Sir Charles Gairdner Hospital

**participant Information Sheet**

**Version 1, 18/09/2013**

# Trial 2013-007: Surveillance of antibiotic resistance, treatment effectiveness, treatment side effects, and bacterial genotypic/phenotypic analyses on clinical Helicobacter pylori isolates

**Prof Barry Marshall**

Please take time to read the following information carefully and to discuss it with your family, friends and general practitioner if you so wish. If any part of the information is not clear to you, or if you would like more information do not hesitate to ask us to explain it more fully. Make certain you do this before you sign the consent form to participate in this study.

**Who is funding this study?**

This study is funded by Vice-Chancellor of University of Western Australia, NHMRC Sir McFarlane Burnett Fellowship grant (572723), Department of Health and Department of Commerce.

Contact persons:

If you have any questions about the study you can contact:

Prof Barry Marshall: 08-9346 4815

Jim Blanchard: 08-9346 4036

**Decision to Participate:**

Your decision to participate in this study is **voluntary**, that is, you may decide to be in this study or not take part in it at all. If do you decide to participate, you are able to change your mind at any time during the study. However, before you make any decision, it is important that you understand why this study is being done and what it will involve, including your rights and responsibilities. You will also be given a copy of this Participant Information Sheet and Consent Form to keep for your personal record.

Any decision you make will not affect your regular medical care or any benefit to which you would otherwise be entitled.

**The Participant Information Sheet explains the study and includes details such as:**

* why this study might be suitable for you;
* possible benefits and risks (side-effects) of the study drug/medication;
* the type, frequency and risks of any medical tests or procedures that you will need to have as part of this study;
* what your rights and responsibilities are if you agree to participate; and
* what alternative treatments are available to you if you do not wish to participate.

# What is the purpose of this study?

This study can be divided into two parts:

1. Surveillance of antibiotic resistance and treatment cure rate (extension of previous study, Trial No. 99-026)
	1. Continue monitoring the antibiotic resistance profile of *H. pylori* among Western Australians.
	2. Continue monitoring the side effects and efficiency of the prescribed treatment.
2. Bacterial genomic analysis
	1. Understand the development of antibiotic resistance.
	2. Understand the association of *H. pylori* genomes to different disease outcome.
	3. Identify other Helicobacter species, eg. *H. suis*, *H. heilmannii* and *H. felis*, etc from patients with a positive diagnosis but negative bacteria culture.
	4. Improve current diagnostic methods.

**Why is this study suitable to me?**

You are being invited to take part in this study because you have failed at least once (or more) courses of triple therapy and you are coming into Sir Charles Gairdner Hospital for an endoscopy examination.

What will happen if I decide to be in this study?

Three extra biopsies will be collected by the gastroenterologist in Sir Charles Gairdner Hospital during your endoscopy visit. In rare cases where your *H. pylori* is hard to detect, additional samples of the following may be collected by trained medical or nursing staff on duty during your endoscopy visit to aid your diagnosis: 10 mL of blood, 10mL gastric juice, 2mL saliva, 10mL urine and a stool specimen. All your donated samples together with your private information will be stored in a secure place indefinitely for future research reference. Your identity will be protected and will not be used in any research. You will be continuously followed up until your *H. pylori* is proven eradicated. A quick 5-10 min survey will be sent to you to help us understand the side effects of the treatment. Return postage envelop will be provided in the survey.

Are there any reasons I should not be in this study?

This study is focusing on patients who are carrying antibiotic resistant *H. pylori.*  You should not be in this study if (1) you are under 18 years old or pregnant (2) you are not infected with *H. pylori*;(3) you have not tried the standard triple therapy which can be prescribed to you by your general practitioner.

# What are the costs to me?

There will be no extra cost to you

**What are the possible benefits of taking part, to me and to the wider community?**

This research could (1) monitor on the impact of antibiotic resistance of *H. pylori* in Western Australia; (2) provide resolutions for patients carrying antibiotic resistance *H. pylori* strains; (3) understanding of the genetic makeup of *H. pylori* that leads to its virulence; (4) lead to new medical discoveries which could make endoscopy unnecessary in the future and help us better understand stomach complaints.

What are my alternatives if I do not want to participate in this study?

Taking part in this study is entirely voluntary and you may refuse to take part or withdraw from the study at any time. If you do refuse or withdraw, you will still continue to receive equal care from the Sir Charles Gairdner Hospital Gastroenterology Unit. You will still continue to be followed up until your *H. pylori* is proven eradicated. Your medical records in our database and donated samples will be destroyed. However, the *H. pylori* isolated from you will continue to be studied but not be able to link to any of your medical records.

**What are the possible side effects, risks and discomforts of taking part? What if something goes wrong? How will my safety be ensured?**

Three stomach biopsies will be requested from the gastroenterologist during the upper gastroendoscopy session performed in Sir Charles Gairdner Hospital under the hospital’s standard procedure (for detail, please refer to the gastroscopy patient information). It is usually harmless and painless. However, there is a small risk of bleeding (less than 1 in 10 000 biopsies) and putting a hole in the stomach is also very rare.

**Who owns the samples collected from me?**

The samples (biopsies, blood, saliva, stool, and urine) collected from you will be treated as a donation and therefore owned by the research community. However, you are able to withdraw from the study at any time and we will have your samples destroyed. To withdraw from this research program, please contact the research associate, Dr. Alfred Tay, on 08-9346 4817.

Are my donated samples be used in any future research projects?

The stored samples will be archived for future research related to the pathogenicity of *Helicobacter* spp. infection.For example, bacterial genome sequencing was almost impossible 10 years ago when we started our previous trial (Trial No. 99-026). Now that the technology has advanced, we will be able to study the whole bacterial genome instead of a few virulence genes. This study will only be focusing on bacterial DNA. No human DNA will be used for cloning and investigate paternity issues.

**Will my taking part in this study be kept confidential?**

The research team may need to collect personal data about you, which may be of a sensitive nature, eg, year of birth and relevant health information. They may also need to obtain some health information about you from other health service providers, eg, from another hospital, pathology laboratory, x-ray department, GP or other medical specialist.

This personal or health information will be kept private and confidential, and will be stored securely. Only authorised persons, who understand that this information must be kept confidential, will have access to it. Your study details will be given a unique number so that your identity will not be apparent to anyone else. All participant records will be kept in The Marshall Centre for Infectious Diseases Research and Training, University of Western Australia during the study and in a locked archive for at least 5 years from the time the study is closed.

Authorised representatives of the study Doctor, the Sir Charles Gairdner Group Human Research Ethics Committee, Research Governance and specific pharmaceutical regulatory bodies may require access to your study records to audit study procedures and/or data. As well, some of your information may be sent to research staff in other countries for similar reasons. If this should occur, these personnel are required to comply with the privacy laws that protect you when dealing with your information.

The results of this research may be made available to other Doctors through medical journals or meetings, but you will not be identifiable in any of these communications. By taking part in this study you are agreeing not to restrict the use of any data even if you withdraw. However, your rights under any applicable data protection laws are not affected.

**How can I find out the results of this study?**

In general, participants will not be informed about the finding outcome unless it is requested or are directly impacted by the research.

# Who has reviewed this study?

The Sir Charles Gairdner Group Human Research Ethics Committee has reviewed this study and has given its approval for the conduct of this research study. In doing so, this research conforms to the principles set out by the National Statement on Ethical Conduct in Human Research and abides by the Good Clinical Practice Guidelines.

**In the case of a medical emergency contact:**

**The Clinical trial co-ordinator, Jim Blanchard**

**08 9346 4036**

|  |  |
| --- | --- |
|  | **CONSENT FORM** |

**Study Title: Surveillance of antibiotic resistance, treatment effectiveness, treatment side effects, and bacterial genotypic/phenotypic analyses on clinical Helicobacter pylori isolates**

Researchers: Dr Barry J Marshall

Participant Name:

Year of Birth:

**NOTE: If you are still unclear about anything you have read in the Participant Information Sheet and Consent Form, please speak to your doctor before signing this Consent.**

1. I have been given information, both verbally and in writing, about this study and having had time to consider it, am now able to make an informed decision to participate.
2. I have been told about the potential benefits and known risks of taking part in this study and I understand what this means to me.
3. I have been given the opportunity to have a member of my family or a friend with me when this study was being explained to me. I have been able to ask questions and have had all my questions answered.
4. I know that I do not have to take part in this study, and that my decision to take part is voluntary. I understand that I can withdraw from this study at any time without this decision affecting my medical care.
5. I understand that participating in this study does not affect any right to compensation, which I may have under statute or common law.
6. I accept that by taking part in this research, that any information obtained about me during the study may be published, provided that my name andother identifying information are not used.
7. I understand that my donated samples will belong to the research community and stored indefinitely for future research.
8. I give permission to this research group to access my medical records from both public and private pathology laboratories.

Name of Participant Signature of Participant Date

Name of Researcher Signature of Researcher Date

The Sir Charles Gairdner Group Human Research Ethics Committee has granted approval for the conduct of this study. If you have any concerns about the ethics or code of practice of the study, please contact the Executive Officer of the Sir Charles Gairdner Group Human Research Ethics Committee on (08) 9346 2999.

**Study participants are to receive a copy of the Participant Information Sheet and Consent Form for their personal record.**