DIAGNOSIS independent consultee information sheet

Study title: *DIAGnosis using NOvel technology for Subtypes In Stroke*

Short title: *DIAGNOSIS*

Chief investigator: *Prof Adrian Parry-Jones*

We would like to invite a patient to participate in a research study. We believe that at this present time, the patient lacks capacity to decide whether to participate. The patient does not have a person who is willing to act as a personal consultee, so we are asking you for advice about whether you feel he/she should take part.

If you decide the patient should be included in the study, we will ask you to read and sign the independent consultee declaration on the last page of this information leaflet. We will 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keep you fully informed during the study so you can let us know if you have any concerns or think the patient should be withdrawn.

If you decide that the patient should not take part, it will not affect the care they receive in any way.

If you are unsure about taking the role of independent 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 the patient or their personal consultee.

About the research

- **Who will conduct the research?**

The research is being conducted by a team of researchers from the University of Manchester. The research is being led by Professor Adrian Parry-Jones (Chief Investigator).

- **What is the purpose of the research?**

This research project will assess whether a new fingerprick blood test, when combined with clinical assessment, can help identify if a patient is having a serious type of stroke.

Most people with stroke-like symptoms call an ambulance and are taken to the nearest hospital for assessment. In some cases, hospital tests confirm a stroke, while in others, a different condition, such as a migraine or infection, is diagnosed. If a serious stroke is identified, such as a blockage of a large blood vessel to the brain or a brain haemorrhage, patients may need to be transferred to a specialist hospital for advanced tests and treatment, unless their local hospital is already a specialist centre.

Treatment for strokes must happen quickly to achieve the best outcomes. For example, if the stroke is caused by a blocked brain artery, a clot-busting drug must be given within four and a half hours of symptom onset to save as much brain tissue as possible. If the stroke is caused by a brain bleed, treatment focuses on reversing blood-thinning medication and rapidly lowering blood pressure to reduce the risk of further bleeding. Because these treatments are very different, it is essential to identify the stroke type as quickly as possible.

Currently, ambulance staff do not have specific tests to confirm whether symptoms are caused by a stroke and cannot tell which type of stroke has occurred. A stroke diagnosis can only be confirmed after a brain scan at hospital. If ambulance staff could identify the stroke type earlier, they could make better decisions about where to take patients and start treatment sooner—either upon arrival at the hospital or even during the transfer. This could improve outcomes for stroke patients.

Recently, a new fingerprick blood test has been developed that may help identify the type of stroke. This test quickly measures two blood chemicals, ‘d-dimer’ and ‘glial fibrillary acidic protein’ (GFAP). Earlier research suggests that these two chemicals, when measured together, may indicate a specific stroke type.

This study will evaluate how well this test, when combined with clinical assessment, can identify specific stroke types. If the approach proves accurate, it could be used in ambulances in the future to start treatment earlier and ensure patients are taken directly to the most appropriate hospital.

- **Is the patient suitable for the study?**

The patient you are acting as an independent consultee for has been invited to take part because they had symptoms suggesting they might be having a stroke, and the new fingerprick blood test was carried out when they arrived at the hospital. The result of the test was not used to as part of the

patient care and the result was not and will not be known by the team caring for the patient. This study is looking at around 300 people who had stroke-like symptoms and underwent the fingerprick test. Some participants in the study will have been diagnosed with a stroke, while others will have a different condition. By supporting the patient's participation, you will help us learn how well the blood test works when combined with clinical assessment for different patients.

- **Will the outcomes of the research be published?**

The outcomes of this research will be published in academic theses, presented at relevant academic conferences and submitted to peer-reviewed journals for publication. A summary of the research findings can also be made available upon request.

- **Who has reviewed the research project?**

This research has been approved by the University of Manchester Information Governance Team, NHS Health Research Authority (IRAS ID: XXXXX, REC reference XX/XX/XXXX) and the participating NHS institutions.

What would the patient's involvement be?

- **What would they be asked to do if they took part?**

To find out whether the new fingerprick test may help diagnose serious strokes, researchers need to compare its results with those of the existing tests currently used to diagnose a stroke.

The new test is a lateral flow test that uses a drop of blood obtained by pricking the patient's with a small needle. You may have heard of lateral flow tests from COVID-19 testing. However, unlike COVID-19 tests, which used throat or nose swabs, this test uses blood. In some cases, two fingerpricks may have been needed to collect enough blood for the test to work. The staff who performed the test recorded the pattern of lines that appeared after the blood was added, as these lines represent the test result.

When the patient's routine assessments and tests were completed, an extra standard tube of blood was also taken. If you agree for the patient to participate in the DIAGNOSIS study, this sample will be used to measure two chemicals, GFAP and d-dimer, which are also measured by the new test. This comparison allows researchers to check whether the new test gives accurate readings for these chemicals. The extra blood sample will be processed in an onsite research laboratory and samples will

be frozen, for later testing of GFAP and d-dimer. Any remaining sample may also be used to test for other markers that may help in stroke diagnosis.

Although staff explained that they were performing the fingerprick and extra blood tests, they did not provide detailed information about the research at the time, as this could have delayed the patient's care. They still received all the usual tests, care and treatments currently available. Because the new test is still being evaluated, its results were not used to influence the patient's care and the results were not known by the team looking after the patient.

There are no additional assessments or interviews required for the patient to take part in the study. Instead, researchers would like to use the following information:

1. The pattern of lines that appeared on the new fingerprick blood test (the test result).
2. The GFAP and d-dimer values measured in the research laboratory from the extra blood test.
3. Results of the standard tests performed during the patient's emergency assessment, which will be obtained from the patient medical records.
4. Copies of any brain scans the patient had, for researchers to review.
5. Details about the patient, such as presenting symptoms, the diagnosis made and the treatments they received, also obtained from the patient medical records.

The researchers are based at the University of Manchester, UK, working in collaboration with NHS hospitals, hospital staff and the company that developed the fingerprick test. The company manufacturing the lateral flow test is UpFront Diagnostics, who are based in the UK.

The fingerprick test was performed by hospital staff. Some information from your medical records (such as your diagnosis) and the results of the new test may also be shared with UpFront Diagnostics to support quality control of their test and help with future improvements.

The information will be shared with both the University of Manchester and UpFront Diagnostics using a coded number. Patient's name and contact details will not be shared.

- **Will they be compensated for taking part?**

There are no payments for participation in this study.

- **What happens if the patient does not participate or if you change your mind?**

It is up to you to decide whether or not the patient to take part. If you do decide to provide consent on their behalf, you will be given this information sheet to keep and asked to sign a consultee declaration form. Patients are free to withdraw consent at any time without giving a reason, and this will not affect their care in any way. However, it will not be possible to remove the patient's data from the project once it has been anonymised, as we will not be able to identify specific data. This does not affect the patient's data protection rights. If you decide not to provide consent, no further action will be taken. The blood sample we collected and the lateral flow tests (including the result) will be discarded.

- **What happens to my blood sample?**

The blood samples given by the patient will be prepared for analysis and temporarily stored by research staff at the recruiting hospital before they are transferred to the Chief Investigator's laboratories at the University of Manchester for storage and analysis. Some of the sample will also be sent to UpFront Diagnostics for measurement of GFAP and D-dimer. With your permission we would like to treat these blood samples as a gift. After the study has finished, the Chief Investigator's team would like to keep components of the patient blood samples indefinitely. These blood samples will be kept in a Research Biobank at the Chief Investigator's institution. Blood samples will not be identified using names (see section on Confidentiality) and once the trial has completed, the link between the patient name and the ID code will be permanently broken. If new knowledge becomes available in the future, such as the discovery of new stroke diagnosis markers, this will allow the samples to be used and avoids repeating studies where there are existing samples that can be used to investigate new research questions. We may also share the samples with researchers from other institutions where they may be used for projects studying stroke and related disorders.

The Chief Investigator's team would also like to be able to use remaining components of the sample given by the patient to check the quality and consistency of the tests they carry out, and to develop new tests.

The patient is under no obligation for their samples to be used in this way and you will be asked to sign a consent form to allow the patient samples to be used for these purposes. These samples would only be used for research relating to stroke and would not be used to investigate other disorders.

Data protection and confidentiality

- **What information will you collect about the patient?**

To participate in this research project, we need to collect information that could identify the patient, called "personal identifiable information". Specifically, we will need to collect:

- Name
- Address, postcode and email address
- NHS number
- Date of birth
- Demographic information, such as your ethnicity and sex
- Other information related to patient's medical history and clinical investigations

- **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law, which protect the patient's rights. These state that we must have a legal basis (specific reason) for collecting this data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

- **What are the patient's rights in relation to the information you will collect about them?**

The patient has a number of rights under data protection law regarding their personal information. For example, they can request a copy of the information we hold about them.

If you would like to know more about these different rights or the way we use their personal information to ensure we follow the law, please consult our Privacy Notice for Research at https://documents.manchester.ac.uk/display.aspx?DocID=37095.

- **Will the patient's participation in the study be confidential and their personal identifiable information be protected?**

In accordance with data protection law, the University of Manchester is the Data Controller for this project. This means that we are responsible for making sure that the patient's personal information is kept secure, confidential and used only as described in this document. All researchers are trained to handle data securely and appropriately. Only the research team at the University of Manchester and NHS Trusts will have access to the patient's personal information.

Consent forms will be stored separately from research data. The patient's name and any other identifying information will be removed from the study data and replaced with a random ID number (pseudonymised) upon entry into the study. Only the research team will access the key that links this ID number to the patient's personal information. Consent forms will be kept for 5 years after the study ends. Personal details will be retained for 1 year after the study results are published in order to allow us to collect the relevant medical data for the project. The patient's anonymised study data will be retained for 15 years. After this, the data will be destroyed in a secure manner. This includes data in both paper and electronic format. Please also note that individuals from the University of Manchester, NHS Trusts or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to the patient as a research participant.

With your consent, anonymised information will be shared in order to support additional research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify the patient and will not be combined with other information in a way that could identify them. The information will only be used for the purpose of improving the diagnosis of stroke in ambulances and cannot be used to contact them regarding any other matter. It will not be used to make decisions about their future care or services. At the end of the project, we will deposit a fully anonymised dataset in an open data repository where it will be permanently stored. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

What if I have a complaint?

- **Contact details for complaints**

If you have a complaint that you wish to direct to members of the research team, please contact:

- Prof Adrian Parry-Jones
- Email: adrian.parry-jones@manchester.ac.uk
- Tel: 0161 206 4458

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

The Research Ethics Manager, Research Office, Christie Building, the University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

Contact details for queries

If you have any queries about the study, then please contact:

- Prof Adrian Parry-Jones
- Email: adrian.parry-jones@manchester.ac.uk
- Tel: 0161 206 4458

Thank you for taking the time to read this consultee information sheet. Please do not hesitate to contact the study team as above for any further information or if you have any questions.