

MS Register and SWIMS Participant Information Leaflet

We would like to invite you to take part in the UK MS Register and SWIMS projects. Before you decide, you need to understand why this research is being done and what it would involve for you. Please read the following information carefully to decide whether or not you wish to take part.

Take the time to talk to others about the study. Please ask us if there is anything that is not clear or if you would like further information.

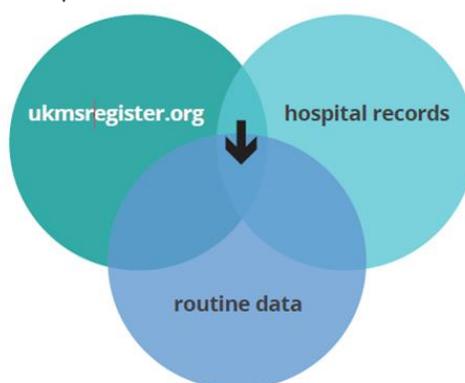
Why have I been invited?

Recruitment for the MS Register and SWIMS is being carried out at a number of Neurology centres across the UK. All people with a confirmed diagnosis of MS who attend your neurology clinic are being invited to join the studies.

What is the purpose of the MS Register?

The purpose of the MS Register is to capture better, higher quality information about living with MS in the UK today. More data needs to be gathered about the physical, environmental and social effects for people and carers affected by the condition. Capturing and analysing this data will help provide better information to improve care and treatments. As can be seen below, Register data is captured from 3 main areas:

*Having these linked sources provides the richest data



What is the purpose of SWIMS?

The South West Impact of MS (SWIMS) Project is a sub-study that collects additional information from people living in Devon or Cornwall about the impact that MS or clinically isolated syndrome (CIS) has on their lives over time. This information will be used to try to develop better ways of predicting what will happen to someone with CIS or MS in the future and to find better ways to assess the success of new treatments in clinical trials.

Who is organising and funding this research?

Swansea University College of Medicine and Plymouth University Peninsula Schools of Medicine and Dentistry are organising this research with a grant from the MS Society.

What are the benefits in taking part?

We cannot promise that the study will help you personally, but the information we obtain will help improve the care and treatment of people with MS.

Research from these studies has already contributed to a number of articles published in peer reviewed journals; an updated list of these is always available at **blog.msregister.org**. This is the best place to keep up to date with the activities of the MS Register whilst the SWIMS Project has its own website: <http://research.psmd.plymouth.ac.uk/cnrg/swims.php>

We send out regular newsletters updating you on the research that the Register and SWIMS are currently undertaking and summaries of the findings so far.

Do I have to take part?

No you don't have to take part. Participation is entirely voluntary, if you do decide to participate, you will still be free to withdraw at any time, without giving a reason.

This will not affect the care you receive in any way.

What will happen to me if I take part?

If you take part, information that is collected during your visit to the neurology clinic will be anonymised and included on the MS Register. You will also be encouraged to visit the MS Register website to provide your own views and experiences. This information will also be anonymised before it is included.

We may also collect information about your MS from other sources including your GP, central NHS databases and the Office of National statistics (see pages 4 and 5).

Everything that you provide will be safeguarded and protected to ensure your privacy. The anonymous information on the Register will be used to carry out research studies and service planning to help people with MS.

The use of anonymously linked datasets is of immense value in chronic health condition research.



What if I live in Devon and Cornwall?

If you live in Devon or Cornwall and join the MS Register you will become part of an established sub-study called the South West Impact of MS (SWIMS) study that has been collecting information about the impact of MS since 2004. You will be asked to complete regular questionnaires that help us to understand the impact of MS over time. This information will also be anonymised before being included on the MS Register. The information will be accessible to both the SWIMS and MS Register teams.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical practice and all information about you will be handled in confidence. Your identifiable information (name, address and date of birth) will be stored separately from the Register. The Register team will, from time to time, contact you by post, email or telephone, to collect more data about you and your health condition. In the future, other researchers might want to contact you, to ask you to take part in some research.

The Register team will not pass on your contact details to anyone else, without asking your permission first.

Who has reviewed the study?

The study has been reviewed and been given approval by NRES Committees South West - independent NHS Research Ethics Committees in order to protect your safety, rights, wellbeing and dignity:

- The UK MS Register: NRES SW Central Bristol (11/SW/0160)
- SWIMS: NRES SW Plymouth and Cornwall (04/Q2103/8)

What will happen if I don't want to carry on with the study?

It is your right to withdraw from either or both studies at any time. This will not affect your clinical care in any way.

If you live in Devon or Cornwall, to withdraw from the study, simply contact the SWIMS Team. Otherwise inform your clinician or contact the MS Register.

We will retain all the information you have already provided in our database unless you tell us that you wish to withdraw your data and have it destroyed.

What will happen if I want to be involved with the research but do not want to complete regular questionnaires?

You do not have to complete the questionnaires. If you start completing questionnaires you are still free to skip some of them or stop entirely whenever you want to.

We let everyone know when we would like them to complete a questionnaire but you can ask us to stop sending out these notifications if you do not want to receive them anymore.

What if I have a query or a concern?

Should any issue arise during the study that you are unhappy with please do not hesitate to contact us. We will do our best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting Rod Middleton by email at:

r.m.middleton@swansea.ac.uk

or by post via:

Institute of Life Science 2,
College of Medicine,
Swansea University,
Swansea, SA2 8PP

You can also contact the SWIMS Project Co-ordinator at:

swimsproject@plymouth.ac.uk

Plymouth Schools of Medicine and Dentistry
N16, ITTC Building 1
Plymouth Science Park
Plymouth, PL6 8BX
0800 015 3430 (FREEPHONE)
01752 315246 (Direct)

What will happen to the results of the project?

Regular reports on the progress of the project are sent to our funders - the MS Society and the South West Ethics committees.

Updates on activity about the MS Register can always be found at:
blog.msregister.org

The South West sub-study (SWIMS) also produces newsletters and has its own website:

<http://research.psmd.plymouth.ac.uk/cnrg/swims.php>

We have also published a number of articles in peer reviewed journals. We present at conferences and meetings.

The knowledge we gain from this study will fuel campaigns for fair, relevant policy and improved healthcare for people living with MS.

The detail

All the information collected by the MS Register (and SWIMS) is stored on secure servers with the highest levels of encryption. Where you give your consent for us to collect identifiable data, this is stored separately from the clinical data.

What do we mean by identifiable information?

Identifiable information is that data that specifically identifies you: name, date of birth, gender, postcode and identifying numbers such as NHS Number or a National Insurance number. In the context of the Register such information never forms part of your Register 'record' and will never be published in any format.

The identifiable part is used to create an anonymous identifier which we can then use to link to other records, which are also anonymous.

Identifiable information is stored separately from the main Register record in the event that we want to contact you.

What do we mean by anonymous?

Identifiable information is used to create the anonymous identifier, unique to you, that allows us to link your data. Once your data have the anonymous identifier attached, all other identifiers are removed. However, when we want to analyse your data we will include the following: your gender; week and year of birth; and an Ordnance Survey code for the area in which you live. MS progression is known to be associated with an individual's age, gender and region of residence. For this reason, they are kept with your study records for analysis.

Often, these data are called "**pseudonymous**" because they still have this small amount of personal information as well as the anonymous identifier. Without access to the key used to create your unique code, however, the data is treated as being anonymous. The key will not be accessible to those who analyse the data nor stored with the study data.

The unique anonymous identifier will not be included in the dataset made available for analysis

What do we need from your medical notes?

Every time you visit a health care professional they keep a record of what happened at that visit. These records are primarily kept on paper. As computerised systems within the NHS become more common more data will be held on them, but for the moment the medical notes remain the first document of entry. It is possible that we will need to have access to these notes wherever they are held to capture some data that is not recorded within a clinical system.

What are Health Related Records?

These are records from outside of your neurology department that primarily exist on other electronic systems. So examples of these would be MRI scans or data that exists on laboratory systems such as Biochemistry or Haematology. We may also approach your General Practitioner to capture related data from their systems too.

The NHS centralises some records in the Health and Social Care Information Centre (HSCIC) including MRI scans and records of Hospital Admissions. We may ask the HSCIC for this information. This will mean that we share some of your identifiable information with the HSCIC e.g. NHS Number and Date of Birth to ensure we receive the correct records.

The Office of National Statistics (ONS) also provides researchers with details of the cause of death of individuals via the HSCIC. If needed, we will request this information.

Sometimes we lose contact with people when they move. The HSCIC and ONS provide a joint service to allow researchers to check contact details of individuals and we may use this service at some point.

Health related records will be linked to data you provide to the MS Register and SWIMS using Data Linkage.

What is Data Linkage?

Data linkage is the merging of two or more separate data sets (e.g. General Practice information and outpatient data about the same person) for research purposes.

The Register does this by deleting anything identifiable within your neurology record and replacing it with a unique code. Data from any other related clinical records are also anonymised in the same way and replaced with the same code. This code lets us link these records together so we can perform wider analysis.

The anonymisation is carried out by a trusted NHS third party so we are unable to re-identify any individuals after this process has been carried out. A small amount of your identifiable data is shared with the chosen trusted NHS third party to ensure that the correct unique code is given to records from the same person in each dataset we want to link.

The trusted NHS third party we use is the NHS Wales Informatics Service. However, we may ask the HSCIC to perform this service when we ask for data from them, if this option reduces the number of people who have access to personal data.

The final dataset will still contain your unique anonymous identifier; gender; week and year of birth; and an ordnance survey code for the area in which you live.



Devon and Cornwall residents

Everyone who joins the MS Register is encouraged to regularly visit the website and provide information about their experiences.

If you live in Devon and Cornwall you will be asked to complete questionnaires at regular intervals about your current health and the impact MS is having on your everyday life. You can do this either by logging on to the MS Register website or by completing postal questionnaires if you prefer. We will tell you when it is time for each questionnaire to be completed and, if you choose postal questionnaires, we will provide FREEPOST envelopes for their return. We will also provide a FREEPHONE helpline if you have any queries about the questions.

Other MS researchers

It has long been recognised that the lack of information about living with MS in the UK affects both people with MS and the MS research community. It makes sense that the information that we collect via the Register be accessible to more than the Register team.

Should a researcher approach us with appropriate ethical permissions and should they pass the appropriate governance measures that the Register has in place they could be granted access to a small selection of the anonymised data to carry out their own research.

This may sometimes include information about your gender; week and year of birth; residential region; and information collected from your health and medical records (including the HSCIC and ONS).

How long will the data be kept?

Anonymously linked datasets are very valuable to those researching MS. For this reason, when the study ends, we intend to archive the anonymous data indefinitely in the SAIL Databank (The Secure Anonymised Information Linkage Databank) so that genuine researchers may apply to analyse the data.

If you wish to have your data removed from the archive dataset you will need to tell us before it is archived. The archived data will be anonymous and so we will not be able to identify your data in order to remove it at a later date.

What will I have to do?

There are two main ways that you can get involved with the Register:

1. By signing the consent form within this pack you can agree to take part in the clinical element of the UK MS Register study. Once you do this your clinician will securely transmit relevant portions of your clinical data to the MS Register.
2. If you, a carer or your family have access to the internet you can also add your experiences to the data collected. If you join up at ukmsregister.org you will be given the opportunity to complete questionnaires covering a variety of topics related to living with MS in the UK today. New questionnaires are added regularly so we will keep in touch with you by email regarding updates.

SWIMS participants receive questionnaires on a different schedule to other MS Register participants and will have the choice of answering questions via the Register website or by completing paper booklets. We will contact you when each questionnaire is due.

For further information about the MS Register please contact:

01792 606354
contact@ukmsregister.org
facebook.com/UKMSRegister
twitter.com/UKMSRegister

UK MS Register
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0800 015 3430 (FREEPHONE)
01752 315246 (Direct)
swimsproject@plymouth.ac.uk
<http://research.psmd.plymouth.ac.uk/cnrg/swims.php>

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