DIAGNOSIS participant information sheet

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

Short title: *DIAGNOSIS*

Chief Investigator: *Prof Adrian Parry-Jones*

You are being invited to take part in a research study. The aim of this research to improve the diagnosis of stroke in ambulances.

Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

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 whether someone 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.

- **Am I suitable to take part?**

You are being invited to take part because you had symptoms suggesting you might be having a stroke, and the new fingerprick blood test was carried out when you arrived at the hospital. The result of the test was not used to as part of your care and the result was not and will not be known by the team caring for you. This study is looking at around 300 people who had stroke-like symptoms and underwent the fingerprick test. Some people in the study will have been diagnosed with a stroke, while others will have a different condition. By taking part, 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. Participants can request a summary of the research if they would like to know the study findings.

- **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 my involvement be?

- **What would I be asked to do if I 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 your finger 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 your routine assessments and tests were completed, an extra standard tube of blood was also taken. If you agree 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 would not have provided detailed information about the research at the time, as this could have delayed your care. You 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 your care and the results were not known by the team looking after you.

There are no additional assessments or interviews for people who agree 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 you received during your emergency assessment, which will be obtained from your medical records.
4. Copies of any brain scans you had, for researchers to review.
5. Details about your illness, such as your symptoms, the diagnosis made and the treatments you received, also obtained from your 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.

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

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

There are no payments for participation in this study.

- **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part, you do not need to do anything further. 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 you 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 your 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 your 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 you to check the quality and consistency of the tests they carry out, and to develop new tests.

You are under no obligation for your samples to be used in this way and you will be asked to sign a consent form to allow your 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 me?**

In order to participate in this research project, we will need to collect information that could identify you, called "personal identifiable information". Specifically, we will need to collect:

- Your name
- Address, postcode and email address
- NHS number
- Date of birth
- Demographic information, such as your ethnicity and sex
- Other information related to your 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 your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

- **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you.

If you would like to know more about your different rights or the way we use your 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. Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team.

- **Will my participation in the study be confidential and my 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 your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after appropriately. Only the research team at the University of Manchester and NHS Trusts will have access to your personal information.

Consent forms will be stored separately from research data. Your name and any other identifying information will be removed from study data and replaced with a random ID number (pseudonymised) upon entry to the study. Only the research team will access the key that links this ID number to your personal information. Your consent form 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. Your 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 you as a research participant.

When you agree to take part in a research study and with your informed consent, the information about you may be provided to researchers running other studies here or at other organisations. With your consent, your 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 you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of improving the diagnosis of stroke in ambulances and

cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you. 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.

If you consent for us to do so, we will keep your contact details on a separate password-protected database that can only be accessed by the research team to allow us to contact you about future research studies. You can withdraw your consent for us to contact you in this way at any time and we will not pass your contact information to others for any other purpose. If we cannot reach you, we will try one more time to get in touch. We will delete the contact information we keep for you after 15 years or upon your request.

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.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, the University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information Tel 0303 123 1113

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 information and considering whether or not you would like to take part in this study.