# The University of Sydney

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**Human Research Ethics Committee**
www.usyd.edu.au/ethics/human
**Manager: Gail Briody**
Telephone: (02) 9351 4811
Fax: (02) 9351 6706
Email: gbriody@usyd.edu.au
**Deputy Manager: Marietta Coutinho**
Telephone: (02) 9036 7566
Email: mcoutinho@usyd.edu.au

**Human Secretariat**
Telephone: (02) 9036 9309
(02) 9036 9308
(02) 9036 7274
Facsimile: (02) 9036 9310
**Mailing Address:**
Room 313, Level 3, Old Teachers College – A22


18 November 2008

Dr N Tebbutt
c/- Ms Kate Wilson
MAX Study Co-ordinator
NHMRC Clinical Trials Centre
Mallett Street Campus – M02
The University of Sydney

Dear Dr Tebbutt

**Title:** **The MAX Study: A randomized Phase II/III study to evalute the role of Mitomycin C, Avastin and Xeloda in patients with untreated metastatic colorectal cancer**

**Ref. No.:** **03-2005/8067**

**Authorised Personnel:** **Dr N Tebbutt**
**Associate Professor T Price**
**Ms K Wilson**
**Ms B Cakir**
**Associate Professor M Stockler**
**Professor J Zalcberg**

The Human Research Ethics Committee, at its Executive Meeting held on **11 November 2008**, considered and approved the request dated 3 November 2008 to modify the above-mentioned protocol. Specifically, the Committee approved the request to proceed with planned translational research using tumour tissue samples of study participants who have provided written informed consent for tissue collection for use in biomarker studies. Additionally, the Committee approved the request to add Associate Professor Timothy Price to the research team and to remove Dr Sanjeev Gill from the research team.

The Committee found that there were no ethical objections to the modifications and therefore recommends approval to proceed. The following documents were approved:

- Amended MAX Study Protocol No. AG0501CR Protocol Version 7, October 31, 2008, including appendices A, B, C, D, E, F, G, H, I, J, K, L, & M
- Summary of amendments for The MAX Study Protocol No. AG0501CR Version 7, October 31, 2008
- Completed University of Sydney Modification Form: Version 4, 15 February 2008

**Chief Investigator / Supervisor's responsibilities to ensure that:**

(1) All serious and unexpected adverse events should be reported to the HREC as soon as possible.

(2) All unforeseen events that might affect continued ethical acceptability of the project should be reported to the HREC as soon as possible.

(3) The HREC must be notified as soon as possible of any changes to the protocol. All changes must be approved by the HREC before continuation of the research project. These include:-

- If any of the investigators change or leave the University.
- Any changes to the Participant Information Statement and/or Consent Form.

(4) All research participants are to be provided with a Participant Information Statement and Consent Form, unless otherwise agreed by the Committee. The Participant Information Statement and Consent Form are to be on University of Sydney letterhead and include the full title of the research project and telephone contacts for the researchers, unless otherwise agreed by the Committee and the following statement must appear on the bottom of the Participant Information Statement. *Any person with concerns or complaints about the conduct of a research study can contact the Senior Ethics Officer, University of Sydney, on (02) 9351 4811 (Telephone); (02) 9351 6706 (Facsimile) or gbriody@usyd.edu.au (Email).*

(5) Copies of all signed Consent Forms must be retained and made available to the HREC on request.

(6) It is your responsibility to provide a copy of this letter to any internal/external granting agencies if requested.

(7) A report and a copy of any published material should be provided at the completion of the Project.

Yours sincerely

***Professor D I Cook***
**Chairman**
**Human Research Ethics Committee**

Encl: Summary of Changes in Protocol No: AG0501CR Version 7, October 31, 2008: Amendment 5

Amended MAX Study Protocol No. AG0501CR Protocol Version 7, October 31, 2008, including appendices A, B, C, D, E, F, G, H, I, J, K, L, & M (Page 1 included for your records)

University of Sydney Modification Form: Version 4, 15 February 2008