



UK FSHD Patient Registry

**Principal Investigator/Data Controller: Dr Chiara Marini Bettolo,
Translational and Clinical Research Institute, Newcastle University**

Information for children – Aged 11-15

You are being asked to take part in a research project so that we can learn more about FSHD. Before you decide if you want to join in it is important to understand why the project is being done and what it will mean for you. Please read this sheet carefully and talk about it with your family and friends. There is a glossary at the end of this information sheet to help explain what some words mean.

Why are we doing this research?

We are interested in people like you with facioscapulohumeral dystrophy (*FSHD*). We want to learn more about the disease and maybe help make new treatments. To help do this we want to set up a *database* made up of information about people like you. To make this *database* we want to ask if it is OK with you to store information about you on a computer. If you are happy to be involved in this then we will ask you to sign an 'assent' form and your parents to sign a '*consent*' form so we can collect and keep the information.

If new treatments are made that may help you, we can then contact you to see if you wanted to try them ('*clinical trial*'). You do not have to be involved in any *clinical trials* and we would talk to you again at a different time if this was a possibility. You and your parents would need to sign a different *consent form* at that time as well.

Why have I been asked to take part?

You have been asked to be part of this project because you have *FSHD*. We are asking all children with the disease if they would like to take part. We are hoping to have children from all over the country on our database.

Do I have to take part in the registry?

You do not have to take part in this project. Deciding not to take part will not change how we look after you. If you do want to take part then you, and your parents, will be asked to sign a *consent form* to say that you agree to take part and that we can keep information about you. You will also have a copy of this form to keep.

If you change your mind and decide you don't want to be part of this project anymore then we will remove the information about you from the *database*. Again, this will not change how your doctor will look after you.

What happens after my 16th birthday?

In the UK, once you are sixteen, you are able to choose for yourself whether or not you would like to participate in clinical studies such as the UK Myotonic Dystrophy Registry. It will no longer be your parents' decision. Following your sixteenth birthday, the registry team will

contact you and your parents to ask if you would like to continue participating in the registry. It is completely up to you and there is no problem if you choose not to continue. However, if you are happy to continue, we will transfer login details from your parents to yourself and ask you to re-consent to being part of the registry.

What will happen to me if I take part?

You and your parents will put the information about yourself on to the database. It is stored on a secure computer that is protected by passwords. You will not be asked to have any extra tests done for this project. You will not need any time off school other than to come to your usual clinic appointments.

Will this project help me?

The project may not help you specifically, but the information we collect should help us learn more about *FSHD* and help develop new treatments in the future.

What happens when the project stops?

We hope to be able to keep the *database* running for a long time and we would like to keep information about you for as long as possible.

What if something goes wrong with the project?

We do not think that anything will go wrong. The only people who can see the information about you are members of Dr Marini Bettolo's team who help with the project. The *database* is secure and *password protected*.

Will anyone else know I'm doing this?

Only people allowed by Dr Marini Bettolo will be able to see the information about you. Your parents will also need to know, as they too need to sign the *consent form*.

Some people from *research companies* may ask for information about you if they think they have a treatment that may help you. If Dr Marini Bettolo thinks it may be of help she will write to you to ask if you would like to take part. This would be your decision.

Who decided the project could be done?

Before any *research* can be done it has to be checked by an *Ethics Committee (NRES Committee North East- Newcastle and North Tyneside 1)*. This is to make sure that the *research* is a good idea and is safe to do.

This project is organised by the John Walton Muscular Dystrophy Research Centre (Newcastle University).

Contact Details:

If you would like to talk to someone about taking part, you or your parents can call

Dr Marini Bettolo on 0191 241 8606

or email: Chiara.Marini-Bettolo@newcastle.ac.uk

Or you may contact the Patient Advice and Liaison Service (PALS) 0800 0320202

GLOSSARY –What do these words mean?

Clinical trial – an experiment involving patients with a particular disease

Consent – giving permission for something, or agreeing it can be done

Consent form – agreeing to something in writing

Database – a collection of information

Ethics Committee – a group of people who look carefully at research projects to make sure they are properly carried out

Medical Research Council – an organisation who support research to improve human health

Password protected – a way of stopping people from looking at your information

Research – careful investigation of a particular subject

Research companies – a business that pays for investigation of a particular subject

Thank you for reading this information