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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 21 October 2015 |
| **Meeting venue:** | Digital Meeting |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.10pm | New applications (see over for details) |
|  | i 15/NTA/161  ii 15/NTA/160  iii 15/NTA/158  iv 15/NTA/159  v 15/NTA/162  vi 15/NTA/163 |
| 3.10pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Christine Crooks | Non-lay (intervention studies) | 01/07/2013 | 01/07/2015 | Present |
| Dr Sarah Gunningham | Non-lay (intervention studies) | STH co-opt | STH co-opt | Present |
| Dr Patries Herst | Non-lay (intervention studies) | CEN co-opt | CEN co-opt | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | NTB co-opt | NTB co-opt | Present |

## Welcome

The Chair opened the meeting at 1pm and welcomed Committee members, noting that apologies had been received from Dr Karen Bartholomew and Dr Mark Smith.

The Chair noted that fewer than five appointed members of the Committee were present, and that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Dr Sarah Gunningham, Dr Patries Herst and Miss Tangihaere Macfarlane confirmed their eligibility, and were 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.

## New applications

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| **1** | **Ethics ref:** | **15/NTA/161** |
|  | Title: | A study of Nivolumab With or Without GS-4774 for Virally-Suppressed Subjects with Chronic Hepatitis B |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 08 October 2015 |

Prof Edward Gane 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. This is the first study of a PD-1 inhibitor in patients with HBV infection (phase I study).
2. The Researcher explained that PD-1 enhances immune response. It has been used largely in oncology, in solid tumours such as non-small cell lung cancer.
3. The intervention’s effect on the immune system should be effective in treating Hep B as Hep B reduces the immune system (impacting / reducing T cell responses). This study aims to increase response of the T cells against the virus. The virus will already be suppressed with oral treatment. The hope is that the virus can be eradicated from the body.

Summary of ethical issues (resolved)

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

1. The Committee queried if patients are screened for PD-1 expression. The Researcher stated that screening is not necessary in this patient population. They will look at expression, though is not an entry criterion. Once safety data is gathered the researchers will raise the dose – they start at a very low level dose, and add further treatment options as data is generated to support increasing it.
2. The Committee asked what standard care is for these patients. The Researcher explained the patients remain on their standard of care. The study aims to help clear the virus which means the patients don’t need lifelong treatment.
3. Please explain why study is only conducted in New Zealand. The Researcher noted that this is a pilot study.
4. The Committee noted that blood samples are to be stored for 15 years, is this for future unspecified research? The Researcher stated that it is for the optional studies, to develop further studies.
5. P.4.3.1 is there an update re Maori consultation with Helen Wihongi? The Researcher explained that it is on-going.
6. The Committee noted that on pg.25 (P.4.1) of application – the last 3 sentences of response are appropriate and relevant while the first 5 are not. This is a note for future applications.
7. The Committee queried whether all groups receive same amount of compensation. The Researcher explained the compensation, adding that the last cohort receive additional treatment and or procedures, compared to the earlier cohorts.

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

1. The optional genomic studies need more information as required by tissue guidelines e.g future research won’t be approved by a New Zealand HDEC. Please review the guidelines for future unspecified research and ensure all sections are met: <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>
2. Check first sentence 2nd para pg. 11 of the main PIS - remove reference to MREC.
3. Pg.13 states participants are not able to access data until study is over. HDEC note that participants always have a right to access their health information, as per health privacy code, but that this may result in withdrawal from the study. Please remove the statement as participants cannot give up the right to access their health information.
4. PIS: pg. 2 or pg. 7 'consult with a kaumatua' should read 'consult with someone of your choosing'. Otherwise use the example in the future unspecified research document (pg. 2, last paragraph).
5. pg. 4 or pg. 12 Reference to Chief Advisor Tikanga: Tikanga's should read Tikanga (there is no ’s’ in Maori language). Or suggest re-word i.e. 'Office of Chief Advisor Tikanga' Submission.
6. Please add radiation risk from CT scans.

Decision

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

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| **2** | **Ethics ref:** | **15/NTA/160** |
|  | Title: | Regional Anaesthesia and Breast Cancer Recurrence |
|  | Principal Investigator: | Dr Elizabeth Maxwell |
|  | Sponsor: |  |
|  | Clock Start Date: | 07 October 2015 |

Dr Elizabeth Maxwell and Ms Davina Macalister 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 (resolved)

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

1. Please clarify statement under 'Can I have other treatments?' - can patient participate in other trials while on this trial (for 7 years)? The Researchers stated that all participants standard of care continues, with respect to the organisation they are being treated at. The researchers are not randomising any chemo or radiation therapy.
2. The Committee queried whether this would impact the outcome for the study? The Researcher noted that the regional differences globally will be random and should not impact the outcomes of the randomised arms.
3. The Researcher confirmed participants can enrol in other studies and will continue to have standard of care. The Committee asked that his is made clearer in the participant information sheet.
4. The Committee noted that application (a.5.1) states no sponsor. PIS states ADHB and Breast Cancer foundation are funding the study. Are these two organisations the sponsor? The Researcher stated that the Cleveland clinical team has organised the study (outcomes research group).
5. If possible, please provide update re Maori consultation (Helen Wihongi). The researchers stated that it was with the Maori research office.
6. The Researchers clarified the monitoring arrangements – the international CI and the locality are involved, but are not the sponsor. The Committee confirmed that was fine.
7. The Committee noted that to reduce likelihood of causing additional/unnecessary grief ensure that checks are made to determine status of participant prior to 6-monthly contacts. The researchers explained they check hospital records prior to calling. There are good quality hospital records for this group as they are regularly followed up. They also try and schedule appointments when they are already coming into hospital to make things easier for participants.
8. Make sure that both arms are completely equal with regards to benefit and risk (equipoise). F.3.2. of application.
9. Please confirm the DSMC monitoring – how often do they meet? Researcher stated it should be every 6 months.
10. The Committee queried if the participants receive a report, at any point in time. The Researchers stated that they may do an annual report to participants as part of the breast cancer funding. The committee supported an update report for participants, in lay language.

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 queried the sample size discrepancy, noting that N = 100-200 application says n=100.
2. R.2.1.1 please confirm participants provide consent prior to screening.

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

1. Pg. 2 Remove 'flipping coin' reference.
2. The Committee suggested taking out the paragraph regarding the potential benefit and perceived improvement of the experimental arm – it biases the study towards it being better prior to the study (page 2). The paragraph above ‘why this study is being done’.
3. The study is being done, rather than ‘we are doing’. Third person.
4. Make it clear that no payments are made to participants (re-funding from breast cancer).

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Clarify R.2.1.1 and the sample size discrepancy.

This following information will be reviewed, and a final decision made on the application, by Secretariat.

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| **3** | **Ethics ref:** | **15/NTA/158** |
|  | Title: | Cast vs Splint for distal radius fractures |
|  | Principal Investigator: | Dr Tarun Ahuja |
|  | Sponsor: |  |
|  | Clock Start Date: | 07 October 2015 |

Dr Tarun Ahuja 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. First in human study for new splint device, in adults.

Summary of ethical issues (resolved)

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

1. The Committee queried if this is a pilot study. The Researcher explained that a similar device had been used in paediatric groups, though not the exact same design. For this particular device this was the first study (phase I) and was a pilot.
2. The Committee asked if the similar design is standard of care in paediatrics. Researcher stated no, standard of care is still a cast.
3. The Committee asked how the researcher became involved with the device. The Researcher explained that he worked with a registrar who developed this device, who started a company and is now wanting to trial the device. The researcher explained that the company is not involved in the trial at all.
4. The Committee asked who owns and can access the data generated from the study. The researcher stated Zerocast is not involved, the researchers came up with the study design – data is owned by the DHB. The DHB is informed about the study. They are on board and have given written approval. All study information remains at the DHB and will be used by the DHB.
5. Please clarify if there is data safety monitoring. The Researcher explained that the only potential problem is that the splint is not useful in stabilizing the fractures, this would be a worst case scenario. The cast and splint participants will receive same treatment, they are seen and reviewed at 1, 2 and 6 week visits. At each visit an x ray occurs to reassess fracture stability. If the study indicated that fractures were not healing in the splint n, and this would be obvious throughout continued visits (usually within first 2 weeks), they will stop the study.
6. The Committee asked when exactly the study would be stopped. The researcher stated there are degrees of movement in the fracture, that are to be expected, however if there are significant losses of bone positions the splint is not working. The researcher explained that there is internal monitoring of all participants across both hospitals.
7. The researcher confirmed that they are not the treating doctors.
8. The researcher explained the training process given to hospital staff in ED who will put the splint on. The clinicians also conduct the consent process, so there is no conflict as the researchers don’t approach patients to consent.
9. The Committee asked how patient’s fracture will be managed if splint does not work. How much discomfort will be caused, will healing be delayed? The researcher stated that even those with a cast (20-30%) will also lose position, and will require re-manipulation, a new cast or surgical intervention.
10. The Committee asked if Zero-cast providing splints free of charge, and will they have any rights to data and control publication of results? The Researcher stated Zero-cast provide the splints free of charge but have no access to data or any involvement in publication of the results.
11. The Committee asked who will own the intellectual property. The Researcher stated the DHB.
12. The Committee noted that Study ID not name should be on questionnaires.
13. R 2.5 Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).
14. The Committee noted the use of pictures in participant information sheet was helpful.
15. The Committee noted that P.4.3 Maori consultation is required. The Researcher confirmed the hospital consultation process has been conducted.
16. The Committee asked why there are so many participants in a phase I trial. The Researcher noted that the power was statistically calculated. The committee noted that power calculations were not done for a phase 1 trial and that it would be good if the first few patients could be evaluated to establish if the splint is effective before enrolling more patients.

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 requested that there is an independent study ID.
2. The Committee suggested a formal interim analysis after 5 or 6 patients by those who are internally monitoring to check that the splint is working early on. Please confirm this and update the protocol.
3. P.4.6 The Committee requested that the researcher collects ethnicity data.

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

1. The Committee discussed the PIS – and suggested that the PIS template from HDEC is used – fill in information as prompted by the HDEC template.
2. Retitle ‘participant leaflet’ as product information sheet.
3. pg. 5 Insert Northern A (HDEC)
4. Add contact details needed for Investigator, HDEC, Maori health support, and health advocacy (as per template).

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Provide details of the Data Safety Monitoring plan, in terms of the interim analysis *(Ethical Guidelines for Intervention Studies para 6.50).*

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

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| **4** | **Ethics ref:** | **15/NTA/159** |
|  | Title: | Heparc-2008:Study of ARC-520 alone and in combination with other drugs in patients with Hepatitis B (MONARCH) |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 07 October 2015 |

Prof Ed Gane 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. Phase II study, multicentre. IV – every 4 weeks treatment. Adds a small molecule to stop production of Hep B. The treatment should also enhance immune responses. Treatment itself or in combination with standard of care. Patient population have Hep B.
2. Committee commended the participant information sheet.

Summary of ethical issues (resolved)

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

1. P.4.1 pg. 25 Last 3 sentences only appropriate and relevant. Other statements are not.
2. P.4.3.1 pg. 25 Update re Maori consultation f.1.1 pg 26 Suggest response should be 'Yes' (refer response at f.1.2 with exception of first sentence). The researcher acknowledged the Maori prevalence of Hep B (20% of people who have hep B in NZ are Maori and acknowledged study could reduce inequalities.
3. The Researcher noted Chinese and Pacific Islanders have hep B at least as high as Maori and acknowledged this information should have been in the application.
4. The Researcher noted those who remain Hep B positive remain on standard of treatment but will stop experimental treatment, post study. They hope most will not require any further treatment.

Summary of ethical issues (outstanding)

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

1. R.1.4 pg.15 The Committee queried why there was no formal data safety monitoring arrangements (re serious adverse events) in spite of response at r.1.5. The Researcher explained that there is internal monitoring by the study team in our area. The CI noted they would like to review data if there is no independent data safety monitoring. Committee requested internal DSMC, but more formalised than currently planned, with the CI involved.
2. The Committee noted the storage of blood samples for 10 years, and asked the investigator to clarify whether all research is specified? If not why store blood samples for 10 years? Researcher to follow up with sponsor. The Committee noted that if there is future unspecified research a separate and optional information sheet must be provided.

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

1. pg. 10 Ensure that it is stated to participants that samples will be sent overseas.
2. Add lay title.
3. Arc 530 rather than arc 520 typo (table).
4. Termination in the commercial interests of the sponsor – please remove.
5. Please direct participants to call study unit in cases where injury occurs – revise ACC statement.

Decision

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

* **IF REQUIRED:** Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Provide details of the Internal Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*

This following information will be reviewed, and a final decision made on the application, by Secretariat.

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| **5** | **Ethics ref:** | **15/NTA/162** |
|  | Title: | Testing the combination of an experimental agent (Pexa-Vec) with standard of care Sorafenib versus Sorafenib alone in patients with advanced liver cancer |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 07 October 2015 |

Professor Ed Gane and Ms Jan Biddle 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 study compares experimental study drug against standard of care for treatment of patients with advanced liver cancer.
2. Study drug is unfunded in New Zealand, but approved for use.
3. Experimental arm has gold standard plus experimental treatment.
4. The study involves a modified virus. They have deactivated a gene in the virus that would allow the virus to activate in non-cancer cells. It can infect non-tumour cells but it can’t replicate in them.
5. The experimental treatment has been effective intravenously or injected, in other phase II studies. This study involves direct injection to the tumour.
6. The experimental treatment should increase the response rate to the gold standard of care.
7. 600 patients. Phase III.
8. No successful treatment for this disease. Current survival time with standard of care is 4-5 months.

Summary of ethical issues (resolved)

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

1. The Researcher explained that 20%-25% 0f patients or 1/21 treatment administrations with Pexa-Vec develop potentially infectious lesions – more common with IV dosing, can occur up to a week of exposure – no reported occurrence of further infection, including to staff or other patients.
2. The Committee discussed the patient context. The Researcher explained these patients are told they have incurable cancer and attend weekly clinics. They are told they are likely to die. Regarding consent process for the study, participants have the participant information for a week at home to consider.
3. The Committee noted the autopsy request in the participant information. The Researcher noted the sensitive manner of this request. The Committee asked if the autopsy procedure is essential, and if it needs to be part of the study? The Researcher noted they would never demand an autopsy, adding that they do not often refer participants with this disease to coroner. The Committee requested that the autopsy request is removed.
4. Remove the statement about the HDEC being favourable to the study during review - use standard wording (i.e. approved by HDEC).
5. pg. 26 p.3.3.1 Seems to contradict r.1.8 States participants will not be paid other than for reimbursement of travel expenses
6. The Committee noted P.4.1 2nd sentence inappropriate. Also P.4.2 Consider following cultural issues: Storage, transportation, disposal. Significantly also: 'injection of genetically modified organism'.
7. Heading, drug and drug side effects – page 7. Changes from Pexa-Vac to side effect of standard of care. Make it clear when it changes drug.
8. R.3.3 – are existing samples from a tissue bank? The Researcher clarified it was from clinical samples.

Summary of ethical issues (outstanding)

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

1. r.1.8 Define payment per visit
2. The Committee queried if samples would be transferred to another tissue bank? Please clarify tissue testing.
3. The Committee and researcher discussed the surveys uploaded. Is the client (demographic, income info) questionnaire required? Please justify this questionnaire with regards to scientific necessity, or remove it.

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

1. Para 2 end of line 2: delete word 'for' Ensure Maori health support contact details include extension # or 0800 # - or at least ensure support is easily accessible.
2. Review for basic editing, spelling etc.
3. Make it clear that pregnancy follow up is optional.
4. b.4.5.3 Ensure overseas transportation of tissue is made clear to participants

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Clarify whether all questionnaires are required and or appropriate.

This following information will be reviewed, and a final decision made on the application, by Dr Sarah Gunningham.

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| **6** | **Ethics ref:** | **15/NTA/163** |
|  | Title: | Standard versus symptom-based antibiotic duration |
|  | Principal Investigator: | Dr Richard Everts |
|  | Sponsor: |  |
|  | Clock Start Date: | 07 October 2015 |

Dr Richard Everts was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

1. R.1.4 states there is no formal data safety monitoring. Committee discussed this was acceptable as treatments were not being changed, other than duration of prescribed treatment.
2. P.4.2 Consider the following cultural issues: tissue collection, transportation, storage and disposal. This is a comment for future applications.

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 queried A1.6 on antibiotic resistance. Is there increased risk with reduced duration of antibiotics? Please explain further.
2. Please provide confirmation from co-investigators (named in the Protocol) that they are supportive of the structure and design of project.
3. Please confirm who will be contacting the patients and whether their health records will be continually updated, in practice.
4. A.1.5 states there is no sponsor, please explain who is responsible for trial governance and how this will be managed.
5. The Committee noted the importance of receiving the independent peer review. Please explain if the reviewer is at all concerned about patients stopping antibiotics early and please comment on safety.
6. P.2.3 Potentially inappropriate level of flippancy.
7. Unclear when participants give consent. Please clarify. How long do they have to think about this?
8. How will compliance be tested? Perhaps during phone calls? Suggestion for research assistant to call participants.
9. Please explain when an interim analysis occurs to ensure participant safety.
10. The Committee was unsure how to assist with the question in P.4.2, noting study participation must be optional and free from coercion.
11. Please justify theory of study, noting concern of resistant bacteria due to non-completion of antibiotics.
12. Generally, the HDEC was of the view that the Researcher should use the template participant information sheet and consent form, as much information is missing.

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

1. PIS / GIS: Add Maori Health support contact details Submission:
2. Please use PIS HDEC template. The current information sheet is not adequate for informed consent.
3. Consent Statements under 'there is no reason why I can't take part in this study' could be confusing for participant...please consider revising.
4. The statement: I hope the antibiotic treatment will be exactly a long as it needs to be, may bias the participant’s responses: they may feel an obligation to report “good outcomes” which could skew the results. Remove all statements to your expectations of the outcome of the study.
5. Name all of the commonly used NSAIDs.
6. Name all the ibuprofen containing formulations: nuromol, maxigesic etc.
7. All extra information in the consent form should be in the participant information sheet.
8. HDEC do not look at private health information – please remove this statement from the participant information sheet.
9. All forms must have abbreviated name, version number and date and page numbers
10. Pre-read: name of study in title. End of first par: add: you can decide not to take part or to stop taking part on the study later on. This will not affect the healthcare you receive now or in the future
11. Exactly how many visits are there: PIS suggests only 1 at the starts. Protocol suggests” compliance will be documented at each visit? How will compliance be tested: count the number of tablets? Patients must then be told to bring in their medication or will they have to count the pills themselves? PIS also mentions further possible visits by specialist when needed?
12. Add nuromol and maxigensic to the list of meds they cannot take. This list should also be in the pre-read.
13. Add ACC claim paragraph from HDEC template

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Provide further information on the study design, *in particular the compliancy checks, the overarching scientific basis for the study with regards to reduced antibiotic consumption* (*Ethical Guidelines for Intervention Studies para* 5.4)
* Provide further information on the recruitment process (*Ethical Guidelines for Intervention Studies para 6.2)*

This following information will be reviewed, and a final decision made on the application, by full electronic committee.