**Rates, Risks and Routes to Reduce Vascular Dementia (R4VaD)**

**Participant Information Sheet - Recovered Capacity**

**You are being invited to consider continuing 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 ask me if there is anything that is not clear or if you would like more information. Thank you for reading this.**

**Why am I already in this study?**

You have been asked because you have recently had a stroke or mini-stroke. The clinical team looking after you thought that you might be suitable. At the time, you were unable to give consent for entry into a study. We therefore asked a close friend or relative to give their assent for you to enter this study. This is permissible under Common Law in Northern Ireland.

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

Sometimes patients can experience memory, thinking or mood changes, or dementia, after a stroke but we do not yet know enough about how to treat these conditions. We are looking at these conditions to help more people to make a better recovery. We are not testing any new treatments and there is no change to your normal medical care.

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

No. It is up to you to decide whether to continue to take part in the research or not. If you decide to continue to take part you will be free to change your mind at any time and without giving a reason and this will not in any way alter your care, now or at any stage in the future. If you decide to not continue, you can allow all the anonymous information and samples collected so far to remain in the study. This is better scientifically. However, if you feel strongly that you do not want your anonymised information or samples to remain in the research, then we will ensure that the samples and information are destroyed so that you will be completely removed from the study. Deciding not to take part, or withdrawing from the study, will not affect your healthcare, or your legal rights

You may have a day or more before deciding if you want to continue with the Study. You may do as much or as little of the Study as you like. In some hospitals, there are extra tests (for example brain scans) which we will ask about separately.

**What will the Study involve?**

One of our team will go through this information with you and explain how much of the study has taken place already and what is yet to come.

**First assessment**: Will take place soon after the stroke, in the hospital or clinic. We will take and store your personal details including name, hospital number, date of birth, details of a close relative or friend, and other details so we can contact you). We will record medical details from your case notes and by asking you. We will also ask you (and somebody who knows you if possible) a few brief questions to assess your memory, thinking skills and mood We will take a small blood sample (about 2 teaspoons) to analyse for genes (DNA, to determine whether there might be a hereditary risk for memory impairment after stroke) that may be linked to thinking problems after stroke.

**Second assessment**: Between four and eight weeks after the first assessment, we will ask you about your health after the stroke, more questions about your memory, thinking and mood, and check your blood pressure. This may be done at the hospital, or some of the tests can be done by post or phone. This assessment can take up to an hour, but we can stop at any point. We may take another small blood sample (3 teaspoons).

**One year after stroke**: We will contact your GP to check that it is OK to contact you. We will then contact you (and somebody who knows you, if possible) by phone or post to ask about your health, memory, thinking skills and mood. This may take up to 40 minutes.

**At two, and up to three or four years after stroke**: We will go through the same procedures as at one year after stroke until the end of the Study.

**What will happen to my information?**

All information that we record about you will be kept in the **strictest confidence**. The data that we collect for the Study will be held in a special secure computer record at the University of Nottingham where we have lots of experience of records in stroke studies. The Study information is only identified by your Study number, not by any personal information such as your name. The paper questionnaires and consent forms will be stored at each hospital in special research areas in secure cabinets in case they need to be checked. So that we can contact you during the study, your name and contact details will be stored in a separate secure computer record also at the University of Nottingham, where it will only be seen by approved study team members, who may be based at other universities that are helping with the study, in order to do the follow-up questions, and by the computer programmer in charge.

In order to monitor and audit the study we will ask your consent for responsible representatives from the sponsor(s) and NHS Institution(s) to access your medical records and data collected during the study, where it is relevant to you taking part in this research. We would also like to use your Community Health Index (CHI) and/or NHS number since this enables us to contact you for follow-ups and make sure that we do not confuse you with someone else. The Sponsors are responsible for overall management of the study and providing insurance and indemnity

Copies of the brain scans done as part of your routine care will be anonymised and sent electronically using a secure connection to the University of Edinburgh for analysis. The blood samples will be sent to and stored anonymously by the University of Manchester or Cambridge for analysis.

All hospitals in the UK collect information about patients with recent stroke as part of the Sentinel Stroke National Audit Programme (SSNAP), the Scottish Stroke Care Audit, or other similar audits. We would like to obtain information that is relevant to the Study from these audits to avoid asking you questions that you have already answered.

So that we do not need to keep asking you questions and can find out about your health in the years to come (after the active part of Study has finished), we would like to obtain information about your health from your routine health records. With your permission, we can ask the NHS Central Health Records, Hospital Records, General Practice Records, Drug prescribing records, NHS Digital in England and Wales and the Information Statistics Division in Scotland, to give us information about your future health problems or tell us if you have died and the cause.

These processes involve sharing your personal data with other organisations to obtain additional information and are closely guarded by data and privacy experts.

**Who will see my information and will it be kept confidential?**

All the information we collect during the Study, including scans and blood samples, will be kept in the **strictest confidence** and there are strict laws which safeguard the privacy of the participant at every stage. With your consent we will inform your GP and any relevant healthcare professionals that you are taking part in this study and of any relevant clinical findings. The results from the genetic analysis will not be shared with you or your GP as these are of research relevance only.

**Can I join other studies?**

Yes. In general we would encourage you to take part in other research.

**What are the possible benefits to me from taking part?**

You will get more detailed assessments of memory, thinking skills and mood than would happen in standard care. The results of the memory, thinking skills, mood and any other medically relevant results can be shared with the hospital team looking after you or your GP, which may be useful to your care.

**Are there possible disadvantages and risks from taking part?**

Some people may find these extra questions tiring and they will take up your time.

**What if there is a problem?**

If you have a concern or questions about any aspect of this Study, please speak to the Study team, or you may also speak to a Consultant Physician who is not involved in the Study - details are at the end of this information sheet.

If you have another medical problem that occurs during the Study and you cannot consent to be in the Study any longer, then if appropriate we would like to continue to follow you up including finding out from the person who knows you well (partner, relative, close friend or carer) about your health and thinking skills.

If you are unhappy about the Study and wish to make a formal complaint, then you can use the normal NHS complaints procedure (details at end of this form).

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone’s negligence, then you may have grounds for a legal action for compensation against the NHS, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

**What happens when the Study is finished?**

We think that this Study will improve our understanding of memory and thinking problems that follow stroke. When we have results, we will want to share these with everyone that may find these useful.  We will present the results at medical and scientific meetings and write papers for scientific journals, provide summaries for our and the Funder’s websites and via post or social media methods (see below). We will ask you if you would like to be kept updated about the study results. You will not be identifiable in any published results.

With your permission we would like to store the anonymised data long-term with no time limit on how long we will keep the information for, to answer important research questions in the future.

To make the most use of the Study effort and meet the funders’ requirements, we will share the data with other researchers and eventually make the anonymised data available for other researchers to analyse, including on the World Wide Web.

At the end of the Study, any remaining blood samples will be stored in the Universities of Manchester or Cambridge or transferred to a long term secure storage facility such as the UKBiobank.

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

This Study is funded by charities (Stroke Association, the British Heart Foundation, The Alzheimer’s Society) and the Medical Research Council through the Dementias Platform UK as part of work by the UK Government. Universities and hospitals in Edinburgh, Glasgow, Manchester, Nottingham, Leicester, Cambridge, Oxford, and London (University College and Kings College) have set up the Study and others are taking part.

The study is being sponsored by University of Edinburgh and NHS Lothian

**Who has reviewed and approved this Study?**

The Study was looked at by scientific experts and lay representatives for the Stroke Association, the British Heart Foundation, and the Alzheimer Society before the Study funding was approved and by an independent Research Ethics Committee <insert name> gave ethical approval. NHS management approval has also been given.

**If you are interested in participating in the Study, please contact:**

Telephone: **Dr** Local site on XXXXX or XXX-XXX-XXXX

Email: XXXX@XXXXX

Postal address: Dr XXXX,

**If you have any further questions about the Study please contact:**

**Dr XXXX**, local site,

Phone: XXXXXXXXXX, Email: XXXXXXXXXX

Or  
**Study manager or someone medical in Study centrally**

**If you would like to discuss this Study with someone independent of the Study please contact:**

**TBD**, details, Phone: XXXX, Email: XXXX

**If you wish to make a complaint about the Study please contact:**

[Insert site specific information]

Tel: Email:

Thank you for taking the time to read this information sheet.