



## Participant Information Sheet (11 – 15 years)

### **Study of Outcome of Childhood Stroke (SOCS)**

[www.childstroke.org.uk](http://www.childstroke.org.uk)

We are asking you to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve for you. Please take time to read this information sheet and discuss it with your family, friends, doctor or nurse if you want to. Ask us if there is anything that is not clear or if you would like to know more. Take time to decide whether or not you wish to take part.

#### **Why are we doing this research?**

A stroke is what happens when blood doesn't get to part of the brain. This can damage part of the brain and may mean that part of the brain may not work properly. Any of the brain's many functions may be affected. For example, the brain may no longer be able to properly control the arms or legs.

Most people affected by stroke are adults. However, some children are affected by strokes as well. We are trying to find out how many children are affected by strokes. We aim to find out how stroke can affect children's movement, intelligence, behaviour and quality of life. Lastly, we aim to take part in research about stroke in children that is happening across the world.

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

You are being invited to take part in this study because you have had a stroke. The study aims to invite all children affected by stroke who live in the south of England to take part. We estimate that we will ask 200 children to take part in 1 year.

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

No, taking part is up to you. If you decide not to take part you do not have to give a reason and no one will be upset. Your treatment will not be affected if you decide not to take part. If you do decide to take part we will ask you and your parents or guardians to sign a form. We will give you a copy of this information sheet and the form to keep. If you decide to take part you can still withdraw at any time.



## **What will I be asked to do if I take part?**

We would ask that you be involved in the study for 12 – 14 months although you would not need to do anything for most of that time. We would get information from your medical notes. We would record things such as your age, blood test results, brain scan results, and treatments given. With your permission, we would also take copies of your brain scans. We would also like to store a bit of your blood. In the future we may be able to use that blood to find out more about strokes. Your doctor will probably need to take blood tests from you to help you get better. We would always try to do the blood test at the same time so that you didn't need any extra tests.

We would have no part to play in your treatment as this will be done by your own doctor. Taking part in the study will not affect your treatment in any way.

At 12 – 14 months we would visit you at home to assess how the stroke had affected you. We would assess how the stroke has affected you through a variety of questionnaires and tests. We would ask you to do some tests for about 1 hour. Then we would ask your parents or guardians some questions for about 1 hour. Then we would ask you to do some more tests for 1 hour. With your permission we will film you doing some of the tests so that we can get an accurate score for those tests. Finally, we would leave you some questions to fill in and post back to us. They would take up to 30 minutes to complete. The tests and questions will see how well your brain is working after the stroke.

With your permission we would put some information about you that we have collected onto an international database. This database is maintained by the International Paediatric Stroke Study (IPSS). The information put here would not have your name or address on it so no one could identify you.

That would be the end of your part in the study. However, we would like to ask your permission to contact you again in the future. This would be to invite you to take part in future research. Any further treatment you required would still continue through your own doctor.

## **Is there anything to be worried about if I take part?**

Your treatment will not be changed by taking part. However, you may find the assessment at the end of the study boring or long. We aim to make it as easy as possible by breaking up the assessments into small chunks of testing alternated with questions. If you would prefer we can do the testing on more than one day. Also, the assessments will be conducted by an experienced children's doctor who has worked with children for many years. Although we would like to store a bit of your blood we would try to take it when your doctor needs to take blood. This should mean you don't need any extra blood tests because of taking part in this study.



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

After we have assessed you we can give you the results if you would like to know. We might get information about strokes in children that could help other children with strokes in the future.

### **Are there any restrictions on what I might eat or do?**

No, participation in the study does not involve any restrictions. However, your doctor may advise things as part of the treatment of your stroke. This advice will not be altered by taking part in this study.

### **Who will know I am taking part in the study?**

We will look at your medical records. However, all information which is collected about you during the course of the research including the video will be kept confidential. This means that we will only tell those who have a need or right to know. You will not be able to be identified from any report that is published. Your name and address will not be put on any of your test results or video.

With your permission we would let your GP and hospital doctor know that you are participating in this study.

### **What will happen to the results of the research study?**

The results of this study will not be known until the last child has been assessed by around February 2010. The results may be reported in medical publications or meetings but you will not be identified by name. We will put a summary of the results on the website.

### **Who is paying for the research?**

This study is being funded by a charity called the Stroke Association. Your doctor will not receive any money for asking you to take part.

### **Who has reviewed the study?**

Before any research goes ahead it needs to be checked that it is fair. This study has been approved by the National Research Ethics Service.

### **What do I do now?**

Thank you for thinking about taking part in this research. If you agree to take part in this study we will ask you and your parents or guardians to complete a consent form.

If you would like further information please contact:

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