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

**Information sheet for Personal Consultee**

**We feel your relative/friend is unable to decide for himself/herself whether to participate in this research.**

**To help decide if he/she should join the study, we’d like to ask your opinion whether or not they would want to be involved. We’d ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.**

**If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the consultee declaration. We’ll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.**

**If you decide that your friend/relative would not wish to take part it will not affect the standard of care they receive in any way.**

**If you are unsure about taking the role of consultee you may seek independent advice.**

**We will understand if you do not want to take on this responsibility.**

**The following information is the same as would have been provided to your relative/friend.**

**What is the purpose of the 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.

**Why has the patient been chosen?**

Your relative/friend is being considered because they have recently had a stroke or mini-stroke. However, they currently lack the capacity to make an informed decision about whether they can take place in a research study. We are therefore asking you as their consultee to give your opinion as to whether or not they would want to be involved. This is permissible under the Mental Capacity Act.

We are not testing any new treatments and there will be no change to their normal medical care.

**Do they have to take part?**

No. If you do advise that you believe the patient would want to take part, you are free to change your mind at any time and without giving a reason and this will not alter their care in any way, now or at any stage in the future.

You can have a day or more before providing your opinion. We would value your opinion whether your friend/relative would have wanted to contribute to the whole, or part, of the Study. In some hospitals, there are extra tests (for example brain scans) which we will ask about separately.

**What will the Study involve?**

**First assessment**: Will take place soon after the stroke, in the hospital or clinic. We will take and store your relative/friends personal details including name, hospital number, date of birth, details of a close relative or friend, and other details so we can keep in touch. We will record medical details from their case notes. We will also ask the participant and an informant a few brief questions to assess their memory, thinking skills and mood. We will take a small blood sample (about 2 teaspoons) to analyse for genes (DNA analysis, 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 the participant about their health after the stroke, more questions about their memory, thinking and mood, and check their blood pressure. This information will be collected by the research team. 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 their GP to check that it is OK to contact them. We will then contact your friend/relative (and somebody who knows them well, if possible) by phone or post to ask about their 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 their information?**

All information that we record about your relative/friend 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 dealing with records in stroke studies. The Study information is only identified by their Study number, not by any personal information such as their 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. Personal information, e.g. name and contact details, will be stored in a separate secure computer record also at the University of Nottingham and will only be seen by study team members, who may be based at other universities that are helping with the study, when doing the follow-up questions, and by the computer programmer in charge.

In order to monitor and audit the study we will ask your ask you opinion whether the participant would agree to responsible representatives from the sponsor(s) and NHS Institution(s) accessing their medical records and data collected during the study, where it is relevant to them taking part in this research. We would also like to use their Community Health Index (CHI) and/or NHS number since this enables us to contact them for follow-ups and make sure that we do not confuse them 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 their 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 the patient questions that they have already answered.

So that we do not need to keep asking the patient questions and can find out about their health in the years to come (after the active part of Study has finished), we would like to obtain information about their health from their routine health records. If it is your opinion that the participant would agree, 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 their future health problems or tell us if they have died and the cause.

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

**Who will see their 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. Study researchers will need access to your relative/friend’s medical records to carry out this research. We will inform the patient’s GP and any relevant healthcare professionals that they are taking part in this study and of any relevant clinical findings. The results from the genetic analysis will not be shared with the participant or their GP as these are of research relevance only.

**Can they join other studies?**

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

**What are the possible benefits to my relative/friend from taking part?**

They 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 them or their GP, which may be useful to their care.

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

Some people may find these extra questions tiring and they will take up 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 your relative/friend has another medical problem that occurs during the Study and you believe that they would no longer want to be involved in the study then the participant will be withdrawn. Any data collected up to that point will be retained.

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 your relative/friend is 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 they may have to pay their own 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. We will ask you if you would like to be kept updated about the study results. Your relative/friend will not be identifiable in any published results.

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: XXXX

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 and considering participation.