**PATIENT INFORMATION SHEET**

**H. PYLORI INFECTION AND GASTRIC SECRETORY FUNCTION**

**What is the purpose of the study?**

There has been a dramatic change in the incidence of diseases affecting the gullet and stomach over the past 25 years. Ulcers of the stomach and duodenum and also stomach cancer have become much less common whereas heartburn and reflux symptoms and cancer of the gullet have become much more common. The cause of these changes is unclear but could be related to the fall in the number of people who carry the bacterium *Helicobacter pylori* in their stomach. The bacterium lives on the inner lining of the stomach and is present in more than 50% of the human population. The infection may be altering the incidence of stomach and gullet diseases by altering the acid our stomach secretes. In order to investigate this, we wish to study the stomach and its acid secretion in healthy volunteers aged between 30 and 75 years. As *Helicobacter pylori* is present in the stomach of approximately 50% of healthy volunteers, this will allow us to compare the stomach in those with versus without the infection.

**You are invited to participate in the research study.**

If you agree to participate, it will involve you attending the hospital on two separate mornings over a 2-4 day period.

You will receive payment for participation in the study at a rate of £50 per half-day attendance. If you decide to leave the study prematurely, you will receive payment for the days you have completed.

**Why have I been invited?**

You have been invited as we wish to examine normal healthy individuals between ages 30 and 75 years who are not taking medication which affects the stomach.

You will only be chosen if you are sure you are not pregnant and are not breast-feeding.

**Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. Taking part in the study will not affect the standard of care you receive in future.
What will happen to me if I take part?

The study will involve you attending the hospital on two separate mornings. The details of what will happen to you on these two days is given below.

Study Day 1:

On the first day, you will attend our Unit in the morning, fasted, having eaten nothing since the previous evening. You will be asked questions regarding your health and your height, weight, and waist & hip circumference measured. A blood sample will be taken and be used to confirm whether or not you have the bacterium Helicobacter pylori in your stomach and if so what strain of bacterium it is. We will also extract DNA from your blood sample and store it in an anonymised form. At a later date the DNA may be used to see if it can predict how much acid your stomach secretes. The total amount of blood taken will be 30ml or 6 tablespoons.

You will then have a breath test which allows us to determine whether or not you have Helicobacter pylori present in the stomach within 30 minutes of the start of the test. The test involves taking a drink which contains a very small dose of radioactive urea. Twenty minutes after taking the drink, you will blow into a tube and your breath sample is then analysed.

Thirty minutes after having the breath test, you will undergo the upper gastrointestinal endoscopy. This involves passing a flexible tube about the width of a pencil through your mouth and down into your stomach. To make this procedure more comfortable, we will spray your throat with a local anaesthetic and if you choose, a small dose of a sedative called Midazolam, into your vein. If you choose to have Midazolam, then you should not drive for 24h. The endoscope will pass through your mouth and your gullet and stomach examined. Twelve biopsies will be taken from the distal stomach and gullet for examination under the microscope. Each biopsy is approximately 1mm deep by 1mm wide by 4mm long and heals within a day without leaving a scar. Two small metal clips will be attached to the GO junction between your gullet and stomach which show up on X-ray. These small metal clips usually fall off within five to ten days and are passed harmlessly in your stool.

If you are receiving sedation with Midazolam, it is essential that someone comes to pick you up. Once home, you are advised to rest quietly and should not drive a car, operate machinery or drink alcohol until the later day.

Your attendance on this first study day will be probably between two-three hours. You will be offered a light snack following the tests.
Study Day 2:
You will again report fasted, having had nothing to eat since the night before. This second attendance will be within two-four days of the first attendance. A flexible probe about half the diameter of a pencil will be passed down your nose into your stomach. This probe will remain in position for two hours. This measures the acidity in 12 different locations from your lower gullet to distal stomach.

Approximately 10 minutes after inserting the probe, you will have an X-ray which allows us to see the location of the probe relative to the little clips fixed during your endoscopy.

Fifteen minutes after inserting the probe, you will eat a standardized meal over 12 minutes and the probe will continue to measure the acidity in different regions of your stomach for a further 90 minutes and then be removed. The meal will consist of spaghetti Bolognese with a glass of milk. The meal is provided by Marks & Spencer.

Your attendance on this second day will be for approximately two hours.

What do I have to do?
The study will not involve you in any additional measures.

What are the possible disadvantages and risks of taking part?
The passage of the endoscope may cause some discomfort. Risks from endoscopy and biopsy, such as perforation and bleeding, are rare – occurring in less than 1 in 10,000 procedures. Sedation with Midazolam could cause respiratory suppression and respiratory arrest has been reported. The risk of respiratory arrest with Midazolam in healthy volunteers is less than 1 in 10,000. The Unit in which the procedure is conducted has full cardio-respiratory resuscitation equipment at hand.

The passage of the pH pressure tube may cause moderate discomfort.

The combined radiation exposure of the X-ray and urea breath test is equivalent to 140 hours background radiation. It represents additional risk of lifetime risk of cancer of one in 500,000.

In the unlikely event that abnormality is detected at the endoscopy or in a biopsy, your General Practitioner will be informed and advised regarding appropriate investigation and treatment. You will also be informed of the finding of any unexpected abnormality. You may, however, be aware that this may have implications for future insurance and mortgage purposes.
What are the possible benefits of taking part?

This research is unlikely to have any immediate direct benefit to yourself. However, it will increase our understanding of the cause of gullet cancer and hopefully point to improved ways of preventing it in the future.

When the study is completed we will forward you a copy of the scientific paper presenting the findings and conclusions of the study.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you.

The contact details of the Hospital Complaints Manager are:

Mrs. Anne Marie Weir,
Complaints Officer,
Complaints Department
Western Infirmary,
44 Church Street,
Glasgow, G11 6NT.
Telephone: 0141 211 2258

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. Your General Practitioner will be informed that you have taken part in the study.
What will happen to the results of the research study?

The results of the study will be presented at medical research meetings and published in medical journals.

Who is organising and funding the research?

The study has been conceived and designed by Professor McColl and his medical colleagues in Gartnavel General Hospital. The study is being funded by the Hospital Endowment Research Fund. The doctors conducting the study receive no personal monetary benefit from involving you in the study.

Who has reviewed the study?

The study has been reviewed by the West of Scotland Research Ethics Committee 3.

Independent Medical Contact

If you wish to discuss any aspect of the study with an independent medical person, you may contact:

Dr. Colin Perry,
Consultant Physician,
Western Infirmary, 44 Church Street, Glasgow, G11 6NT.
Telephone: 0141 211 2000 (radiopage via Switchboard)

Contact for Further Information

If you require to contact anyone before, during or after the study please telephone the Gastrointestinal Unit at Gartnavel General Hospital on 0141 211 3248 and ask to speak to Sister Angela Wirz.

You will receive a copy of this information sheet and a copy of the signed Consent Form to keep.