



Duchenne
UK



DMD Hub Central Recruitment Database
Participant Information for Children aged 11 – 15
Principal Investigator/Data Controller: Prof Michela Guglieri,
Translational and Clinical Research Institute, Newcastle University

Information for Participants

You are being asked to take part in a project which will help doctors and researchers to learn more about children, young people and adults with Duchenne muscular dystrophy (DMD) who might be interested in participating in research studies (e.g. clinical trials or natural history studies). Before you decide if you want to join 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 parent(s)/guardian(s), 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 project?

We are interested in people like you living with Duchenne muscular dystrophy. We want to create a national list of people with Duchenne muscular dystrophy, who are interested in taking part in research studies in the UK, to help them take part in clinical research.

To help do this we have set up a database to collect information about people like you. We want to ask if it is OK with you to store information about you. If you are happy to be involved in this project, then we will ask your parent(s)/guardian(s) to place their initials in text boxes in a consent form so we can collect and keep the information. This consent can be completed online.

If new research studies are taking place in the UK for people with Duchenne muscular dystrophy, a person who works at a clinical trial centre may contact you to see if you wanted to take part. You do not have to be involved in any research studies and a doctor or nurse would talk to you again at a different time if this was a possibility. You and your parent(s)/guardian(s) would need to sign a different consent form at that time as well.

There is no guarantee that registering on the database will mean that you will be automatically approached to take part in research studies. Health Care Professionals looking to recruit people to a clinical trial will have the opportunity to review details about you and if the trial appears to be suitable, they may contact you and your parents to discuss potentially taking part.

Why have I been asked to take part?

You have been asked to be part of this project because you have Duchenne muscular dystrophy. We are asking children and adults with Duchenne muscular dystrophy from all over the country if they would like to take part in this project.

Do I have to take part?

You do not have to take part in this project. Deciding not to take part will not change how doctors and nurses look after you. If you do want to take part, then your parent(s)/guardian(s) will be asked to add their initials to boxes on a consent form to say that you agree to take part and that we can keep information about you.

You can change your mind and decide you don't want to be part of this project at any time.

What will happen to me if I take part?

If you are happy to be part of this project then you, together with your parent(s)/guardian(s), will complete an online questionnaire (that will take roughly between 25-35 minutes). You will not be asked to have any extra tests done for this project and you will not need any time off school. Your personal details, such as your name and address and information about Duchenne muscular dystrophy will be stored on a secure computer that is protected by passwords and is looked after by the project team at Newcastle University. For further information about how Newcastle University manages personal data, including participant rights under law, and the contact details of the University's Data Protection Officer, please visit the website: <https://www.ncl.ac.uk/data.protection/>.

Doctors and nurses who are looking for people with Duchenne muscular dystrophy to take part in research studies can ask the project team to give them information to help identify people who might be suitable for research studies. The information that you and your parent(s)/guardian(s) provide in the online questionnaire may help with this process. You can always let us know if you have changed your mind and do not want to be on the database anymore, and this would not affect your care in the future.

Will this project help me?

The project may not help you specifically, but the information we collect should help us find people with Duchenne muscular dystrophy like yourself who are willing to take part in research studies in the future.

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 the project team and people working at clinical trial sites who help with the project. The database is password protected in a similar way to online bank accounts.

Will anyone else know I'm doing this?

Only people allowed by Prof Guglieri will be able to see the information about you. Your parent(s)/guardian(s) will also need to know, as they have to place their initials in text boxes in the consent form.

Who decided the project could be done?

Before any research can be done it has to be checked by the Ethics Committee at Newcastle University. This is to make sure that the project is a good idea and is safe to do. This project is organised by Newcastle University.

Participation in the DMD Hub CRD?

The DMD Hub CRD is designed to be a sustainable resource for the DMD community and therefore there is not a defined end date.

Once participants express their interest in being informed about clinical trials, they are potentially eligible for, they will remain in the database however participants are able to remove their data from the CRD at any time.

If the DMD Hub CRD will be discontinued for whatever reason, participants will be notified.

Are there any risks involved in taking part?

There are no direct risks involved in participating in the DMD Hub CRD. However, participants will be made aware that there is no guarantee that registering on the DMD Hub CRD will mean they will be approached to take part in any clinical research study. Participants are selected according to eligibility criteria set by the company running the study, and randomly selected from a pool of eligible patients.

Registration is always voluntary. Participants have the right to withdraw their consent to participate at any time, and any information provided will be deleted. To do so, the participant or parent / guardian must simply contact: dmdhub@newcastle.ac.uk

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 take part in clinical studies. Following your sixteenth birthday, the registry team will contact you and your parent(s)/guardian(s) to ask if you would like to continue participating in the Duchenne Muscular Dystrophy Hub Central Recruitment Database Project.

Contact Details:

If you would like to talk to someone about taking part, you or your parent(s)/guardian(s) can email the DMD Hub Central Recruitment Database Manager, (email: DMDhub@ncl.ac.uk / Tel: 0191 241 8621).

GLOSSARY –What do these words mean?

<p>Clinical trial – an experiment or observation involving participants</p> <p>Consent – giving permission for something, or agreeing it can be done</p> <p>Consent form – agreeing to something in writing</p> <p>Database – a collection of information stored electronically or on a computer</p> <p>Ethics Committee – a group of people who look carefully at research projects to make sure that they are fair and properly carried out</p> <p>Password protected – a way of stopping people from looking at your information</p> <p>Research – careful investigation of a particular subject</p>
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Thank you for reading this information