King's College Hospital NHS
NHS Foundation Trust

King's College Hospital NHS Foundation Trust
King's College Hospital
Denmark Hill
London SE5 9RS

Tel: 020 3299 9000
Fax: 020 3299 3445
www.kch.nhs.uk

PATIENT INFORMATION SHEET, Version 3 10/11/2016

Project title: Motor Neuron Disease Register for England, Wales and Northern Ireland

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. Talk to others about the study 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 the study?
Motor neuron disease (MND) affects about 5000 people in the UK at any one time, but the true figure is not known as there is no single source of information about who is affected. The purpose of the study is to collect and store information about every person with MND in the UK. Counting every person with MND allows us to work out the number of people diagnosed with MND per year, how many people currently have the disease and how this is changing with time. Information such as gender and ethnicity can be used to look for characteristics of people more likely to develop MND. We will also collect information about where people with MND live to allow for planning the care of people with MND to take place. It will also tell researchers more about the possible causes of MND. We collect information about the disease itself, for example, where you first noticed symptoms, so we can look at how this relates to disease progression.

Why have I been invited to take part in this study?
You have been invited to take part because you have been diagnosed with MND and are a resident in England, Wales or Northern Ireland**.**

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. The standard of care you receive will not be affected.

What will happen to me if I take part?

Nothing will happen to you directly. A research worker will collect information, including confidential information which is why we require consent, from your clinical notes and store it in a secure database (a computer program for storing information).

How can I withdraw my data if I change my mind?
You will be free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. If you would like to withdraw your data please contact the project manager [insert project manager contact details] . We will remove any identifiable information about you but keep anonymous clinical data for analysis. If you decide to withdraw from the study, any non-identifiable information already collected will be included in the study.

What confidential information will you collect?
We will collect your name, date of birth, hospital number, NHS number and post code of residence. This information will be used to check that no one is entered more than once and so that we can access medical records to collect the clinical data.

Where does my confidential information go?
This information will be stored on computers owned by King's College London or Oxford University. These computers will be securely controlled by the research team, under the direct responsibility of Professor Ammar Al-Chalabi or Professor Kevin Talbot. We, and other research collaborators, will use an anonymised version of your information to find out more about people with MND.

In the future it is possible we might have new research questions which could be answered by looking at your information in new ways. However, if applicable, we would seek approval from a Research Ethics Committee to use your information for entirely new research projects. If a Research Ethics Committee believed we should contact you again to ask your permission to re-use your information, we will do so.

The information we collect in this project will be kept for 10 years after the project has ended when data use will be reviewed. Wherever you are being treated has a duty to ensure research conducted here is of a high standard and auditors from the hospital may need to review any information we hold about you. The auditors will maintain the highest standards of confidentiality. Procedures for handling, processing, storage and destruction of your information are compliant with the Data Protection Act 1998.

What do I have to do?
If you would like to formally consent for the study, ask the person who gave you this leaflet for a consent form (if they have not already given you one with this information sheet). The information will then be collected from your medical records by the project workers.

What are the potential risks of taking part?
It is possible that your confidential data could get lost or stolen. To minimise this risk your information is stored in a secure, password protected database in accordance with NHS recommendations and standards. Your confidential information is stored in a separate file to the clinical and demographic information and is only visible to the project managers, the

principal investigators and the computer scientist. When other researchers use the database the only data they see will be non-identifiable.

What are the possible benefits of taking part?
There is no specific benefit to you in taking part in this research. We anticipate that this information will improve our general understanding of disease progression, likely survival times and in identifying those who may be at risk of developing MND. This will contribute to improved care planning. However, it is possible, through this Register, that you may be given the opportunity to take part in other research studies.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the Patient Advice and Liaison Service at your local hospital. Details can be obtained from the hospital *Insert site/online specific contact details here*

Will my taking part in this study be kept confidential?
If you agree to take part in this study, the project managers will need to collect your clinical records from your local neurologist or GP. This would be done with the full approval and knowledge of your neurologist or GP.

What will happen to the results of the research study?
We hope that the results of this study will be suitable for scientific publication in biomedical journals, and for communication to patients via the Motor Neurone Disease Association. You will not be personally identified in any way.

Who is organising and funding the research?
This research is being organised by Professor Ammar Al-Chalabi at King's College Hospital and Professor Kevin Talbot at the John Radcliffe Hospital, Oxford and is funded by the MND Association. The research team or your doctor will not receive any payment if you take part.

Who has reviewed the study?
This study has been reviewed by [insert name of REC committee] on behalf of the National Research Ethics Service for England (NRES). They have checked this study with your interests in mind to ensure that you will not be harmed by the study and to ensure that your care is unaffected. It has been given a favourable ethical opinion for conduct in the NHS. An external review process run by the Motor Neurone Disease Association reviewed the scientific basis of the study before we were awarded our funding.

Participation in future research:
Independent from the current study, and if you consent, you may be offered the opportunity to participate in other studies. These studies will be explained separately, and you would give consent for them specifically. Agreeing to be contacted about other research does not oblige you to take part. You can decline to be contacted and this will not impact on your ability to participate in the current study or your future clinical care.

Contact Details:

Motor Neuron Disease Register project manager [insert project manager details here].

[THIS SECTION TO BE DELETED IF REGISTERING ONLINE: You will be given a copy of the information sheet and a copy of your signed consent form to keep if you wish.]

Thank you for considering taking part in this research project, and thank you for taking the time to read the information sheets.