

Scottish Regenerative Neurology Tissue Bank Participant Information Sheet

Name of researchers: Professor Siddharthan Chandran, Dr Suvankar Pal, Shuna Colville

Please ask if anything is unclear or if you would like further information.

Studying genes and mechanisms that may contribute to neurological conditions

Participant information sheet

You are being invited 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 friends, relatives and your GP if you wish. Ask 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 purpose of this study?

We research disorders that damage the development or function of nerve cells (neurons) in the brain and spinal cord. These disorders are called neurological conditions, and include motor neurone disease, multiple sclerosis, Parkinson's disease, Fragile X syndrome, dementias and stroke.

You are being asked to consider providing consent to allow some of your blood, saliva (or sample taken through clinical care (spinal fluid or blood sample)), for research or to be stored in the form of CSF/serum/plasma and/or DNA for future research. We hope to create a comprehensive bank of samples from patients with neurological conditions. If you give your consent, we will use the sample to study the causes and mechanisms of these conditions. The samples will be valuable for understanding why these conditions affect certain people and also for the development and evaluation of new diagnostic tests.

How will I be involved?

If you have had a sample taken as part of your clinical care you will be asked to sign a consent form to allow researchers to use any spare sample for research purposes. If a clinical sample is not available you will be asked for a blood sample (usually approximately 9 mls or two teaspoons but may vary depending on the study and may on occasions be up to 100mls). Blood is made up of different components (red cells, white cells, plasma), which we will extract and store for research purposes. It may be possible to take this blood sample at the same time that you are having other routine blood tests. If taking a blood sample is not possible then an alternative is to donate some saliva, from which the DNA can also be extracted.

What will happen to the sample I donate?

The different components, including DNA, will be extracted from the sample and used for the research or stored in a dedicated and secure tissue bank in the Wellcome Trust Clinical Research Facility at the Western General Hospital, Edinburgh.

Will the sample and information obtained be confidential?

Your sample will be coded so that no personal information is available to staff outside the research team. The Scottish Regenerative Neurology Tissue Bank Steering Group is required to approve any studies involving the use of these samples. Researchers who are given permission to analyse the coded samples will be unable to access your personal data. Access



to the link between the code number for your sample and your name will be restricted to the core members of the research team. No identifiable information will be given to a third party.

The questions that we ask you with regards to your symptoms, previous illness and family history will be stored in a secure NHS-approved computer.

Why have I been chosen?

You have been chosen as you are being investigated for, or have, a neurological condition that we are interested in studying.

Do I have to take part?

No. Participation in this study is entirely up to you. If you decide not to participate, this will not affect your care or treatment. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to participate you are free to withdraw your sample from the Tissue Bank at any time and without giving a reason. If you request, your anonymised data can be withdrawn from any future analysis and, at your request, your sample will be destroyed.

Use of samples in future projects

Current knowledge of the genetics and disease-causing factors of neurological conditions is limited, but as this understanding increases there may be new studies that we can undertake using the donated samples. For this reason we are seeking your permission to use your stored sample in future research projects that arise as our understanding increases, which could include whole-genome analysis.

Our future studies may involve collaboration with high-quality international research centres that are linked in collaborative networks to share non-identifiable data. The best research increasingly requires partnerships with other research centres, and in working together one maximises the value of the precious samples that have been donated. Ultimately we hope that the research will lead to the involvement of pharmaceutical companies in the development of new therapies. We will grant access by pharmaceutical companies to the anonymised samples if the Regenerative Neurology Tissue Bank Steering Group agrees that this is the best way forward.

Are there any benefits or disadvantages to taking part in the studies?

You are unlikely to personally benefit directly from the results of this study, but the results may be of benefit to people with a neurological condition in the future. It is anticipated that our research will lead to a better understanding of these disorders and could help in producing new and better treatments, and ultimately, in preventing neurological conditions.

The only disadvantage to taking part in the study is the need to give up the time to have an ordinary blood test, which can be a little uncomfortable and/or leave some bruising.

What will happen to the results of the studies?

The results of any research may be presented at academic meetings and published in academic medical journals online and/or in print. All study reports will use anonymised data, so you will not be identified in any presentation or publication. Unfortunately it is not possible for us to feedback individual results on anonymised research samples.

What if there is a problem?

We do not anticipate any problems with this study but if you do have a problem/complaint, please report this using the standard NHS Lothian Complaints Procedure (0131-558-3681) or discuss the problem with the Principal Investigator, Professor Siddharthan Chandran, or Dr Suvankar Pal using the address below. The NHS indemnity scheme will cover participants in the conduct and management of the research in the unlikely event of them being harmed.



Who is organising the research?

The study is part of the Regenerative Neurology Research that is led by Professor Siddharthan Chandran, MacDonald Professor of Neurology, at the Anne Rowling Regenerative Neurology Clinic, University of Edinburgh.

Who has reviewed the study?

The Chief Scientist Office for Scotland has reviewed this study.

Contact for further information?

If you would like to know more about the science behind these studies please contact Professor Mary Porteous, Consultant Clinical Geneticist, South East of Scotland Genetics Service, Western General Hospital, Crewe Road, Edinburgh, EH4 2XU, Tel: 0131-537-1116, email: anne.rowling.clinic@ed.ac.uk

You may wish to discuss whether to participate with your local medical team.

Thank you very much for taking the time to read this document and for considering taking part in this study. If you decide to participate you will be given a copy of this information sheet and a signed consent form to keep.

Contact for further Information:

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