Participant Information Sheet (14-15 years)

A Longitudinal Laboratory and Real-World Study of Gait and Balance in People with Friedreich's Ataxia

- We would like to invite you to take part in a research study so that we can learn more about Friedreich's ataxia.

- Before saying 'yes' or 'no', it is important you understand why this study is being done and what it will mean for you.

- Please read this information sheet carefully. You might also want to talk about it with your family and friends.

- Please ask if you have any questions.

There are a few things you should know about the study:

- You get to decide if you want to be in the study.
- You can say 'No' or you can say 'Yes'.
- Whatever you decide is OK.
- If you say 'Yes', you can always say 'No' later.
- Nobody will be upset if you say 'No'. We will still take good care of you no matter what you decide

What is this study about?

We know that having Friedreich's ataxia can make it difficult to move steadily and keep your balance. It can also make it harder to speak or swallow, or might make your legs feel weak, tired or tingly.

In this study we want to learn more about how Friedreich's ataxia affects your balance and walking. We also want to know how these things change over time.

We are hoping that 16 people (aged between 14 and 65 years) with Friedreich's ataxia will take part.

Why am I being asked to take part?

You are being asked to take part in this study because you have Friedreich's ataxia and can walk a short distance (20 metres) without any help.

Do I have to take part?

You do not have to take part in this study. Deciding not to take part will not change how we look after you.

If you take part, you can change your mind at any time.

What happens if I change my mind?

It is OK to change your mind at any point if you no longer want to be part of this study.

Changing your mind will not affect the care your doctors and nurses give to you.

We will keep the information we have already collected about you for this study but we will not collect any more.

What happens if I take part?

If you want to take part, or want to find out more about the study, we will talk to you and your parent (or carer) about it.

You will be able to ask us questions. If, after this, you are happy to take part, you will be asked to sign a form (called an assent form). Your parent (or carer) will also be asked to sign a consent form.

This study involves three visits to the Clinical Ageing Research Unit (CARU) in Newcastle. These visits will happen over one year- at the start, at Month 6 and at Month 12. Each visit will last about four hours.

At each visit we will do some tests and ask you to do some activities. We call these study assessments.

We will do the following assessments:

- **Collect information** about you and what illnesses you have had in your life. We will also ask about how Friedreich's ataxia affects you and about any medicines you are taking.

- **Physical examination:** A doctor will examine you and we will check how tall you are and how much you weigh.

- **Friedreich's Ataxia tests:** We will do some tests with you that have been specially designed for people with Friedreich's ataxia.

- **Hand and keyboard tests:** We will ask you to do a test using a computer keyboard and another test putting pegs in holes in a board.

- **Memory and thinking tests:** We will ask you to do some activities to test your memory and the way you understand things**.**

- **Questionnaires:** You will fill-in questionnaires about your balance and life. These questionnaires can be filled in online (via computer or smartphone) from your home or can be completed on paper.

- **Tests of walking and balance:** These assessments will take place in a room called a gait laboratory. Special sensors will be attached to your back and feet (see the below picture for examples) and we will ask you to walk at different speeds. We will also look at your balance and will ask you to stand in different ways. We will record you on video during these tests. The videos will be stored securely by the gait lab team at Newcastle University. We may wish to use these videos in the future for teaching and training purposes however your parent can choose on the informed consent form whether you and they would like your videos to be used in these ways.

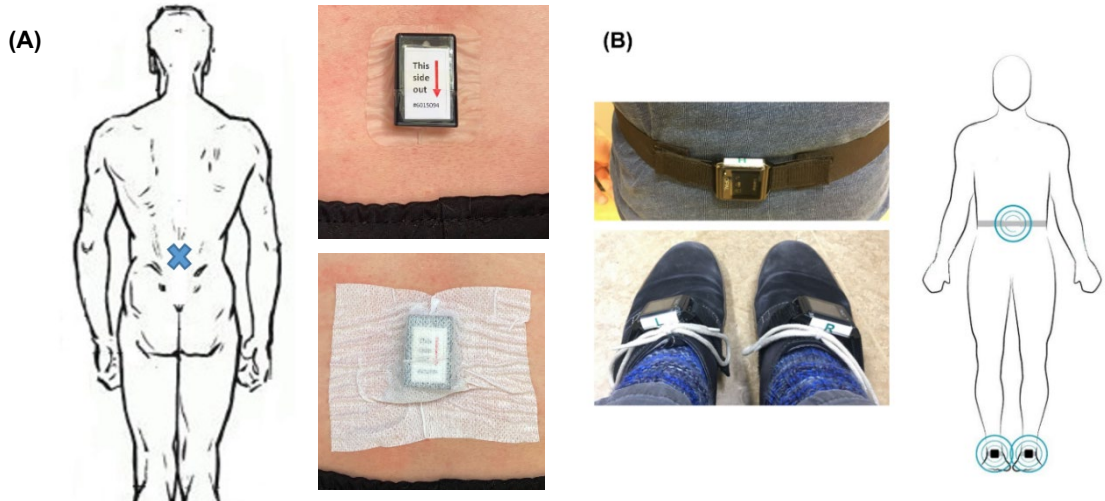

Figure. (A) Axivity, AX6 (single sensor). (B) Opal sensors, one placed in the lower back and two others on feet.

- **Collection of information from medical records:** We will collect information that has already been written in your medical records (this includes results from things like blood tests).

- **Wearable technology for seven-day monitoring:** We will ask you to wear an Axivity AX6 sensor, as shown above, for the next

seven days to measure your movement in your normal everyday life. You will need to keep the sensor on at all times apart from if you have a bath or go swimming. At the end of this time, you will post the sensor back to us. We will give you full instructions on wearing and using the sensor and a separate instruction sheet will also be provided.

All the above assessments will be done at each study visit at CARU.

Once you have finished the Month 12 visit (and returned your wearable sensor) you will have finished taking part. At the end of the study, we will ask you how you felt about taking part.

Who is managing this study and looking after my data?

Newcastle University are sponsoring this study which means they are responsible for it.

Newcastle University and The Newcastle upon Tyne Hospitals NHS Foundation Trust (Newcastle Hospitals) will look after the information we collect from you as part of this study. They are called the data controllers, which means that they are responsible for looking after your information and using it properly.

This study is part of a larger project involving researchers from Tubingen in Germany.

Data collected from this study will be shared with researchers in Tubingen. However, this data will be de-identified, this means that the researchers in Tubingen will not know who you are (instead of your name your data will be identified by a code).

People from the Sponsor, Newcastle Hospitals, or people who make sure research in the NHS is done properly, may look at the study records to check that the study is being run properly. This may include looking at information about you. Any people looking at your information will keep it safe.

Identifiable data about you from this study will be kept by Newcastle Hospitals for at least five years after the study has ended. Data that does not include your name will be held by Newcastle University and the project partners (in Germany) for longer (20 years or more).

How will you use information about me?

We will need to use information from you for this study.

This information will include:

- Your full name
- Your date of birth
- Your NHS number
- Your home address
- Your email address (optional)
- Your or your parent (or carer's) telephone number (including mobile phone number which is optional)
- Details of your medical history and Friedreich's ataxia genetic diagnosis
- Videos of you in the gait laboratory

We will use this information to do the study or to check your records to make sure that the study is being done properly.

We will also let your local doctor (GP) know you are taking part in this study.

As described above, people who do not need to know who you are will not be able to see your name. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Once the study has finished we may also share the data we collected with other researchers (in the UK and in other countries) so that they can use it for their research. Any data we share will be de-identified so that the other researchers do not know who you are.

Can I choose how my information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to look after your records in special ways for the study results to be reliable. This means that we will not be able to let you see or change, the research data we hold about you.

Where can I find out more about how my information is used?

You can find out more about how we use your information

- By talking to your parents/carers who have also been given information about the study
- at https://www.ncl.ac.uk/data.protection/ and/or by contacting the Newcastle University Data Protection Officer rec-man@ncl.ac.uk or the Newcastle Hospitals Data Protection Officer nuth.dpo@nhs.net.
- at www.hra.nhs.uk/information-about-patients/
- via a leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to **nuth.mitoresearch@nhs.net** or
- by ringing us on **0191 2083105**

If you have any concerns about the way your data is handled as part of this study, you have can report these to the Information Commissioners Office (ICO), https://ico.org.uk/.

Will taking part in this study help me?

There will be no direct benefits to you for taking part in this study.

However, we hope that the things we learn from the study as a whole will help us to better understand Friedreich's ataxia and what research we should do in future in this condition.

Are there any disadvantages to taking part?

The research study visits will last much longer than your usual clinic appointments. We will give you plenty of breaks and a drink or snack during this visit.

The questionnaires we ask you to complete at home will take approximately one or two hours. They can be filled in on paper or online.

The study assessments that will be performed are safe will be performed by researchers who are used to delivering them.
We will make sure before you take part that you are able to complete the assessments safely.

You may feel unsteady when you do some of the balance assessments, or when you are asked to fast in the gait laboratory, however trained staff will be with you at all times to during these assessments to ensure that you are safe and comfortable.

If you are not sure about anything you can ask a member of the research team about it or we can arrange for you to talk to one of your usual doctors or nurses.

When the wearable sensors are attached to your body, you may experience some itchiness or redness from the sticky label used to attach them. Any itchiness or redness should not last long and you can tell the research team if you have any problems.

We do not expect to find any new medical problem to worry about during the study assessments. If anything is found that needs to be looked at, the study doctors will talk about this with you and your parents. They may send you to see your GP or another hospital doctor about it.

What happens once this study has finished?

Once you have been to your three study visits you will have finished the study.

Once the study is completely finished you, and your parent (or carer) will be sent a copy of the overall study results with a thank you letter. Unfortunately, we will not be able to tell you your own results.

Who has reviewed this study?

All research study that take place in the NHS are looked at by a group of people, called a Research Ethics Committee. They make sure that your rights and welfare are protected.

This study has been reviewed and approved by the East of England - Cambridge South Research Ethics Committee.

Who will be managing this study?

Newcastle University are sponsoring this study which means they are responsible for how it is set-up and managed.

The Chief Investigator for this study is Dr Yi Shiau Ng. Dr Ng has responsibility for the how it runs.

Newcastle University work closely with Newcastle Hospitals, where the study visits will be taking place.

How is this study funded?

The French Friedreich's Ataxia Association (AFAF) have provided money so that we can run this study.

Who should I contact if I have any questions?

Chief/Principal Investigator: Dr Yi Shiau Ng
Email: **nuth.mitoresearch@nhs.net**
Study Contact Name: Isabel Barrow
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Email: **nuth.mitoresearch@nhs.net**

You can get in touch with the study team on the details above if you have any questions or need any further information.

Thank you for reading this information sheet