Great Ormond Street Hospital for Children NHS Foundation Trust

STUDY TITLE: Setting up of a Rare Diseases biological samples bank (biobank) for research to facilitate pharmacological, gene and cell therapy trials in neuromuscular disorders (NMD).
REC reference: 06/Q0406/33
GENERAL DATA PROTECTION REGULATION

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 indefinitely**.** This 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 our Data Protection Officer at: your.data@gosh.nhs.uk

Great Ormond Street Hospital will use your name, NHS number and contact details to contact you about research studies, 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 the research study from your hospital notes. This information will include your name/ NHS number/ date of birth/ gender / ethnicity / diagnosis and if applicable management of condition/ neuropsychology and functional assessments / age when samples taken and time of day / sample tests results and interpretation / Dual X-Ray scan (DEXA), MRI findings / 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 disorders we are studying as part of the research project.

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 the 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 doctors looking after the affected children will have access to their case notes. The researchers, sponsors, regulatory authorities & R&D audit will have access to the laboratory results generated by the study. Only if the laboratory studies show beyond any doubt that a patient with a specific identifier has a gene defect that is responsible for his/ her disorder will the investigators involved identify the patient so that we can inform your doctor of this result. 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 and the samples will be stored in the biobank database and shared with other researchers around the world without divulging identifiable details. There is a very small risk that an individual could be identified from their DNA sequence data if this can be matched to other data which is linked to identifiable information, although this is very unlikely. The recipient of any sample/data must agree not to make any attempt to identify the original donors of the sample. The recipient must also agree that any genetic or genomic data generated from the use of the samples will be held securely and only used in biomedical research, and will only be made available to third party researchers under a Data Access Agreement.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or 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.

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).