Great Ormond Street Hospital for Children NHS Foundation Trust

TITLE OF PROJECT: Improving standards of care and Translational Research in Spinal Muscular Atrophy (SMA)
IRAS ID: 122521
GENERAL DATA PROTECTION REGULATION

We are writing to provide more information related to this study and in particular of the rationale for collecting information related to individuals affected by Spinal Muscular Atrophy. In addition this document also provides you with information on who to contact in case you wish to receive more information, or to change the level of consent previously assigned to us to handle your data or the data from your child.

This project was set up to collect detailed information related to the clinical course of children affected by various forms of spinal muscular atrophy, and to develop novel methodology to measure disease progression and response to therapies, and to validate these measures.

Great Ormond Street Hospital is the sponsor for this study based in the United Kingdom. We will be using information from your medical record in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. Personal data will be stored for the duration of the study and for 15 years after data collection has ceased. This is will be required to link the patient to the database should clinically relevant data become apparent. The participant / parents / guardians / personal consultee will then be informed about the findings by the participant's clinician.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the Data Protection Officer on your.data@gosh.nhs.uk

Great Ormond Street Hospital could use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Great Ormond Street Hospital and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

Great Ormond Street Hospital will collect information about you for this research study from your hospital notes. This information will include your name/ NHS number/ date of birth/ gender / age / ethnicity / / medications / any relevant clinical, genetic or biochemical history and health information, which is regarded as a special category of information. Great Ormond Street Hospital will pass these details to the research team based at UCL Great Ormond Street Institute of Child Health along with information collected from your medical records. The research team will use this information to help them understand more about the disorder (Spinal Muscular Atrophy (SMA) we are studying as part of this research project. Furthermore, the information gathered will help us to establish the first national clinical and research network named SMA REACH UK to develop a national agreement on clinical, physiotherapy assessments and standards of care.

The doctors and physiotherapists looking after the affected children will have access to their case notes. This information will be put onto a secure computer database to store the information with strict arrangements as to who can access this data. Each individual participating in this study will be allocated a unique identifier. Only a limited number of designated individuals will have access to this information and will be able to de-anonymise the data. Members of the extended research team will not have access to patient names or other identifiable information. The researchers, sponsors, regulatory authorities & R&D audit will have access to the results

generated by this study. Only selected people who analyse the information will be able to identify you. They will not however be able to find out your contact details.

The only people in Great Ormond Street Hospital who will have access to information that identifies you will be people who need to contact you if something is found that may be relevant to your clinical care or audit the data collection process.

Anonymised data generated from the assessments will be stored in the natural history database and shared with other researchers around the world without divulging identifiable details. The recipient of any data must agree not to make any attempt to identify the subject. The recipient must also agree that any data generated from the research will be held securely and will only be made available to third party researchers under a Data Access Agreement.

When you agree to take part in this research study, your clinical data may be provided (upon your consent) to a Biotechnology company called Biogen in a strictly anonymised form. Your data could also be shared with other organisations which may be universities, NHS organisations or commercial companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. These companies have a strong interest in collecting anonymised natural history data on the entire spectrum of SMA severity from routine clinical visits. The data collected will be collated on a separate IT platform which will contain anonymised clinical and physiotherapy data from patients who have consented to take part in this initiative.
Our longer term plan is to have a system that is fit for the purpose to monitor how people with SMA respond to different therapeutic interventions. This could be used in collaboration with drug companies and health authorities to monitor the drug response also post approval, together with the detailed recording of potential side effects.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).