

MTM Registry Consent

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Myotubular and Centronuclear Myopathy (MTM and CNM) Patient Registry:
information for patients under 16 years old

Principal Investigator: Dr Chiara Marini Bettolo, Newcastle University and Newcastle Hospitals
NHS Foundation Trust

Data Controller: Newcastle University

We are asking you if you want to be part of a registry (*database*) called the Myotubular and Centronuclear Myopathy Patient Registry, because we want to learn more about *myotubular and centronuclear myopathy*.

Before you decide, it is important you understand what will happen if you agree to be part of the registry. Please read this information carefully and talk about it with your family and friends. There is a glossary at the end of this information to help explain what some of the words mean.

If you have any questions after reading this information, please talk to your parents or guardians, to your doctor, or contact the Registry Curator, at mtmcmregistry@newcastle.ac.uk.

You can also use the link above to download or print a copy of this information to keep.

1. Why are we doing this research?

We are interested in people like you with *myotubular or other centronuclear myopathies*. We want to learn more about the disease and maybe help make new treatments. To do this we have set up a registry (*database*) containing information about people like you. To make this registry we need to ask for your permission to store information about you on a computer. If you are happy to be involved, please talk to your parents and ask them to complete the consent statements on this page so that we can collect and keep your information.

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

2. Do I have to take part in the registry?

No, you do not have to take part in this registry. Deciding not to take part will not change how your doctor looks after you. If you are happy to be involved in this then you and your parents will need to agree to the consent statements on this page. You can also download or print a copy of this information to keep, using the link at the top of the page.

If you change your mind and decide you don't want to be part of this registry anymore, we will remove the information about you from the registry. This will not change the way your doctor looks after you.

3. What will happen to me if I take part?

If you are happy to be part of this registry we will collect information about you from you, your parents, and sometimes your doctor. You will not be asked to have any extra tests done for this registry. You will not need any time off school other than to go to your usual clinic appointments.

When you and your parents have completed this consent page, you can answer the online questionnaire to enter your information on to the registry. It is stored on a secure computer that is protected by passwords.

4. Will this project help me?

The registry may not help you specifically, but the information we collect should help us learn more about *myotubular and other centronuclear myopathies* and help develop new treatments in the future.

5. What if something goes wrong with the registry?

We do not think that anything will go wrong. Only people allowed by Dr Marini Bettolo will be able to see the information about you. The registry is secure and *password protected* and is looked after in the UK by Newcastle University.

6. 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 will need to complete the consent statements on this page.

If you want to, you will also be able to name your doctor when you register, and we will ask them to complete an extra part of your questionnaire. If this happens, they will be able to see (but not change) the information you have provided. You will also be able to see (but not change) any information that they provide about you.

Some people from *research companies* may ask us for information about you if they think they have a treatment that may help you. Any information we provide to them would be *anonymous*. If Dr Marini Bettolo thinks that a treatment could be helpful to you, we will write to you to tell you about it, so that you can find out more if you want. This would be your decision.

7. Did anyone check this study is OK to do?

Yes. Before any *research* can be done it has to be checked and allowed by an *Ethics Committee* (ours is NRES North East - Tyne & Wear South Research Ethics Committee). This is to make sure that the *research* is a good idea and is safe to do.

8. Who do I contact if I have any questions or need more information?

If you want to talk to someone about taking part in this registry, you or your parents can contact the Registry Curator by emailing mtmcmregistry@newcastle.ac.uk.

If you live in the UK, you may also contact the Patient Advice and Liaison Service (PALS). You can [find your nearest PALS office](#) on the NHS website.

If you are worried about how we are looking after your personal information, you can tell the Information Commissioner's Office, UK: <https://ico.org.uk>.



GLOSSARY -What do these words mean?

Anonymous information - information which does not contain any names or contact details

Clinical trial - an experiment involving patients with a particular disease

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

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

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