Government of **Western Australia**
Department of **Health**

Ethics Ref: 2013-007 approval SCGOPHCG
Ext 2999

Sir Charles
Gairdner Hospital

10 October 2013

Dr Alfred Tay
H.pylori Research Laboratory
Room 2.13 L Block
QEII Medical Centre
Hospital Ave
NEDLANDS WA 6009

Professor Barry Marshall
H.pylori Research Laboratory
Room 2.13 L Block
QEII Medical Centre
Hospital Ave
NEDLANDS WA 6009

Dear Dr Tay

APPLICATION TO CONDUCT HUMAN RESEARCH AT SCGOPHCG:
TRIAL No: 2013-007
TRIAL TITLE: New detection method, surveying of antibiotic resistance profile and genome analysis of clinical Helicobacter pylori isolates

On behalf of the Sir Charles Gairdner and Osborne Park Health Care Group Executive (SCGOPHCG) I give approval to conduct your research project at QEII Medical Centre based on the favourable reviews provided to me by Research Governance and the Sir Charles Gairdner Group Human Research Ethics Committee. This approval is granted until 10 October 2016, and on the basis of compliance with all requirements laid out in your application and with the provision of reports as required by the Research Governance and the approving HREC in giving their favourable opinion (attached).

The responsibility for the conduct of this study remains with you as the Principal Site Investigator. You must notify the HREC Office of any relevant issues arising during the conduct of the study that may affect continued favourable opinions by the hospital or by an HREC.

Please quote Study number 2013-007 on all correspondence associated with this study.

Yours sincerely

Dr Robyn Lawrence
EXECUTIVE DIRECTOR
SIR CHARLES GAIRDNER AND
OSBORNE PARK HEALTH CARE GROUP

Government of **Western Australia**
Department of **Health**

Sir Charles Gairdner Hospital

Sir Charles Gairdner Group (SCGG)
Human Research Ethics Committee (HREC) Approval

DETAILS OF STUDY				
SCGG HREC No:	2013-007			
Site Investigator:	Professor Barry Marshall			
Department:	H.pylori Research Laboratory			
Title:	New detection method, surveying of antibiotic resistance profile and genome analysis of clinical Helicobacter pylori isolates			
Meeting Date:	SRS	7 March 2013	HREC	22 August 2013

OUTCOME

The following documents are endorsed:

- Protocol, version 1 dated 8 July 2013
- Participant Information Sheet and Consent Form, version 1 dated 13 September 2013
- Participant Invitation Letter
- Patient Information Booklet
- Treatment side effect evaluation for Helicobacter Pylori

As Delegate of the Chair of the HREC I approve these documents for use as part of the study, subject to satisfactory annual reports and monitoring compliance of the study.

JENNY WESTGARTH-TAYLOR J Westgarth-Taylor 10-10-13

Name *Signature* *Date*

A waiver of consent is granted for this study under Section 2.3.6 of the National Statement on Ethical Conduct in Human Research. An additional recommendation of the National Statement (under Section 4.4.14), is that participants should be informed of the research as soon as reasonably practicable and given the option to withdraw from the study without any reduction in quality of care.

Details of how the decision to provide a favourable ethical approval and the members present at the meeting can be supplied on request. The SCGG HREC is registered with the Australian Health Ethics Committee and operated according to the NHMRC National Statement on Ethical Conduct in Human Research

It is the responsibility and obligation of the researcher to advise the HREC of any departure from the original protocol that could impact on the ethical approval of the study. Please note that the attachments entitled 'Adverse Event Reporting for Clinical Trials' and 'Terms of Approval' forms part of this approval. Under these reporting guidelines you are required to submit formal notice of any changes to documentation, relevant information arising out of ongoing safety monitoring and annual reports on the ethical aspects of your study. An annual report form for your study will be posted to you several weeks in advance of the anniversary of the project's approval date.

As the responsibility for the conduct of the trial lies with you as the investigator, you should sign

all communications to the committee.

Institutional approval must be obtained before the above trial can commence at any site within WA Health.

TERMS OF APPROVAL

The following general conditions apply to all approvals by the Sir Charles Gairdner and Osborne Park Health Care Group (SCGOPHCG), and starting a research project following the issue of approval will be deemed to be an acceptance of them by all investigators:

1. The responsibility for the conduct of projects lies with the site investigator, all correspondence should be signed by that investigator or their delegate.

2. Projects that do not commence within 12 months of the approval date will have their approval cancelled and the trial will be closed.

3. The submission of an application for approval will be deemed to indicate that the investigator and any sponsor recognises the approving Ethics Committee as a registered (with AHEC) Human Research Ethics Committee and that it complies in all respects with the National Statement on Ethical Conduct in Human Research and all other national and international ethical requirements. **The HREC will not enter into further correspondence on this point.**

4. A list of the HREC members that attended specific meetings is available on request, but no voting records will be provided.

5. The investigator will report adverse events accompanied by a cover sheet, available on the website, indicating whether or not the project should continue. Reporting requirements are as per the NHMRC AHEC Position Statement May 2009 which is summarised in the attached sheet regarding adverse event reporting. Additional reports other than those outlined that are submitted to the HREC will be returned without acknowledgement.

6. For projects where SCGH is acting as the sponsor (ie. investigator initiated project) it is the responsibility of the investigator to report serious and unexpected drug/device reactions, as well as other reactions/events to the Therapeutic Goods Administration (TGA). Please refer to TGA website for further information and the relevant forms (see http://www.tga.gov.au/pdf/clinical-trials-guidelines.pdf - p71 for medications or p77 for devices)

7. Where a project requires a Data Safety Monitoring Board (DSMB) it is the investigator's responsibility to ensure this is in place before the commencement of the project and the HREC notified of this. All relevant reports from the DSMB should be submitted to HREC.

8. If this project involves the use of an implantable device a properly monitored and up to date system for tracking participants is to be maintained for the life of the device in accordance with the National Statement section 3.3.22 (g).

9. The investigator is responsible for notifying the Therapeutic Goods Administration of a device incident in accordance with the National Statement section 3.3.22 (g)

10. All project drugs must be dispensed by the Pharmacy Department. A fee is levied for this service and investigators must regard this fee as an item requiring a budget allocation. Alternatively, if a sponsor agrees, separate direct funding of pharmacy services may be undertaken.

11. The site investigator will inform the HREC about any changes to the project. Further information regarding the submission of amendments is available on the website http://www.scgh.health.wa.gov.au/Research/ApprovalInformation.html

12. An annual report (including a brief outline of events and progress) on each project approved will be required on the anniversary date of the trial's approval. HREC approvals are subject to the submission of these reports and approval may be suspended if the report is not submitted. The report form will be sent to the site investigator named on the approval the month prior to the report falling due; it is also available on the website.

13. Your project may be subject to Institutional monitoring, however you will be notified if your project has been selected.

14. The SCGOPHCG has the authority to audit the conduct of any project without notice. Exercise of this authority will only be considered if there are grounds to believe that some irregularity has occurred, if a complaint is received from a third party or the SCGOPHCG wishes to undertake an audit for QA purposes.

15. Complaints relating to the conduct of a project should be directed to the HREC Chair and will be promptly investigated according to the Committee's complaints procedures. Please refer to Section 8 of the Standard Operating Procedures available on the SCGH website or a copy of the complaints procedure can be supplied on request.

16. Investigators of sponsored projects are advised to draw the above conditions to the attention of the sponsor. Investigators are reminded that records of consent or authorisation for participation in special projects (including clinical trials) form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the WA *Health Patient Information Retention and Disposal Schedule (Version 2) 2000.* A copy of the 'Participant Information Sheet' should also be included in the medical records as part of informed consent documentation.

17. The duration of institutional approval for a project is 3 years from the date of approval. The date of approval expiry is stipulated in the institutional approval letter.

18. If the study is to continue beyond the stipulated approval expiry date a request for an extension should be submitted prior to that expiry date - a letter must be sent to the Delegate of the Chair of the SCGG HREC with the new estimated end date and justification for the extension of the research. One extension of 3 years can be granted but approval beyond this time period may necessitate further review by the HREC and Research Governance.

19. Once the approval period has ended, a letter will be sent to the investigator, requesting that they submit an annual report or request an extension. If no reply is received within 30 days the project will be closed and archived. A letter notifying the investigator that the research project is now closed will be sent at this point.

20. If a project is suspended or terminated by the principal investigator or a project sponsor the investigator must immediately inform the SCGOPHCG of this and the circumstances necessitating the suspension or termination of the project. Such notification should include information as to what procedures are in place to safeguard participants.

21. In extreme cases the SCGOPHCG may immediately and without warning withdraw its approval to conduct research. (Please refer to Standard Operating Procedure 705 for further information).

22. Once the SCGOPHCG has suspended or terminated the research approval the project must cease. The investigator is required to ensure that the needs of the participants involved in the project are met.

23. If a project fails to meet these Terms the SCGG HREC will contact the investigator(s) to request they rectify the identified issues. If, after being contacted by the HREC, the issues are not addressed the HREC approval will be withdrawn and a recommendation made to the Sir Charles Gairdner and Osborne Park Health Care Group that institutional approval be withdrawn.

SIR CHARLES GAIRDNER GROUP
HUMAN RESEARCH ETHICS COMMITTEE

Effective Date: 14 February 2013

Adverse Event Reporting for Clinical Trials

Please be advised that, consistent with previous statements, the Sir Charles Gairdner Hospital Human Research Ethics Committee does not require sponsors or investigators to submit individual reports of Serious Adverse Events that occur outside of our institution for review. The HREC has adopted the reporting requirements outlined in the NHMRC AHEC Position Statement May 2009
http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf

Summary of Reporting Requirements

Type of Reporting	Event
24 (death) 72 hours (other)	SAEs occurring on site
In a prompt manner	Information which materially impacts the continued ethical acceptability of the trial or Information that requires, or indicated the need for a change to the trial protocol including changed safety monitoring in the view of the investigator or sponsor.
Six monthly	Listing of all SUSARS, Australian and international, occurring with a compound including Sponsor and investigator comments as to whether action is planned for the trial on the basis of the reports. (EU format is acceptable)
Annually	An updated Investigator brochure or An EU ASR (or similar format report) or Current, approved Product Information (PI), if appropriate (eg in a study for a product approved in Australia or where an Investigator Brochure is no longer maintained) Other reports consistent with section 5.5.5 of the National Statement and Good Clinical Practice (GCP) as adopted by the Therapeutic Goods Administration (TGA)

Investigator Initiated Trials
Please note that if you are the Principal Investigator of an Investigator Initiated Trial utilising a CTN for a medication or device where SCGOPHCG is the sponsor, it is a TGA requirement that you report adverse events that occur to the TGA, in addition to reporting to the HREC. Please refer to the TGA website for further information regarding definitions and reporting requirements available at http://www.tga.gov.au/pdf/clinical-trials-guidelines.pdf (See pages 70-75 regarding medications and pages 76-80 for devices).