group will manage data and determine who has access to this.
16. Please add a suitable ACC statement to the Participant Information Sheet.

Decision

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

1. Please confirm the data and sample access arrangements in relation to the study funder.
2. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (Ethical Guidelines for Observational Studies para 6.10).

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

## 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:** | 12 April 2016, 01:00 PM |
| **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 4:00pm.