Health and Disability Ethics Committees
Ministry of Health
C/- MEDSAFE, Level 6, Deloitte House
10 Brandon Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

09 July 2014

A/Prof Jonathan Koea
North Shore Hospital
Private Bag 93-503
Takapuna 0740

Dear A/Prof Koea

| | | |
|---|---|---|
| Re: | **Ethics ref:** | **14/NTB/77** |
| | Study title: | Resection of Colorectal liver metastases with or without routine hilar lymphadenectomy |

I am pleased to advise that this application has been ***approved*** by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

The main issues considered by the HDEC in giving approval were as follows.

- The Committee clarified that the outcome for these patients was not good. A/Prof Koea explained that historically the 5 year survival rate was 30% but with new chemotherapy treatments it has increased to 60%. A/Prof Koea added it is not as good as it could be but it is improving.
- The procedure does not require any additional surgery, occurring during the standard surgery operation.
- The Committee queried the starting date, noting it stated 2010. A/Prof Koea explained that this study has had started overseas but recruitment had been slow. A/Prof Koea explained that he felt this study was worthwhile and could be conducted in New Zealand.
- The Committee queried if the universal trial number is still pending, given the study started in 2010. A/Prof Koea stated he would look into this.
- The Committee queried why there is no mention of tissue banking or tissue samples in the patient information sheet? A/Prof Koea stated the tissue will go through normal lab process and will not be used for any other study. A/Prof Koea confirmed there will be no tissue banking.
- R.5.4 is the Co-ordinating investigator the usual health provider? A/Prof Koea stated that they will be in some cases. Please explain how this conflict will be managed. A/Prof Koea explained they will introduce the study and then leave the patient information sheet with the potential participant. At a later stage they will then have a nurse talk to them about the study. This occurs in an outpatient context. A/Prof Koea will then approach the participant with their family to discuss further if interested. The Committee was satisfied with this process.

- Please explain the decision to state that the study involved a Kaupapa Maori research methodology? A/Prof Koea explained that a high proportion of the participants will be Maori and there is substantial Maori support in place. The Committee noted that this is not a research methodology.
- Committee queried if the study was blinded. If this is the case it must be made explicit in the patient information sheet particularly that they will not be told which treatment arm they are in unless there is a good clinical reason to disclose the arm of the study.
- The Committee requested the following changes to the Participant Information Sheet and Consent Form:
    - Please reword ACC statement to say 'may' not 'will' receive compensation, as compensation is a process not a guarantee.
    - The Committee noted participants have a right to their information. Please include information on participant rights.
    - The Committee noted that they participants can withdraw their data but can't withdraw their surgery; although it may seem obvious please make this clear.
    - Please include HDEC contact information.
    - Pg.7 last bullet point – please make it a statement 'GP will be informed' rather than having it as an option.
    - Please make it clear to participants what is standard treatment and what the experimental treatment procedure component of the study is.
    - Please do not explain randomisation as 'flip of the coin'.
    - Please make it clear that telephone follow up will continue for 2 years.
    - The Committee noted the incorrect HDEC has been referenced (Northern Y rather than Northern B). Please review and amend.
    - Please explain what the quality of life changes are? A/Prof Koea explained that from his personal experience there is no difference in length of hospital stay or quality of life resulting from different interventions. Committee suggested rewording to make it clear that it is not known if there will be any differences between treatments.
    - Please provide an alternative to mobile number as some participants may be unable to pay to call a cell phone prohibiting them from contacting.
    - Please add an additional space for an interpreter to sign if you do plan to use one.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern B Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

- The Committee requested the following changes to the Participant Information Sheet and Consent Form:
  - Please reword ACC statement to say 'may' not 'will' receive compensation, as compensation is a process not a guarantee.
  - The Committee noted participants have a right to their information. Please include information on participant rights.
  - The Committee noted that they participants can withdraw their data but can't withdraw their surgery; although it may seem obvious please make this clear.
  - Please include HDEC contact information.
  - Pg.7 last bullet point – please make it a statement 'GP will be informed' rather than having it as an option.
  - Please make it clear to participants what is standard treatment and what the experimental treatment procedure component of the study is.
  - Please do not explain randomisation as 'flip of the coin'.
  - Please make it clear that telephone follow up will continue for 2 years.
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  - Please explain what the quality of life changes are? A/Prof Koea explained that from his personal experience there is no difference in length of hospital stay or quality of life resulting from different interventions. Committee suggested rewording to make it clear that it is not known if there will be any differences between treatments.
  - Please provide an alternative to mobile number as some participants may be unable to pay to call a cell phone prohibiting them from contacting.
  - Please add an additional space for an interpreter to sign if you do plan to use one.

Non-Standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to HDEC before commencing your study.

If you would like to submit your Non-standard conditions please email Non-standard conditions to HDECS@moh.govt.nz. Do not submit Non-standard conditions as a Post Approval form.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

**Your next progress report is due by 9 July 2014**.

Participant access to ACC

The Northern B Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Mrs Raewyn Sporle
Chairperson
Northern B Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

**Appendix A**
**Documents submitted**

| *Document* | *Version* | *Date* |
|---|---|---|
| Protocol: Protocol. Dated 2013 | 1 | 01 December 2013 |
| PIS/CF: PIS/ICF. Tracked .Dated 6th June 2014 | 1 | 06 June 2014 |
| PIS/CF: Original PIS/ICF. Version 1. Dated December 2013 | 1 | 31 December 2013 |
| PIS/CF: PIS/ICF. Version 1. Dated 6th June 2014. Clean. | 1 | 06 June 2014 |
| CV for CI: CV of CI. | 1 | 06 June 2014 |
| Survey/questionnaire: Health Questionnaire.2013 | 1 | 31 December 2013 |
| Evidence of CI indemnity | 1 | 06 June 2014 |
| Evidence of CI indemnity | 1 | 06 June 2014 |
| Evidence of scientific review: document scientific review form PI.12/06/2014 | 1 | 12 June 2014 |

**Appendix B**
**Statement of compliance and list of members**

Statement of compliance

The Northern B Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

| *Name* | *Category* | *Appointed* | *Term Expires* | *Present on 01/07/2014?* | *Declaration of interest?* |
|---|---|---|---|---|---|
| Mrs Raewyn Sporle | Lay (the law) | 01/07/2012 | 01/07/2015 | Yes | No |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Yes | No |
| Mrs Kate O'Connor | Non-lay (other) | 01/07/2012 | 01/07/2015 | Yes | No |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Yes | No |
| Dr Paul Tanser | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Yes | No |
| Ms Kerin Thompson | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Yes | No |

**http://www.ethics.health.govt.nz**