



12 May 2015

Dr Daniel Brungs
 Illawarra Health and Medical Research Institute
 University of Wollongong
 IHMRI, Building 32
 Northfields Ave
 WOLLONGONG NSW 2522

Dear Dr Brungs,

*****THIS LETTER CONSTITUTES ETHICAL APPROVAL ONLY. THIS RESEARCH PROJECT MUST NOT COMMENCE AT A SITE UNTIL SEPARATE AUTHORISATION FROM THE CHIEF EXECUTIVE OR DELEGATE OF THAT SITE HAS BEEN OBTAINED.*****

Project Title: Personalisation of systemic therapy in gastric cancer: Development of Patient-Derived Gastric Cancer Cell Models for Genetic, phenotypic and Drug Response Analysis And Investigation of the role of Circulating Tumour Cells and Circulating Tumour DNA in Gastric Cancer.
HREC Reference: HREC/15/LPOOL/121
Local Project Number: 15/072

Thank you for your response dated 1 May 2015 to our request for further information dated 20 April 2015. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that the Committee has granted ethical approval of the above project.

The following documentation has been reviewed and approved:

Document	Version	Date
National Ethics Application Form	AU/1/07AD110	12/03/2015
Protocol	2.0	May 2015
MASTER Participant Information Sheet	4.0	May 2015
MASTER Consent Form	3.0	March 2015

Please ensure for all future documents submitted for review include a document version number, document date and page numbering.

Monitoring Requirements:
 (National Statement Chapters 2.1 and 5.5)

- The Committee has classified this project as:

Low Risk

- Monitoring required for this study will be:
 - Submission of Annual Progress Reports with the first report due **12 May 2016 and annually thereafter for the duration of the approval period**

Approval has been granted for the following site(s):

- Wollongong Hospital
- Wollongong University
- Ingham Institute for Applied Medical Research
- Liverpool Hospital
- St George Hospital

Please note the following conditions of approval:

- **Insert Local Project Number 15/072 at the end of the complaints paragraph**
Please note the Office does not require a copy of the updated Participant Information Sheet and Consent Form. Please amend these before issuing to Participants
- 1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - any serious or unexpected adverse events; and
 - unforeseen events that might affect continued ethical acceptability of the project.
- 2. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review. For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each sites so that they can notify their Research Governance Officer.
- 3. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.
- 4. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
- 5. The Principal Investigator must reassure participants about confidentiality of the data.
- 6. Proposed changes to the personnel involved in the study are submitted to the HREC accompanied by a CV where applicable.

HREC approval is valid for (5) years. If the study is ongoing at the conclusion of the five year approval period, a full resubmission may be required. Ethics approval will continue during the re-approval process.

Optional: It is the responsibility of the sponsor or the principal (or co-ordinating) investigator to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trials Registry www.anzctr.org.au)

The South Western Sydney Local Health District Human Research Ethics Committee has been accredited by the NSW Ministry of Health to provide single ethical and scientific review of research proposals conducted within the NSW public health system and Victorian and Queensland Public Health Organisations participating in the Mutual Acceptance Scheme.

You are reminded that this letter constitutes ethical approval only. This research project must not commence at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. It is your responsibility to forward

a copy of this letter together with any approved documents as enumerated above, to all site investigators for submission to the site's Research Governance Officer.

Should you have any queries about your project please contact **Annamarie D'Souza** on the telephone number listed above. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the SWSLHD website: <http://www.sswahs.nsw.gov.au/swslhd/ethics/default.html>

Please quote the Local HREC reference **15/072** in all correspondence. The HREC wishes you every success in your research

Yours faithfully



Professor Jeremy Wilson
Chairperson, SWSLHD Human Research Ethics Committee

for

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

