

INSERT LOCAL LETTERHEAD

## **PATIENT INFORMATION SHEET**

### **Looking for new genetic causes of stroke**

**(Full title : A DNA resource for lacunar (small vessel disease) stroke)**

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. Ask us if there is anything that is not clear to you, or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

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

Risk factors such as smoking and high blood pressure contribute to stroke risk. However, we don't understand fully why people have strokes, and about a half of the factors causing stroke risk remain unknown. Considerable evidence suggests that familial (genetic) predisposition may play a role. However we don't yet know which are the individual genes (building blocks of genetic material) which contribute to stroke risk. If we did, then it is possible that we could use this information to develop better treatments, or to identify particular people who are at risk of stroke who can be given lifestyle advice or particular drug treatments. We now have the technologies to look for new genes causing stroke, but we will only be successful if we look at samples from many hundreds of individuals. This project, funded by the Wellcome Trust, will set up a collection of blood samples from approximately 1000 people with stroke. This resource will be open to researchers throughout the stroke community and we hope that it will be used to help identify a number of new genes for stroke over the next 10 or more years.

Stroke can be caused by many different diseases and each of these may have different genetic predispositions. Therefore in this study we are only collecting samples from patients with a particular type of stroke. This is called small vessel or lacunar stroke and involves blockage of small blood vessels deep in the brain. We are only recruiting individuals who are ages 70 years or under because genetic factors appear to be stronger in younger individuals.

#### **Why have I been chosen?**

You have been chosen because you have had a lacunar stroke and are in the age range of 18-70. Samples are being collected from patients with stroke in a number of centres throughout the United Kingdom and your consultant is one of those taking part in this research project.

#### **Do I have to take part?**

It is up to you to decide whether to take part or not. 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.

### **What will happen to me if I take part?**

If you take part we will ask you about your risk factors for stroke and about the particular stroke you have suffered from. We will also obtain details of this from your medical notes. We will take a blood sample (of 40 mls which is equivalent to 8 teaspoons) which will be used for future genetic analysis. When the genetic analysis is performed this will be done entirely anonymously so nobody will know which sample belongs to which patient. The reasons for this are described in more detail later.

We need brain imaging in all patients who are taking part in this research. It is likely that you would have already had this performed routinely but if not we will ask whether you will be prepared to attend for a scan called an MRI scan. This is a routine investigation in patients with stroke. It is painless and has no known side effects. However some people find the MRI machine claustrophobic, and the scan is rather noisy. It takes about 20 minutes.

The interview and blood test will take about half an hour. This will usually be performed when you are in the hospital either as an in patient or out patient. However we will also be recruiting some patients who had their strokes some time ago. If that is the case we will ask you to attend for one additional out patient visit.

### **What are the possible risks and disadvantages of taking part?**

This is a simple study and there are few risks. However sometimes when you have blood taken it can lead to bruising at the sight of the blood taking.

### **What are the possible benefits of taking part?**

By taking part you may help stroke research and hopefully help us understand better the causes of stroke. This will benefit future patients but there will be no direct benefit to you from taking part.

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

People are naturally concerned about confidentiality when we are looking at genetic material. For this reason there are very rigid measures in place to ensure complete patient confidentiality. All data on computer is protected by a double layer of passwords and is only available to people working directly on the study. The study will retain a record of the identities of the patients who donate each sample. The doctors running the study will take great care to keep that information entirely to themselves. Linkage between individual patients, their samples, and their future genetic study results will be kept because it might be useful for other studies in the future.

Because we have linkage of records if you wish to have your genetics sample removed and destroyed at a later date this can be done at your request.

### **What will happen to my sample and results of future research studies?**

The sample will be stored in a freezer for at least 10 years. We will use it to make cell lines. This is a process by which we can obtain an unlimited supply of genetic material (DNA) for future studies and is carried out by an organisation in the UK called ECACC (European Collection of Cell Cultures). ECACC perform this process for a large number of research studies. ECACC is based in England, and forms part of the Business Division of the Health Protection Agency that reports to the UK Department of Health.

This resource will be made available for research projects on stroke, and will not be used for any other research projects. It is likely that a number of different research questions, looking at different genes for stroke, will be asked over the next 10 or so years. Because these will all be done anonymously you will not receive the results of your individual genetic test. We feel this is the best approach because each gene is likely to only have a small effect on stroke risk, and all the results will need to be repeated on different populations before we can be sure that they are reliable. The results will be published in medical journals and presented at medical conferences. You would retain no rights to the samples or cell lines.

At present we plan to do no additional studies, but it is possible that we would like to look at whether certain genes are associated with a better outcome from stroke. This would involve contacting you or your doctor in future to see how you have been since we took the blood sample. If you are happy for this to be done please tick the appropriate box on the consent form.

**Who is organising and funding the research?**

This project is a four year project funded by the Wellcome Trust which is one of the main medical charities in the United Kingdom. The project is being run by the UK Stroke Genetics Group which is co-ordinated from St George's Hospital Medical School in London. The doctors carrying out the research are not being paid for this research.

The research has been reviewed by the Wellcome Trust's scientific panel who have agreed to fund it. The research has also been reviewed by your local research ethics committee.

**Contact further information.**

If you have any further questions please contact: *insert local contact*