# DMD Hub Central Recruitment Pilot Project
## Participant Information for Children aged 11 – 15
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## Information for Participants

You are being asked to take part in a project so that we can 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 with a disease called Duchenne Muscular Dystrophy . We want to find out if creating a national list of people with Duchenne Muscular Dystrophy, who are interested in taking part in research studies *in the UK*, will help.

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 f*orm* 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 a 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 anytime.

## 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 a 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 better understand how we can help people with Duchenne Muscular Dystrophy like yourself to take part in research studies in the future.

## What happens when the project stops?

This project is running for a short amount of time in the beginning (around 9-12 months) to see if it is working correctly and helping people like yourself and clinical trial sites. 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 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 Dr 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.

## 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 Pilot 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 Pilot Project Co-ordinator, (email: dmdhub@ncl.ac.uk / Tel: 0191 241 8621).

## GLOSSARY –What do these words mean?

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

**Thank you for reading this information**

*This study was approved by the Faculty of Medical Sciences Research Ethics Committee, part of Newcastle University's Research Ethics Committee. This committee contains members who are internal to the Faculty. This study was reviewed by members of the committee, who must provide impartial advice and avoid significant conflicts of interests.*