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

**Information sheet for Informants**

**You are being invited to take part in a research study. Before you decide whether or not to take part, 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. Talk to others about the study if you wish. 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.**

**What is the research about?**

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 to take part?**

Your friend/relative is being considered because they have recently had a stroke or mini-stroke. We are not testing any new treatments and there will be no change to their normal medical care. You are being invited to consider giving your permission to take part in this study as an informant for your friend/relative. We would like you to complete some short questionnaires about their memory and thinking skills. The participant has given their consent for you to provide information about them. If the participant lacks capacity to consent, an appropriate consultee has provided their opinion that the participant would not object to you providing information about them.

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

No, it is up to you to decide whether or not to agree to take part. If you do agree, you will be given this information sheet to keep and be asked to sign a consent form. You will be free to withdraw at any time and without giving a reason. Deciding not to take part, or withdrawing from the study, will not affect the healthcare, or legal rights of your friend/relative.

You can have a day or more before deciding if you want to take part in the Study. You can decide to do as much or as little of the Study as you like.

**What will the Study involve?**

**First assessment**: Will take place soon after your friend/relatives stroke, in the hospital or clinic. We will ask you to complete a short questionnaire about their memory, thinking skills or mood before the stroke.

**Second assessment**: Between four and eight weeks after the baseline 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 may be done at the hospital, or some of the tests can be done by post or phone. We will also ask you some more questions about their memory, thinking and mood. This can be done by post or phone if you are not able, or do not want, to come to the hospital with the participant. At some centres, the researcher may be able to visit the participant at home.

**One year after stroke**: We will contact the participants GP to check that it is OK to contact them. We will then get in touch with you to ask about their recovery and their impression of their memory, thinking skills and mood and how the participant is coping.

**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 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 the participants Study number, not by any personal information such as your, or the participants, 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, and will only be seen by approved 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 consent for responsible

representatives from the sponsor(s) and NHS Institution(s) to access your data collected during the study, where it is relevant to you taking part in this research. The Sponsors are responsible for overall management of the study and providing insurance and indemnity

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

All the information we collect during the Study will be kept in the **strictest confidence** and there are strict laws which safeguard privacy at every stage.

**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 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 NHS complaints mechanisms are still 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.

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.

**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:**

[Enter site specific information]

Tel: Email:

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