

**Hereditary Diffuse Gastric Cancer Data Register**

Tel 01223 330019

**INFORMATION LEAFLET**

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you.

**What is the purpose of the study?** You have recently chosen to undergo genetic testing to see whether you carry genes which increase your risk of stomach cancer. We would like to find out more about how these genes work and how much they increase an individual's risk of stomach cancer. For people at risk for stomach cancer we hope to develop an effective endoscopy (camera examination of the stomach) screening programme and to assess the impact of having a preventative operation to remove the stomach (gastrectomy) on individuals who choose to have surgery. We hope that by recording information from families undergoing testing we can find out more about hereditary gastric cancer and the genes involved and help local genetic centres to give accurate advice to families undergoing testing. The families can then be helped to make well informed choices about their treatment options.

**Who will benefit from the research?** This research may benefit you as a result of the advances which will be made in screening and as a result of our increased knowledge about gene functions. It may also help other members of your family or other people in the future.

**What would I have to do?** We would like to collect information from you regarding your genetic blood test results, previous endoscopy screening results and your medical history. This can be done on the phone by our Research Nurse and by post, in the form of a simple questionnaire. This questionnaire includes questions about the psychological effects that genetic testing has had on you and also questions about the physical impact of having a gastrectomy (should you choose to have surgery).

We would also like you to have a lengthy endoscopy of your whole stomach which would involve taking a large number of biopsies (It is estimated that it may take approximately 20 minutes, and require taking 30 samples). This endoscopy would be part of your routine care anyway should you choose not to have your stomach removed. It is a research procedure which we are trying to develop as part of the study. It is as yet unproven as being effective in detecting early gastric cancers. However, with the information gained from the endoscopies carried out in the study we hope to analyse how effective it is and develop and improve the procedure offered to individuals at risk in the future. This endoscopy could be carried out in Cambridge or London but could also be done at your local hospital, under guidance from Cambridge, if you prefer not to travel. (It would not however be possible to reimburse travel expenses to Cambridge or London). These biopsies would be used to examine the changes in the cells lining your stomach. The biopsies would be analysed by a clinical pathologist and the results would be used to help decide on your medical care. This would be part of your clinical care and reported to your hospital doctor who is responsible for your endoscopy. We would also like to store the

biopsies viewed by the pathologist and some additional frozen biopsies for use in research relating to stomach cancer as new strategies develop.

We would also like your permission to obtain tissue from any biopsies you may have had taken in the past which may be stored at your hospital pathology department.

We will also ask you for a blood sample (20mls or 4 teaspoons) – just like the one which is taken for ordinary blood tests or to provide us with a sample of your saliva. This can be taken when you attend for your endoscopy examination. This will be used to look further at the role of genes which increase the risk of stomach cancer, and to look at how blood cells grow and develop.

If you decide to have an operation then we would like your consent to have the removed stomach stored in Cambridge. This would be done after routine examination of your stomach by the pathologist at your local hospital. This tissue is excess to the requirements of the normal process carried out by your hospital's pathology department as part of your operation and will be used to look for any abnormalities of your stomach lining and to study aspects of hereditary gastric cancer which may help give families better advice in the future.

**Who will know my personal information?** We will not pass on any information to anyone, not even other members of your family, or your **GP**, without your permission. We will, with your consent, contact your GP, simply to inform him that you are taking part in the study. All the information you give us will be completely confidential in accordance with the Data Protection Act 1998. Authorised staff from a research and development audit office may have access to our information in order to assess that we are working to research guidelines.

**How will my samples and data be stored?** The blood or saliva sample will be sent to Strangeways Research Laboratory in Cambridge (part of the Addenbrookes Hospital campus) where it will be stored for as long as the study has ethical approval. It will be given a numerical identification number. All information you give us will be stored on a secure database and in a locked filing cabinet in the department of Oncology in Addenbrookes Hospital in Cambridge. Only members of the research team working with your information, namely the research nurse, research assistant and lead investigator will know your identity. No laboratory staff doing analysis on your sample will know your identity. The pathology samples obtained at endoscopy will also be given a numerical identification and stored for as long as the study has ethical approval. They will only be used to study aspects of stomach or oesophageal cancer as new research strategies develop. Every change to the study regarding the use of these samples will be subject to approval by an ethics committee.

Your stomach, should you choose to have an operation would be divided into sections and sent to a hospital in Portugal for in-depth examination by the team of pathologists there who are very experienced in examining tissue from families like yours. It will then be returned to Cambridge and stored in the same way as the specimens taken at your endoscopy.

**Will there be any results from the samples?** Any findings received from the examination of your blood sample and pathology samples which may be relevant to the clinical care of you and your family will be relayed to you by the geneticist looking after you during your counselling and testing.

**What happens if anything goes wrong?** Side effects of giving a blood sample are uncommon and mostly minor, such as bruising or tenderness. There is no increased risk from the endoscopy examination other than those associated with a routine endoscopy. The risks are very small and will be explained fully to you when you attend for your endoscopy examination. (if you would like a full explanation of these risks at this time please contact Sue Richardson who will be happy to provide you with this information).

The research team is insured (indemnified) should you come to any harm as a result of negligence. If you have a problem or complaint you can contact Sue Richardson (see below). You could also pursue the matter through the NHS complaints procedure in exactly the same way as you would be able to if you were receiving standard NHS treatment and were not participating in a research study.

**If I have any questions who can I ask?** Sue Richardson the Research Nurse will be pleased to answer any queries you may have. She can be contacted by telephone on 01223 330019. Or you can write to her at the above address.

**What if I would rather not take part?** There is no pressure on you to take part, if you would rather not. Also, you can change your mind and leave the study at any time. You don't have to give a reason. Your decision will not affect your own care or treatment in the future, or that of anyone in your family. If you should choose to withdraw from the study you can choose to have your blood samples, tissue samples and all information you have given us destroyed.

**What happens to the results of the study?** The results from the analysis will be discussed at scientific meetings and published in medical peer review journals. Individuals will not be identified in any report or publication. In the long term any discoveries from this research will be used to improve the treatment and advice given to patients.

**Who is doing the Research?** The study is being carried out by a team from The University of Cambridge headed by Professor Carlos Caldas and is funded by Cancer Research UK. The research staff are not being paid for your participation.

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