



UCL INSTITUTE OF CHILD HEALTH

Great Ormond Street  
Hospital for Children

NHS Foundation Trust

**INFORMATION SHEET FOR CHILDREN (11-15 YEARS)**  
**Chief Investigator: Professor Francesco Muntoni****Recording information on the management of your Spinal Muscular  
Atrophy in the UK – SMA REACH UK Database  
in association with the Neuromuscular Clinical UK Network****Explanation (11-15 years old), Why are we doing this research?**

You are receiving the expert care of medical and therapy teams for the long-term management of your Spinal Muscular Atrophy. We would like to collect and record information which will help us to improve and deliver the best care for all children with Spinal Muscular Atrophy in the UK.

This leaflet explains why we are asking your permission to record clinical information into a database called the SMA REACH UK Database.

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

The SMA REACH UK database is a way that we can save all the information that is collected about your SMA in one place. The data collected would be jointly looked after by the Dubowitz Neuromuscular Centre and MRC Neuromuscular Centres in London and Newcastle.

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

The SMA REACH UK Network, supported by the SMA Trust, is a national and international partnership between doctors and therapists involved in the care of children with SMA.

**Why have I been invited to take part?**

You have been invited to take part in this research study because you have SMA and we would like to study how your condition changes over time. All children with SMA who attend clinics in Great Ormond Street Hospital in London and in Newcastle will be invited to take part in this study.

**Do I have to take part?**

No, it is entirely up to you to decide if you want take part. If you do decide to take part, your doctor or physio will ask you to sign a form called an assent form and your parents/guardians will need to sign a consent form. By signing the form you are agreeing to take part in the study. You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the care you receive in any way.

### What will happen to me if I take part? What will I be asked to do?

You will be asked to come to hospital every 6 months as you do for your normal clinic appointments. The only difference will be that some of your physiotherapy assessments may be a little longer. The study will last for 2 years but may be extended in the future.



### What information will we collect?

We would like to record:

- Your NHS number
- Name and date of birth
- General information about your condition for example your age at diagnosis and problems resulting from SMA
- Results of muscle, heart, breathing, growth and general health testing from medical assessments
- Some additional physiotherapy assessment measures.



We will also ask you for your permission to videotape/take photos of you while the physical assessments are carried out. The photos will be used in an instruction book to teach other physiotherapists how to do your assessment. The videos will be used to help teach other physiotherapists to do the correct assessments in SMA. We will also use these videos to test that the physiotherapists know how to score them. You can still be registered on the database if you do not wish to be videotaped/have your photo taken.



### Why are we collecting this information?

We will use the information we collect to help us:

- Collect accurate details about SMA
- Monitor medical and therapy care to make sure it is always up to date.
- Plan and develop services for better management of SMA
- Try out and develop new SMA assessment tools
- Create reviews and reports that will improve what we know about SMA and the current standards of care
- Compare information with data from other international sites
- Prepare for clinical trials

### Who collects the information?

The hospital staff at the clinic will collect this information. This will usually be your doctor, physiotherapist or nurse or may be one of the designated research team: a doctor, physiotherapist or study coordinator.

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

Information will be collected from the medical and therapy records and updated at every clinic visit. We will also invite you and your parents/carer to attend one or

two group sessions in the coming months. This will allow you, your parents/carer and researchers and doctors to discuss the most useful assessment tools for families.

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

Only the NHS staff that care for you will see personal information like your name, date of birth and they will keep all this information private. Any information that is stored on the database will be password protected and saved on a safe system. We will only put information on the database or share information once your name and address removed.

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

If you are happy to be a part of this study you will be asked to sign an assent form. You will be given a copy of this information sheet and an assent form to keep.

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

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

#### **Are there any benefits or disadvantages to taking part?**

There are no direct benefits to you for taking part but we expect that the research will help to improve the standards of care for SMA, and may also benefit children with SMA in the future.



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

This study is funded by a charity called the SMA Trust

#### **Who has reviewed the study?**

All research in the NHS is looked at by a group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favorable opinion by the London- Bromley Research Ethics Committee.

#### **How can I find out more about the study?**

Please talk to the doctor in clinic if you:

- Would like more information
- Have any questions or concerns
- Visit our website [www.SMAREACHUK.com](http://www.SMAREACHUK.com)



Thank you for taking the time to read this information sheet