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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 23 August 2016 |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 26 July 2016. |
| 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  3.00-3.25  3.25-3.50  3.50-4.15  4.15-4.40  4.40-5.05  5.05-5.30 | i 16/CEN/102  ii 16/CEN/104  iii 16/CEN/108  iv 16/CEN/111  v 16/CEN/113  vi 16/CEN/116  vii 16/CEN/117  viii 16/CEN/118  ix 16/CEN/119  x 16/CEN/121  xi 16/CEN/122  xii 16/CEN/123 |
| 5.30-5.45 | General business:   * Noting section of agenda |
| 5.45pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 30/07/2015 | 30/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | 30/07/2015 | 30/07/2018 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |
| Dr Nora Lynch | Non-lay (intervention studies) | 24/07/2015 | 24/07/2018 | Present |

## Welcome

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

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Dr Nora Lynch confirmed her eligibility, and was co-opted by the Chair as members 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 26 July 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/CEN/102** |
|  | Title: | TBI in ALL |
|  | Principal Investigator: | Dr. Lochie Teague |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 July 2016 |

Ms Sarah Hunter 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 the study

1. The committee noted that the researchers are requesting ethical approval for access to collect and use identified health information without consent and that the committee must test whether the Ethical Guidelines for Observational Studies guideline 6.43 is meet. 6.43 states that access to identified or potentially identifiable may be justifiable when
   1. the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and
   2. there would be no disadvantage to the participants or their relatives or to any collectivities involved; and
   3. the public interest in the study outweighs the public interest in privacy.
2. The researchers are not seeking additional consent from patients. There are two main registries where the data with consent for future use is held. The researchers would like to collect some extra data as the earlier forms don’t have the questions for data points that the researchers need in this study.
3. Data that is held in the registry with consent for future use is fine. The researchers are asking to go back to health records and request additional data that wasn’t covered in the original consent.

Summary of ethical issues (outstanding)

The main ethical issues considered by the committee and that need addressing by the researchers are as follows:

1. The researchers explained that the consent form that people had signed is a generic one for transplant related data, e.g. why they are having a transplant, donor source. The committee requested a copy of the original consent to confirm that is it broad enough to cover the data that the researchers want to access.
2. Evidence of Scientific Peer Review: the committee referred the researchers to the HDEC scientific review template that is available on the HDEC website, <http://ethics.health.govt.nz/> which allows for more detail to be provided. The committee asked that the researchers have someone who is independent of the study complete this and submit to the committee. The reviewer can be someone from within the institution with expertise to comment and doesn’t need to be a transplant specialist involved in this specific field of care.
3. The committee asked whether the researchers will have ethnicity data for the five participants in NZ and the researchers confirmed that they will as it is captured in the registry. For future reference, the committee noted that the researchers could include incidence rates for Maori and Pacific peoples in the application form at p.4.2 and f.2.1.
4. The patients would have been children at the time and consent would have been given by parents. The committee asked whether the researchers sought re-consent from them as adults. The researchers confirmed that they do noting that some are lost to follow up but those findable are followed up.
5. The re-consent form notes that parents/guardians gave consent and with their permission the researchers would like their re-consent to continue to use the data. Please provide a copy of this form for the committee. The reason for this is so that the committee can view the content and be confident that use of data is covered by the original consent.

Decision

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

* Please provide copies of the information sheet and consent forms as requested by the Committee.
* Please provide further evidence of scientific peer review from a qualified person who is independent of this study.

This information will be reviewed, and a final decision made on the application, by Dr Angela Ballantyne and Dr Melissa Cragg.

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| **2** | **Ethics ref:** | **16/CEN/104** |
|  | Title: | ARCHES |
|  | Principal Investigator: | Professor Peter Gilling |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 03 August 2016 |

No member of the research 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 the study

1. This is a study that was first submitted earlier this year reviewed by the Northern A HDEC. The study was provisionally approved but before the researchers responded to the queries raised, the study was put on hold due to changes to the study protocol and medication and was withdrawn to allow the researchers to make these changes and resubmit. In this study a placebo arm is added and therapy in patients who are already receiving standard care treatment.
2. The committee noted that the participant information sheet and consent forms had tracked changes and did not appear to be final documents. The committee asked that documents that aren’t final documents not be accepted in future as they do not know what changes will be kept and which won’t be. Also, version numbers are not accurate and up to date.

Summary of ethical issues (outstanding)

The main ethical issues considered by the committee and that need addressing by the researchers are as follows:

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

1. Please revise the information sheets and consent forms for grammar and typos. Please review the language to make sure that it is written in a way that is accessible for the lay person.
2. Page 2, section 5 - What will happen to me if I take part?: please clarify wording around the dose to be taken by participants as it is currently not clear.
3. Page 2, paragraph 4: please include information about the fact that cost for the standard of care androgen deprivation treatment will be at the participant’s expense and not provided as part of the study. Please reference this to section 7 on page 7 of the information sheet.
4. Page 2, paragraph 5: please specifically document what extra procedures will be associated with taking part in this study.
5. Page 2: please include the words “one of the following happens:” after the statement “You will be allowed to continue receiving study drug treatment in this study until” towards the end of page 2.
6. Page 3 states the sponsor may decide to stop study. Please state under what circumstances the trial would be stopped.
7. Page 8: the committee noted that seizures are listed as serious and infrequent events and asked examples of things people should not be doing if they are at risk. For example, if taking shower or bath have some supervision or not lock the bathroom door. The committee also asked that the fact that people should not drive while on this study be featured up front in the information sheet as it is a quality of life issue.
8. Page 9: please include that electrodes will be placed on arms and legs (as well as the chest).
9. Page 10, Radiation Exposure: please state more clearly what study specific extra radiation received over and above standard of care is.
10. Page 11, section 13 ‘Will my taking part in the study be kept confidential?’: Please remove the first 3 sentences as they are not to do with confidentiality. Please also offer to provide a lay summary of results to participants.
11. Page 13, statement that reads “I agree that my health information may be added to research databases and used in the future by Astellas and its affiliated companies to study treatments for patients or to develop a better understanding of diseases”. Please also state that this will happen in the information sheet.
12. Page 14, statement that reads “I agree that if I withdraw from the study before all visits are completed, the study doctor may need to follow up with my doctor (such as medical records or labs results) for safety reporting. The committee queried whether is compulsory and if so, please state this clearly in the information sheet.

Optional Pregnant Partner Information Sheet and Consent Form

1. Page 5: Please remove the statement “I will give the subject partner/legal representative a copy of this signed and dated informed consent”.

Optional Pharmacogenomics Information and Consent Form

1. It is unclear how much blood will be taken.
2. Question r.3.3 on page 21 of the application form states that the study will involve existing stored samples. The committee queried how this was the case as there was no requirement mentioned for this in the study protocol as far at the committee could see.
3. The committee noted that there is conflicting information in the application about whether the samples taken will be used for an optional pharmacogenetics study only or for future unspecified research. In section O the future unspecified research option is not ticked and yet b.4.5 states that it will be. If the researchers would like to use the tissue for FUR then the committee would like to see a separate information sheet and consent form for this aspect.

Decision

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

* Please amend the information sheet and consent form and questionnaires, 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 Dean Quinn and Mrs Sandy Gill.

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| **3** | **Ethics ref:** | **16/CEN/108** |
|  | Title: | Impact Evaluation Work Programme for Services in Schools |
|  | Principal Investigator: | Ms Moira Wilson |
|  | Sponsor: | Ministry of Social Development |
|  | Clock Start Date: | 29 July 2016 |

Ms Moira Wilson and Mr Pete McMillen 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 the study

1. This is a Ministry of Social Development funded and conducted study. It seeks to look at longer term (up to 8 years) outcomes on mental/physical health, education status and employment and contact with the law, in youngsters who received input at intermediate level, from one of the in-school social work services. Comparisons will be drawn with children from decile-matched schools who did not have input from these services. A second study will compare children from schools which had social work services available for different lengths of time. These services are costing the taxpayer $20-30 million per year.

Summary of ethical issues (outstanding)

1. The main ethical issues considered by the committee and that need addressing by the researchers are as follows:
2. The Chair started the discussion by noting that there is increased drive for use of these data sets. This committee has reviewed previous studies, one of which was referred to in this application and noted its concern that the referenced study is not abiding by reporting criteria set by the committee. The committee stressed that it expects that researchers abide by criteria set by the committee.
3. An ethical issue raised was the non-consented use of personal data from the 'Integrated Data infrastructure' matched with identified data on recipients of school social services (including socioeconomic information and family past contact with social services).The committee sought clarification from the researcher on who holds the data and who has rights to use it. For example is it obtained from schools, or does MSD already hold this. The researchers explained that in the past MSD contracted providers and data was entered into a shared database (if approval is given they hope to find a legacy copy of that database). A series of problems arose with the database, providers were given the option to opt out and increasingly they did so. Now the providers hold data and send and there is no centralisation.
4. All the data held identifies individuals. The researchers stated that they are only interested in the NGO data that states which children received the service and the start and end dates. They do not wish to review any rich case work data and content; just the identities of children across the three projects.
5. The committee noted the researcher’s intention to seek ‘historical case work data’ from the NGO contracted providers to ‘strengthen the study’ and asked what the researchers intend to do in the event that an NGO provider cites professional client confidentiality and declines to provide the case records because they think that the release would be a breach of trust. The researcher said that the data was collected with the intention that it would be available for this purpose. At that time of collection it wasn’t envisaged that the data could be linked. At that time they knew it would be used for evaluation and statistical reporting but the notion it could be linked with other information about a person was not contemplated. With retrospective data, the researchers would seek to work with the providers, to talk about their approach and the potential benefits of this study. One possible outcome is that they won’t be able to use the data from the providers they are working with.
6. The committee noted the possibility that this study could be used to justify withdrawing some of the social services funding in schools, if it shows that the long term outcomes for those supported by it are not different from those without it. The 'quasi experimental' design that the researchers are planning on using is an observational design not a clinical trial and appears to be common in such social research projects.
7. Techniques have been employed to deal with confounders. However, the interpretation of results particularly with regard to stating causality, as stated in the protocol, should be guarded. Despite the design attempts to mitigate the effects of non-random allocation between intervention and control populations, the possibility of unidentified confounding factors remains, e.g. with respect to other concurrent community initiatives/influences which may have been going on at the time or factors which did or didn't cause apparently similar schools to enter into the programmes. The scientific peer review submitted with the application makes this point.
8. In this regard the committee was concerned that the study may draw conclusions that aren’t accurate and or come up with findings that could stigmatise lower decile groups.
9. MSD is aware of the need to be aware of limitations and the researchers are not aiming to do randomised controlled studies. This study is useful for coming along behind further studies and will say something about the programmes that are in place. The committee mentioned that this is where the researchers might use a cluster step wedged design. The programme is in place however so there is no opportunity for a step-wedged design.
10. The committee asked how the researchers will know whether conclusions drawn might not have had other factors in play that make for a poor outcome at the start. The researchers cited other preliminary study done and noted that they are aware of the risks.
11. The researchers’ intention is to work with Maori researchers and providers to start a conversation at the formative stage. This is the ground work to design further studies and the researchers want to enter into those discussions with participant data.
12. The committee queried why consultation with the Community Investment Maori Reference Group not being undertaken at the time of study development. As this research definitely involves Maori, there should be prospective consultation, not just a discussion of preliminary results after the study has been done.The committee noted that the researchers had answered in the application form that formal consultation with Maori is not required and asked why this is the case when they are doing a study that takes expansion of service into decile 3 schools. The researchers noted their understanding that the Te Ara Tika framework talks of mainstream research. They have not consulted at this initiating phase but they intend to do so. The committee noted the ethical requirement to consult with Maori before starting any research that involves Maori. The researchers explained that the model they had worked with in an earlier piece of research when they didn’t know the full scope of research at the start was to establish systems to work with Maori as the research progressed and noted that they found the collaboration with Maori advisors useful.
13. The committee noted that the researchers have justified the use of identifiable data from non-consenting individuals as fulfilling all three clauses of guideline 6.43 from the NEAC Ethics Guidelines for Observational Studies. The committee noted that the proposal satisfies guideline 6.43(a), that it would be impractical and (c) as many taxpayers would think the wisest use of such large amounts of public funds overrides individual privacy interests in this case. However, the committee did not think that guideline 6.43 (b) was satisfied as there may be disadvantage to collectivities by the publication of unfavourable social outcomes in disadvantaged groups. There possibly is a disadvantage if they are not being consulted and the results are unfavourable. The researchers stated that they are hoping to get approval in principle for this study to collect the data and then have conversations with the community. The committee advised that it could not approve in principle because the system is set up to approve studies. The researchers have 700 providers and are presenting a quasi-experimental design that will result in them not being involved in the study at all.
14. The committee would like to see that the researchers consult with some types of providers and generic groups (e.g parent and family groups) to come up with a design and then have stakeholders involved. In this way, the key players have a chance to have input about how to release the data while protecting their client safety and confidentiality.
15. The committee noted the importance of MSD needing to provide its researchers with adequate resources to allow them to put in this work up front and before applying to the committee for ethical approval.
16. The committee agreed to decline this application to give the researchers opportunity to get things in line. The committee asked that the researchers resubmit the application to the Central HDEC for review.

Decision

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

Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:

a) the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and

b) there would be no disadvantage to the participants or their relatives or to any collectivities involved; and

c) the public interest in the study outweighs the public interest in privacy.

*(NEAC Ethical Guidelines for Observational studies, para 6.43)*

Any potential cultural and ethical issues pertaining to Maori must be addressed through appropriate engagement with Maori, which may include discussions with appropriate representatives of specific whanau, hapu and iwi as determined by the scope and practice of the study. *(NEAC Ethical Guidelines for Intervention Studies, para 4.9)*

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| **4** | **Ethics ref:** | **16/CEN/111** |
|  | Title: | Clinical Evaluation a New Mobile X-ray System |
|  | Principal Investigator: | Doctor David Milne |
|  | Sponsor: | GE Healthcare |
|  | Clock Start Date: | 11 August 2016 |

Several members of the research team, including Dr David Milne, Mr John Lee and Ms Beth Heckle 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 the study

1. This study aims to collect feedback from clinicians on the usability a new mobile x-ray device used in among other things, urologic and orthopaedic procedures. This x-ray device includes higher resolution and simplified touch screens, uses standard imaging technology to screen and low doses of radiation. The objective is to evaluate and meet user needs potentially bringing the product to market and covers all design needs/complete development with evaluation in a clinical environment.
2. The committee requested that the researchers provide a PIS/CF for the person i.e. surgeon or radiographer who will complete the questionnaires as they will also be participants in this study. Whoever is completing questionnaires is providing data for the study.

Summary of ethical issues (outstanding)

1. The main ethical issues considered by the committee and that need addressing by the researchers are as follows:
2. The committee requested the following changes to the participant information sheet and consent forms:
3. Please provide contact details for the HDEC, Maori support person and contact details for the lead investigator.
4. Consent form: The committee would prefer to see the list of things that the participant is consenting to set out as bullet points rather than grouped together in a paragraph as this makes it difficult to separate out and read.
5. Page 2, ‘Side Effects, Risks and Discomforts’: paragraph two talks about ionising radiation at low levels. Question r.1.13 in the application form states the study will not involve the administration of ionising radiation that is not needed for participants’ normal clinical management. The researchers clarified that they are substituting the standard care device for a higher spec one with lower doses of ionising radiation. Participants will not be submitted to higher doses. The next sentence which reads – “With low dose fluoroscopy for the prescribed use it is not measurable” Does “it” refer to cancer or radiation? Please rewrite this in a way that makes sense to the lay person.
6. Page 4, ‘Costs’: please remove the statement “You or your insurance company will be billed for the costs of your procedure the same as if you had not participated in this research study”, as participants in this study are in the public health system.
7. Page 6, ‘May I Review or copy my information?’: please revise the sentence “Yes, but only after the research is over” as this is contrary to NZ law. In NZ law people can access their own health information whenever they want access and in writing.
8. Page 6: please replace reference to the person’s personal physician with general practitioner as New Zealanders identify more readily with the term general practitioner or GP.

Decision

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

* Please amend the information sheet and consent form and questionnaires, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide an information sheet and consent form for the person who will complete the questionnaires, as they will also take part in this study (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This information will be reviewed, and a final decision made on the application, by Dr Dean Quinn and Dr Melissa Cragg.

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| **5** | **Ethics ref:** | **16/CEN/113** |
|  | Title: | Spectroscopy for diagnosis of coeliac disease |
|  | Principal Investigator: | Dr Sara Miller |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 11 August 2016 |

Dr Sara Miller 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 the study

1. This is a proof-of-concept study aimed a validating a new diagnostic test for use in upper small bowel diseases, using coeliac disease as the initial model. The test uses spectroscopy methods on small bowel biopsies. It is postulated that different diseases produce specific biochemical composition within the tissue which will lead to unique vibratory patterns. The rationale for developing this test is well explained (will be non-invasive if developed and offer a quick result). The participants will be patients from Dunedin Hospital presenting for a routine endoscopy: half will be coeliac and the other half some other diagnosis or normals.
2. Involvement means completing a brief questionnaire and consenting to 2-4 further biopsies than otherwise needed and access to records to check results of coeliac antibody screen.
3. The committee noted that scientific peer review has been presented clearly and responded to appropriately.

Summary of ethical issues (outstanding)

The main ethical issues considered by the committee and that need addressing by the researchers are as follows:

1. The committee noted its concern that the researcher wishes to include non-consenting minors as participants. This only became evident from the HDEC application form that children will be potentially involved as it didn’t appear in protocol. The committee noted that for future reference this is an ethical issue that needs to be highlighted in the protocol.
2. The committee advised the researcher that she will need to develop an information sheet and assent form for the children and explained the purpose of an assent form was to include the children who have a right to know what is going on in the research. The committee noted that the HDEC website has examples of assent forms that the researcher might look to refer to for guidance when she develops the assent forms. The committee would like to see assent forms for the following age groups 4-7years, 7-11years, and 11-14years. The existing information sheet and consent form is okay for young people of 14 years and over but will need to be amended to read ‘you or your child’ instead of ‘you’.
3. The committee noted the increased risk of bleeding or perforation from receiving extra biopsies. The committee was reassured from questioning gastroenterologists in previous similar applications that the absolute risk of fewer than 6 additional biopsies in a usual-risk population is extremely small.
4. The committee noted that the recruitment and consenting process is fairly clear and queried whether only Dr Schultz’s patients will be recruited to this study so that he could be available to answer any questions that participants might raise before signing. The researcher advised that they will seek to recruit patients coming through the gastroenterology unit at Dunedin Hospital. Endoscopy nurses will consent participants to the study and there is currently no single dedicated nurse to do this. With this in mind the committee advised that the researchers need to make sure that if a person has questions about the study that they will be answered by someone who knows about the study. The committee would like reassurance about how that will be handled. The researcher agreed to consult with Dr Shultz and to let the committee know.

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

1. Please mention that you will be accessing records for coeliac serology results in the information sheet.
2. The committee noted that question p.4.2 in the application form mentioned that the consenting process for this study will ensure that all participants can choose to have their specimens disposed of with a karakia. Please include this option in the information sheet and also as an option on the consent form.
3. With regard to compensation, the committee noted that it is important to say the participants can apply for ACC but that it is not guaranteed that they will eligible for it. Please modify the statement to say that participants will be eligible to apply for compensation.
4. Consent form: please revise the statements and include yes/no tick boxes only for statements that are truly optional.
5. The information sheet does not offer enough information about what will happen to participants’ tissue samples. The committee noted that the information stated at question r.3.10 gives a clearer explanation of what will be done with the samples once they have been obtained and some of this information could be included in the information sheet.
6. The committee noted that question ‘G’ on page 2 of the application form was incorrectly answered as this study will involve the use or disclosure of health information. This was just for noting as the form cannot be changed once submitted.
7. The committee noted the answer stated at question p.3.2.2.2.on page 23 of the application form that parents and caregivers of disabled patients could consent on their behalf. The committee reminded the researcher that if the disabled patients are 16 years old or over and intellectually impaired to the extent that they cannot give informed consent then parents or representatives cannot give consent on behalf of for the purpose of research.

Decision

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

* Please amend the information sheet and consent form and questionnaires, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide assent forms for the following age groups 4-7years, 7-11years, and 11-14 years (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Dr Cordelia Thomas.

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| **6** | **Ethics ref:** | **16/CEN/116** |
|  | Title: | Exploring the Effects of Obesity-Related Inflammation and Exercise on Drug Metabolism in Cancer Patients |
|  | Principal Investigator: | Dr Robert Matthew Strother |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 August 2016 |

Dr Mathew Strother, Ms Rebekah Crake and Dr Margaret Currie 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 the study

1. This is a study looking at two factors: the impact of obesity and the impact of exercise in a patient group of women who have breast cancer. The researchers intend to recruit 40 people to include age-matched controls in 20 obese and 20 non-obese participants.
2. The committee noted the prevalence rates for Maori included in the application form and that the researchers made good claim about how the issue is of high importance for Maori. With this in mind the committee asked whether there would be a special effort made to include Maori. The researcher stated that Maori make up 8% of the population in the Christchurch area and therefore if they are able to do a broader study throughout New Zealand they would look to include more Maori participants.

Summary of ethical issues (outstanding)

1. The main ethical issues considered by the committee and that need addressing by the researchers are as follows:

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

1. The committee asked the researchers to review the information sheet and consent form for typos.
2. The committee asked the researchers to revisit the introductory opening paragraph as it is unclear about what the study is about.
3. The committee noted that obesity is not mentioned in the information sheet when the researchers are interested in studying inflammation that comes from obesity and how it affects liver enzyme function in this patient group. The researchers could introduce this in a sensitive way but at the same time there is a need to be transparent and honest because it is deceptive not to touch on this at all. The researchers run the risk of stigmatising if it is not mentioned at all. The committee noted that it is more important to not withhold this and suggested ways in which the researchers might be more transparent in a sensitive way. For example, refer to them carrying some extra weight or having a BMI higher than X.
4. Consent form: the committee asked that the provision for people to opt in or out of the study should be included in the consent form.
5. The committee queried why participants in this study are not being offered parking money for the reason that people shouldn’t be disadvantaged from being in the study. The researchers explained that they had tried to arrange participation in the study around normal patient care and noted that parking is at a premium following the Christchurch earthquake. The committee recommended that the researchers could offer reasonable transport costs given lack of parking as a quid pro quo.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **16/CEN/117** |
|  | Title: | Na in CeD 3,Phase 1b |
|  | Principal Investigator: | Prof Richard Gearry |
|  | Sponsor: | Canterbury District Health Board |
|  | Clock Start Date: | 11 August 2016 |

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 the study

1. The committee noted that a similar study was previously submitted to it and reviewed in May of this year before being withdrawn by the researchers because of changes to the design of the study. The new protocol has two dose levels of hookworm and a smaller placebo group.

Summary of ethical issues (outstanding)

1. The main ethical issues considered by the committee and that need addressing by the researchers are as follows:
2. The committee noted that the tissue will be stored in a non-registered tissue bank in Australia. Storage at a New Zealand bio-bank along with others were mentioned and the committee requested that the researchers provide reassurance, beyond the bio-bank mentioned in the information sheet, that they meet guidelines for sample storage for future unspecified research, along with governance and processes to demonstrate to the committee that donor processes are respected.
3. The committee discussed the letter from the Prince Charles Hospital Foundation primary contact and CEO that was submitted with the application as evidence of scientific peer review. The letter gives an administrative assurance that he is happy for the study to go ahead. A Research Support Scheme Schedule is also included but it was not clear what the make up or expertise level of that committee is. The committee agreed that it would like to see local peer review from an independent gastroenterologist and also from a local infectious diseases specialist or microbiologist.

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

1. The length of the PIS for a relatively straightforward study was discussed. The committee made the general comment that an overly lengthy information sheet can defeat the purpose as people may give up reading and noted that it was the responsibility of researchers to strike a balance.
2. The committee noted that the participant information sheet was poorly ordered and hard to follow and agreed that participants may find it hard to know how this study is ordered. Please rework to follow a chronological order or to deal with the different groups to make it more understandable for participants.
3. With reference to the questionnaires, the committee noted that the information sheet mentions that answering the questions is mandatory for being in the study and thought that in the interests of helping people make an informed decision about whether they will participate that the researchers give an idea or examples or the kinds of questions that participants might be expected to answer.
4. The committee noted the requirement for participants to buy their own worming treatment from the pharmacy before having this cost reimbursed and asked that in the interests of fairness that this requirement be removed.
5. The committee queried whether the risks of eating pasta and flaring coeliac disease in the control group, have been adequately flagged and explained to potential participants.
6. The committee queried what data exists to back up that it could be therapeutic as claimed in the information sheet. Page 2, paragraph 5 states: “However, for this study the placebo might reasonably been seen in its own right as a possible treatment in that some people with coeliac disease may simply respond positively to a regular exposure to small amounts of gluten”. Please provide some justification for this statement. The committee would also like to see the peer reviewer’s comment in this regard.
7. Page 9: the committee noted that the table is hard to read. Please increase the size to one page.

Decision

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

* Please amend the information sheet and consent form and questionnaires, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide reassurance, beyond the bio-bank mentioned in the information sheet, that the guidelines for sample storage for future unspecified research are met, along with governance and processes to demonstrate to the committee that donor processes are respected.
* Please provide local scientific peer review from an independent gastroenterologist and also from a local infectious diseases specialist or microbiologist.

This information will be reviewed, and a final decision made on the application, by Dr Quinn and Dr Cragg.

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| **8** | **Ethics ref:** | **16/CEN/118** |
|  | Title: | Rewarding Blood Glucose Testing |
|  | Principal Investigator: | Dr Rinki Murphy |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 August 2016 |

Dr Rinki Murphy 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 the study

1. This is an interesting project that will test using a 12 week financial incentives reward programme to see whether it helps increase self-monitoring of blood glucose and improves diabetes control in young adults with poorly controlled type 1 diabetes.

Summary of ethical issues (resolved)

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

1. Question b.3.1 on page 11 of the application form: the committee noted that it would have preferred to have seen more detail stated here about the researcher’s qualifications and experience relating to conducting studies of this nature. The committee was able to refer to the researcher’s CV, however and was satisfied that the lead investigator is suitably qualified to conduct this study.
2. Question p.3.2 on page 18 of the application form: the committee noted that the researchers had answered ‘yes’ to this question and was curious as to why as it did not consider that the participants will have a restricted ability to make independent decisions about their participation. The question may have been answered ‘yes’ in error.
3. The committee acknowledged that the researcher had provided further information about cultural questions p.4.1 and p.4.3.1 following a request from the secretariat and that the further information answered those questions in a satisfactory way.
4. The committee discussed whether there might be potential for people who hear about the study to stop looking after their diabetes in order to get into the study and whether with this in mind that the researcher might look at only taking one person per family or excluding people who have multiple contacts.
5. The committee discussed the peer review document submitted with the application, from a layperson at Diabetes NZ approving Dr Murphy’s research grant from a diabetes research fund. The committee agreed that given that this study is a social experiment that is not high risk it would not request further evidence of peer review.

Decision

This application was *approved* by consensus.

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| **9** | **Ethics ref:** | **16/CEN/119** |
|  | Title: | An Exploratory Study of TG02 vaccine to assess safety and immune activity in locally recurrent rectal cancer |
|  | Principal Investigator: | Dr Dean Harris |
|  | Sponsor: | Targovax ASA |
|  | Clock Start Date: | 11 August 2016 |

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 the study

1. This study is a first-in-human Phase 1b safety and efficacy study of a potential vaccine for rectal cancer. The vaccine has been made out of fragments identical to parts of the gene mutation found in 50% of rectal cancers. The idea is it will prime the immune system to those peptides so the immune system unleashes on the tumour tissue. It is to be given with GM-CSF, which is a well-established stimulator of the immune system, to improve the vaccine effect.
2. A similar cocktail containing 7/8 of the peptides in this vaccine has been trialled in a limited number of pancreatic cancer patients, producing evidence of immunogenicity without concerning side effects.
3. The trial is in two parts. This part of the study is called Part 1. Part 2, which adds in another immune therapy, will only proceed if Part 1 is successful. Part 2 is not the subject of the current application.
4. The trial will run in New Zealand and Australia and a group of five participants will take part in New Zealand over two centres. Participants will have relapsed rectal cancer in the pelvis. They will be ‘pre-screened’ through fresh biopsy, for the mutation to which the vaccine is directed. Only those with the mutation will be recruited and enrolled. All will be lined up for further surgery. Some will receive chemotherapy and radiotherapy before trialling immunotherapy and surgery. Some will go straight to the trial immunotherapy. This decision will be made by each oncologist in the best interests of these patients. Five year survival of these patients with existing best treatment is up to 39%.
5. The committee noted that the participants’ blood/tissue is to be sent to an overseas laboratory for analysis. This was well-explained in the participant information sheet and consent forms as was the nature of future research on stored samples.

Summary of ethical issues (outstanding)

The main ethical issues considered by the committee and that need addressing by the researchers are as follows:

1. The committee noted that there will be an 8-10 week delay from diagnosis of relapse until surgery (standard of care) during which immunotherapy will occur. This has been justified in the protocol on the basis that in all the trial centres in Australia, this is the standard time it takes for these people to have a work-up and get a place on a surgical list. The trial is referred to as “occurring in a window of opportunity”. The committee queried whether there is the same routine wait occurring in each of the New Zealand trial centres and if not, then the ‘delay’ is an ethical issue.
2. The safety considerations of a first-in-human trial. The committee noted that novel adverse events are always possible. The stepped enrolment is well-explained. The data safety monitoring arrangements are functioning well but the committee noted that only one of the five members is independent and queried whether that balance such that the independent person’s voice will be heard if things are not going well.
3. The committee noted that participants will receive a series of vaccinations and have skin prick tests to see if they are developing immunity. There is a known small risk of allergic reaction to successive injections of TG02 as the immune system progressively boosts up. The regular hypersensitivity testing will look for developing immunogenicity of the vaccine but also act as a ‘canary in the mine’ with respect to allergic reaction. The committee seeks an explanation as to why the hypersensitivity test will be done just 30 minutes before a further vaccine treatment dose when delayed hypersensitivity can take 1-2 days to appear in the skin. The committee thought that it would be safer to do this a couple of days before the next dose is given.
4. The committee noted that a Medical Council registration certificate for the lead investigator has been loaded instead of a professional indemnity certificate. Please provide a copy of evidence of professional indemnity for the lead investigator.

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

Main PIS/CF

1. The committee would like to see the fact that this study is very early in vaccine development (Phase 1b) emphasised and, that neither the preparation nor schedule for administration is yet optimised. Therefore the likelihood of these participants benefiting is small.
2. Page 2: there is contradictory information on this page about the length of storage – both 10 years and 15 years are stated. Please revise and harmonise this information.
3. Page 6: please define “reasonable travel costs”. For example, would a taxi from 40km away be covered.
4. Page 9: paragraph 2 states that after an allergic reaction, including anaphylaxis, further shots of vaccine will be preceded by an antihistamine. Please review this wording as there should be no further vaccine administered after anaphylaxis.
5. Page10: the committee thought that the wording that participants are “strongly advised to use contraception”, was casual given that the protocol (page 37) clearly states that contraception is mandatory and gives the list of methods to use. Please review and change this wording so that it is in line with the protocol.
6. Page 12: the last paragraph states that the study doctor will advise participants of the results of the study if they wish to know but does not state how this will happen. For example, by letter. Please state how results will be sent to patients who request them.

Withdrawal form –

1. It is made clear enough in the PIS/CF that verbal withdrawal from the study is adequate. The committee thought that the withdrawal form as an option is fine but it would like to know more about the statement that the researcher signs: “I have given a verbal explanation of the implications of withdrawal from the research study”. The committee would like to know what implications these are as this is not a therapeutic study. If there are no implications then the committee requests that this statement be removed.
2. The committee noted that the participant emergency card has Australian contact details. Please replace this card with updated New Zealand contact details.

Decision

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

1. Please provide evidence of professional indemnity for the lead investigator.
2. Please clarify whether the 8-10 week delay from diagnosis of relapse until surgery (standard of care) during which immunotherapy will occur is a routine wait-time across all sites in New Zealand.
3. Please provide your view on whether you think the balance of members on the DSMB is such that the independent person’s voice will be heard if things are not going well.
4. Please amend the information sheets and consent forms, taking into account the suggestions made by the committee.

This information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Sandy Gill.

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| **10** | **Ethics ref:** | **16/CEN/121** |
|  | Title: | Outpatient balloon induction: an RCT |
|  | Principal Investigator: | Dr Michelle Wise |
|  | Sponsor: | FMHS, University of Auckland |
|  | Clock Start Date: | 11 August 2016 |

Dr Michelle Wise 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 the study

1. This study is looking at an alternative approach to induction. It is being done in Christchurch and in a few centres in Canada and Australia.

Summary of ethical issues (outstanding)

The main ethical issues considered by the committee and that need addressing by the researchers are as follows:

1. The committee noted receipt of letter from the ADHB research committee as evidence of peer review but agreed that the letter was brief and did not outline what the considerations were. The committee requested that the researcher send the HDEC peer review template to the writer of the letter and ask them to complete with more detail. The committee would like to see this once completed.
2. The committee noted that there is no formal data safety monitoring committee set up for this study. It is an open study but can the researcher be confident that there are not things happening that she won’t pick up. The committee queried whether there will be an interim analysis of the data and the researcher said that she can put this in place.

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

1. The committee raised a number suggestions it had about how the researchers could increase the clarity of the participant information sheet and consent forms for participants. The committee noted that the researchers could give a comparison between the intervention vs. standard of care and how this induction method will be different from standard of care. The committee asked that the researchers include information that states what the balloon is, how it will be inserted, what the risks are (bleeding and discomfort) and information about withdrawal and what the woman can do if she is at home, i.e. can she come back and under supervision have it removed and what is involved.
2. The committee noted as a general statement, the challenge of striking a balance between brevity and detail in participant information sheets. In this case, some detail is missing that is necessary for participants to have in the interests of giving fully informed consent. For example, that a balloon will be inserted, how it will be inserted and what its size is. The committee suggested that a picture or diagram might be helpful to illustrate this.
3. The committee noted that there is no mention of the research midwife in the information sheet when this person will have a significant role and may encounter the pregnant woman early on. The committee requested that the researchers include detail about the research midwife’s involvement in the information sheet.
4. The committee noted that the format of the consent form as it stands combines a lot of information into paragraphs and asked that the researcher separate this out and also refer to the HDEC consent form pro forma for guidance about how to format the consent form and also what content to include. http://ethics.health.govt.nz/
5. The committee noted that the researchers have stated that they don’t plan to inform participants of the study results. The committee noted that it is a sign of respect to make results available to participants who are often interested in the outcomes and suggested that the researchers include a place on the consent form for participants to state their contact email address so that the researchers can email a copy when it becomes available.
6. The committee asked the researcher whether there is any known difference between Maori and non-Maori in induction rates. The researcher’s understanding is that the rates are lower for Maori women. For future reference the committee noted that this is the kind of information (prevalence rates), it would like to see stated at question p.4.1 of the application form.
7. Please include HDEC contact details and also contact details for a Maori support person or advocate.
8. In regard to participants’ eligibility for compensation in the event that they have an injury as a result of being in this study, the committee noted that it would like to see the following clause from the HDEC pro-forma replace the current wording: *If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *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.
9. The researcher confirmed for the committee that data generated from this study might be made available for use in future research. The researcher noted that her answer at question b.4.4.1 on the application form that data would be ‘de-identified’ was in error. The researcher queried whether she could disclose anonymous data to third parties for future studies if asked. If in future access to completely anonymised data. The committee advised that if the researcher needs identifiers from this study’s data set then it will be better to use a tick box in the consent form where participants are asked to give consent to use of their data for future studies.
10. The committee noted that the participant information sheet does not give information about what to do if labour starts overnight and noted that some women might get the impression that they wait at home overnight and then come in to the hospital. The committee asked that the researchers include information about the risks of labouring at home so that the woman can make the decision.
11. The committee noted that women who are randomised to receive the intervention will be given an explanation of the procedure from the doctor on duty and have an opportunity to ask questions. The committee asked whether the woman’s lead maternity carer would still give support at this point. The researcher explained that as the induction of labour is considered to be secondary care that the LMC would not be involved at this point. The committee asked that it be made clear in the study advertisements that the women can if needed call the hospital midwives from home as having a named person to call is important.
12. The researcher noted that in her experience women do not go into labour at home. They come in to the hospital where the balloon is removed and they break the woman’s waters.
13. The committee noted that the referral guidelines state that women be under care and constantly monitored. Recognise that buck will stop with the obstetrician if something goes wrong. The women need to be fully informed, although the risks are low, about what the risks are and what she should do if anything goes wrong.
14. The researcher agreed to provide the committee a copy of the letter that will be sent to participants after balloon placement and before returning home for the night. Also a copy of the advertisement for potential participants.
15. Please state that ethics approval has been given by the Central Health and Disability Ethics Committee.
16. Risks of prostaglandins vs. balloon. The committee noted that the new variable in this study is that women will be sent home after having the balloon inserted. There is no exclusion criteria noted on transport and getting hospital. The researcher stated that they are not anticipating an adverse event that would have the woman coming back and also noted that each site has its own process in place for women coming back to the hospital. The committee requested that the researchers make a more formal point of what is considered safe for the women to go home in the participant information sheet.

Decision

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

* Please amend the information sheet and consent form and questionnaires, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* ADHB research committee as evidence of peer review but agreed that the letter was brief and did not outline what the considerations were. Please ask the writer of the ADHB research committee letter submitted with this application complete the HDEC peer review template <http://ethics.health.govt.nz/> with more detail and then submit this to the committee.

This following information will be reviewed, and a final decision made on the application, by Dr Peter Gallagher and Dr Angela Ballantyne.

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| **11** | **Ethics ref:** | **16/CEN/122** |
|  | Title: | A Screening Study in Patients with Untreated Paroxysmal Nocturnal Hemoglobinuria |
|  | Principal Investigator: | Dr Peter Browett |
|  | Sponsor: | Clinical Network Services Ltd |
|  | Clock Start Date: | 11 August 2016 |

Ms Mary Ellis-Pegler 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 ethical issues

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

1. The committee noted that there is no information about the treatment study for which this study is screening, in the information sheet. The researcher noted that this is because the treatment study is going to be a separate study with a new information sheet and protocol approved separately as well. The committee put themselves in the shoes of potential participants and noted that if they were going to volunteer to be in this study that they would like to know what they might be letting themselves in for in the subsequent study – that is, what the study involves and what the risks are.
2. The committee asked whether the information for the treatment study will be shown at the same time as for the screening study. If yes, then please include enough information for participants to make a decision about participation if the aim is to get into the following study. For example, is it placebo controlled so that people know that if they take up participation they may then be assigned to placebo.
3. The researcher acknowledged that they were trying to keep things simple and not confuse people but acknowledged the committee’s point that people have the right to know what they are getting into.
4. The committee noted that several of the screening criteria included for the screening study were not relevant to this study but only really exclusionary to the treatment study e.g 75 days since receiving Eculizumab before dosing day 1 of treatment study or participants receiving another trial drug within 30 days of day 1 of the treatment study.
5. The committee noted that the contraception requirements are confusing. Page 4, ‘What you will be responsible for if you take part in this study?’ That the use of contraception only applies to males by itself slightly confusing. Please revise the wording.
6. Page 2: the researcher clarified for the committee that the treatment study has a screening component. If the treatment study is underway people will be potentially screened for the treatment study, not for another purpose.
7. Page 8 notes that one vaccine is not registered in New Zealand. The researcher explained that the vaccine not registered in New Zealand is a meningococcal vaccine that is brought into New Zealand under section 29 of the Medicines Act. The committee noted that the application form submitted for this study states that participants may receive up to 4 vaccinations and only 3 were listed so the committee wondered whether there is a 4th vaccine. The researcher confirmed that there are not four different vaccines but some participants may need booster shots so some may receive up to 4 shots.
8. The committee queried why participants will receive a patient safety card. The researcher explained that is because they will receive vaccinations and also that it is standard for ACS to issue patient safety cards to participants in their trials.

Decision

This application was *approved* by consensus.

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| **12** | **Ethics ref:** | **16/CEN/123** |
|  | Title: | Adalimumab Equivalency Trial in Immunology - Study of ONS-3010 and Humira® for the Treatment of Patients with Moderate to Severe Plaque Psoriasis |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: | inVentiv Health Clinical Australia Pty Limited |
|  | Clock Start Date: | 11 August 2016 |

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.

Dr Quinn declared a potential conflict of interest, and the Committee decided that Dr Quinn would leave the room and not take part in the discussion or decision-making for this application.

Summary of the study

1. This is a Phase 3 bioequivalence study of two biologic drugs and such studies are generally reasonable to do because of the fact that the way drugs are manufactured doesn’t always produce same molecule. Adalimumab biosimilar called ONS-3010 is being tested against the reference form of Adalimumab Humira®. Humira® is widely used across a range of diseases in New Zealand and the participants in this trial have moderate plaque psoriasis. This trial is looking at the efficacy and safety of the drug in this population.
2. This trial will run for 25 weeks and treatment will be given every fortnight. Although the first 17 weeks consist of parallel equal groups on one or other form of Adalimumab, the reference (Humira®) group is split randomly to take either ONS-3010 or Humira® for weeks 17-25 while the initial ONS-3010 group has unchanged treatment from week 1 to 25. An open label extension for another 32 weeks is potentially on offer. This will involve the Humira® “switchers” changing back and forth between the 2 preparations once again. All treatment options stop after 47 weeks.

Summary of ethical issues (outstanding)

The main ethical issues considered by the committee and that need addressing by the researchers are as follows:

1. The committee noted that the washout period for people on topicals will be for 2 weeks and the washout period for other drugs will be for between 4-12 weeks. The committee noted that the likelihood of a flare up in psoriasis is real and that this can sometimes be severe and occasionally dangerous. The committee queried whether they will be liaising with a dermatologist while they are doing this and or whether a participant’s GP will be informed of this before any withdrawal.
2. The committee noted that a practicing certificate for the lead investigator, Dr Quinn, has been uploaded instead of evidence of professional indemnity. Please provide evidence of professional indemnity for Dr Quinn.
3. The committee noted that there were a lot of additional study materials from the company submitted with this application. The committee noted the Master Patient Resource Guide (15 pages) appears to be a surrogate PIS and the committee wondered if it was really needed as it might confuse people.

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

1. The switching is being done to investigate the effect of moving between preparations, on the production of antibodies to adalimumab. At least in theory, coming on and off one form of the drug could increase the risk of these antibodies and the risk of an allergic reaction and/or loss of efficacy to the drug. The committee would like to see this stated in the participant information sheet and consent form. (Page 2, under the heading ‘Study Overview’, paragraph 4)
2. The committee noted that there is a risk of flare up on withdrawal at the end of the study. Although adalimumab is available for psoriasis in New Zealand on Special Authority application, the entry criteria (severity and past meds that have to have been tried) for this trial are considerably less stringent than the PHARMAC access criteria require. So potentially some participants will get a lot better and then have a drug withdrawn from them. On the other hand, it may be argued that participants will get 6 months of treatment that they couldn’t otherwise access. The committee noted that it would like to see stated in the PIS/CF the fact that participants will have the drug withdrawn after the study and then let them decide whether they still want to take part in the study.
3. The committee noted that the side effects of taking the drugs are covered in the participant information sheet. However, the committee thought that more emphasis is needed with respect to the fact that infection fighting can be depressed. The most feared adverse event from adalimumab is serious infection. The committee noted that it is uncommon but can be devastating and rapidly progressive. The committee felt that more emphasis could be added about this both to inform consent but also to protect participants by increasing vigilance throughout the study. The figure quoted of 1:1000 (page 9 of the PIS) seems too low and the committee asked that the researchers recheck this figure. The committee would like to see the statement beefed up to increase participants’ vigilance.
4. Page 8: Please define “reasonable travel costs”.
5. Page 11, section 12, ‘Can I have other treatments during this research project?’: The committee asked that the researchers clarify why participants must pay for medications for symptoms caused by the study drugs.
6. Page 11: please clarify how patients will get a copy of the study results.
7. The committee noted that there are blood samples that will be sent offshore for analysis and asked that in this regard the following statement be included: (insert cultural statement)
8. Page 13, section 17, ‘Complaints and compensation’: the committee noted that the way in which the statement about compensation is currently worded implies that participants will automatically get compensation. Please replace the statement with the following: (insert clause)

Decision

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

* Please address the committee’s query noted at point 3 above.
* Please amend the information sheet and consent form and questionnaires, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide evidence of professional indemnity for the lead investigator.

This information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Helen Walker

## 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:

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| **Meeting date:** | 27 September 2016, 12:00 PM |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington, 6011 |

The following members tendered apologies for this meeting.

* + Dr Cordelia Thomas

The meeting closed at 5.30pm.