



UCL INSTITUTE OF CHILD HEALTH

Great Ormond Street  
Hospital for Children

NHS Foundation Trust

**INFORMATION SHEET FOR PARENTS/GUARDIANS****Recording information on the management of your child with Spinal Muscular Atrophy in the UK – SMA REACH UK Database in association with the Neuromuscular Clinical UK Network**

Your child requires the expert care of medical and therapy teams for the long-term management of Spinal Muscular Atrophy. To help deliver the best care, we would like to collect and record information, which will help us optimise management, not only for your child, but also for all children/adults with Spinal Muscular Atrophy in the UK.

This leaflet explains why we are asking your permission to record clinical information into a database specially designed for use in the hospitals participating in the UK Neuromuscular Clinical Network (NMCN) and more specifically the SMA REACH UK Database.

**What is the SMA REACH UK Network?**

The SMA REACH UK network is a national and international collaboration supported by SMA Trust, between doctors and therapists involved in the care of children with Spinal Muscular Atrophy. We would also like to grow the collaboration within the National Neuromuscular Database (NaND), a network of doctors and therapists involved in the care of children with neuromuscular conditions which is supported by the Jennifer Trust for Spinal Muscular Atrophy and the UK Muscular Dystrophy Campaign. The data collected would be jointly administered by the Dubowitz Neuromuscular Centre and MRC Neuromuscular Centres in London and Newcastle.

**What is the SMA REACH UK Database?**

The SMA REACH UK Database is an internet web based system which can save information about diagnosis, assessment and management of Spinal Muscular Atrophy. Into this new database we aim to merge clinical and genetic data collating the existing registries (SMARTnet and SMA registry).

**What information will we collect?**

We would like to record:

- Your child's NHS number
- Name and date of birth of your child
- General information about your child's condition – e.g. age at diagnosis, results of gene testing, and problems resulting from Spinal Muscular Atrophy

- Results of muscle, heart, breathing, growth and general health testing from medical assessments
- In addition to the standard physiotherapy assessment, some additional functional measures will be used to assess current level of physical functioning.

You will be asked to give your permission for us to videotape/take photos of your child whilst parts of the physical assessments are carried out. The photos will be used for the manual that accompanies the physical assessment. The videos will be used to help teach other physiotherapists to do the correct physical assessments for SMA and then to test that the physiotherapists can score them correctly, these are known as reliability studies. One of the reliability studies will form part of an MSc project.

Your child can still be registered in the database if you do not wish your child to be videotaped/photographed.

You will be asked to give your permission for us to inform your child's GP that he/she is taking part in this study.

The study will last for 2 years but may be extended in the future. We would like to continue to collect and save information each time your child is assessed in clinic. Your child will be asked to come to hospital every 6 months as per usual for routine clinic appointments. The only difference will be that some physiotherapy assessments may be a little longer.

### **Why are we collecting this information?**

We will use the information we collect to help us:

- Collect accurate details about the course of Spinal Muscular Atrophy, and its response to management.
- Monitor medical and therapy care to make sure it is always up to date.
- Plan and develop services for better management of Spinal Muscular Atrophy
- Pilot new assessment tools with the aim to develop more sensitive SMA specific scales.
- Undertake audits, and produce reports that will improve our knowledge of the natural history of SMA, with the clear consequence of implementing the National standards of care, as well as facilitate the preparation of personalized national and international clinical trials.

### **Who collects the information?**

The hospital staff at the clinic will collect this information. This will usually be the doctor, physiotherapist or nurse or may be one of the designated research team: a doctor, physiotherapist or study coordinator. A designated database manager may also help with recording information.

### **When and how will you collect the information?**

The information will be collected and updated at every clinic visit. We will collect information from the medical and therapy records. At times, the doctor/physiotherapist may enter the information directly into the database system, and produce a record for the hospital case notes.

We will also invite you to be involved in one or two focus groups in the coming months. These focus groups will facilitate a discussion between parents, patients, researchers and doctors and will help researchers to design clinical assessment measures which are meaningful to your family.

#### **Who will see the information?**

Only the NHS staff who care for your child will see all the details. There are strict regulations controlling access to personal information like your child's name, date of birth or NHS number. By law, everyone who works for the NHS must keep all personal information confidential and the trust has strict confidentiality and security procedures in line with the data protection act (1998). Only anonymised data will be shared with other institutions (SMA Registry, MRC database).

#### **What is the consent procedure?**

If you are happy for your child's details to be used for clinical care purposes, analysis such as audits to improve clinical care or service delivery, and for clinical information to be transferred between hospitals looking after your child, please give your consent. A signed copy of the consent form and a copy of this information leaflet will be given to you for your information. Your child is free to stop taking part at any time during the research without giving a reason. If you decide to withdraw your child at any point this will not affect the care they receive in any way.

#### **Can I see the records on the database?**

**Yes**, you can get a copy of the information we have about your child. To do this, please talk to the doctor in charge.

#### **Are there any benefits or disadvantages?**

Your child may not personally benefit directly from the database system; however it is anticipated that audit of this data within, and across, neuromuscular clinics in the UK will improve the standards of care for Spinal Muscular Atrophy, and may also benefit children with Spinal Muscular Atrophy in the future. This will provide clinicians and researchers with a rich resource of available information on a large collection of SMA patients, ensuring the functional scales used are suitable and clinically relevant, facilitating translational research in preparation to design National and International clinical trials.

Once the database system has been developed and the information has been appropriately collected, it may provide an accurate and graphic report of the course of the condition, and its response to treatment in the individual child.

**What if there is a problem?**

You may contact one of the study team by email or telephone using the contact details at the end of this leaflet. If you are not happy about your treatment and wish to complain, you should contact the PALS service at Great Ormond Street By phone: 020 7829 7862 (direct line) or By email: [pals@gosh.nhs.uk](mailto:pals@gosh.nhs.uk) so that they can advise you about the steps to take as well as being able to give you the contact details for the appropriate people in the hospital.

**Expenses and payments**

There will be no reimbursements for taking part in this research study as there are no additional appointments outside routine clinic appointments. Refreshments may be offered during the extended physio assessments.

**Who is organising and funding the research?**

This study is funded by the SMA Trust.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the London- Bromley Research Ethics Committee. This research was checked by the **NRES Committee London Bromley 13/LO/1748**.

**How can I find out more about it?**

Please talk to the doctor in clinic if you:

- Need more information
- Have any questions or concerns

Or contact one of the study team by email or telephone:

Dr. Mariacristina Scoto: [m.scoto@ucl.ac.uk](mailto:m.scoto@ucl.ac.uk)

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Or visit our website [www.SMAREACHUK.com](http://www.SMAREACHUK.com)