

## Child Information Sheet and Assent Form

AGES 8 TO 12 YEARS OLD

Royal North Shore Hospital

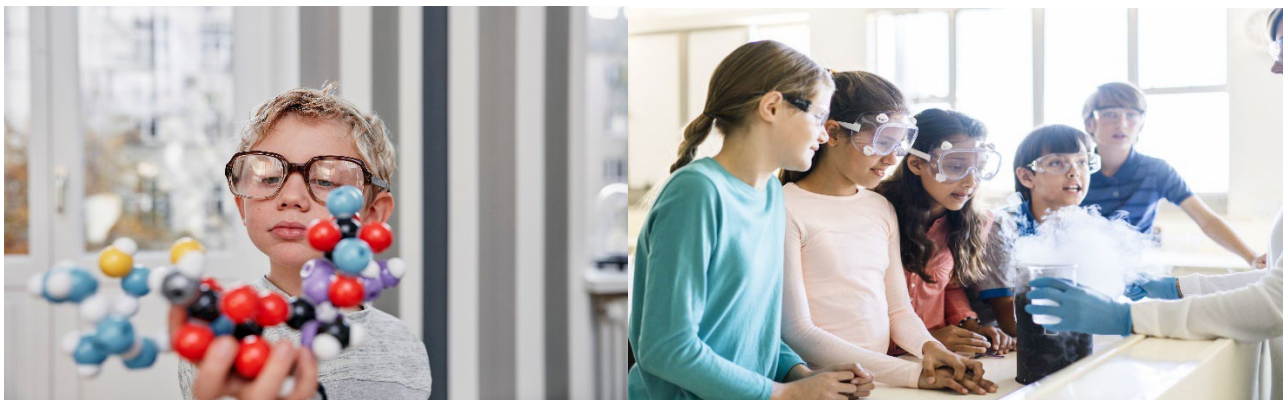
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|-------------------|--|
| Short Study Title | L-Carnitine for Children with muscle weakness and fatigue in NF1 |
| Location          | Royal North Shore Hospital                                       |

|                             |                   |                |              |
|-----------------------------|-------------------|----------------|--------------|
| Study Doctor                | Dr Yemima Berman  | Contact Number | 02 9463 1727 |
| Study Coordinator/<br>Nurse | Ms Nanette Lacson | Contact Number | 0473 425 910 |

### About our research study

A research study is usually done to find a better way to help or treat people. It is to understand how things work and test new ideas. You are being asked to take part because you have NF1 and muscle weakness.

The study will help find out if using an extra medicine (called **L-carnitine**) will treat your muscle weakness.



### How long will study last?

We expect that you will be in this research study for around 6 months.

### What will I be asked to do if I agree to be in this study?

- If it is okay with you, you will be asked to take part in phone calls once a week, with your parents or guardians/carers.
- You will visit the hospital with your parents or guardians/carers every 6 weeks.



- The computer program will decide whether you take L-carnitine or placebo tablets each day. A placebo is any treatment that has no medicine, such as a sugar pill.



**During your visits to the hospital, you will be asked to:**



1. Walk for 6 minutes



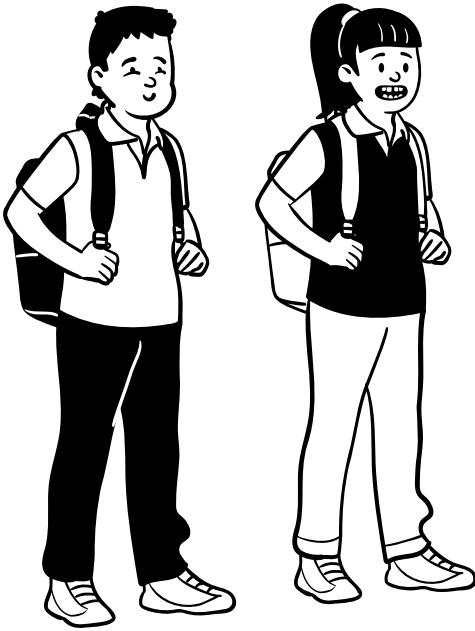
2. Point your toes and lift your foot

3. Grip a machine that measures your strength



4. Wear a watch around your wrist or waist to measure activity every day





### Do I have to join the research study?

You do not have to be in this research study. It is totally up to you and your parents or guardians/carers. If you say yes now, you can still change your mind later. No one will be upset if you change your mind.

We want you to ask any questions that you have. You can ask questions at any time. You can talk to your parents/guardians or carers, your regular doctor, the study doctor, or your teacher.

### Could this research help me?

We cannot promise that this research will help you, but we think may help your muscle weakness and improve your strength to do physical activities. And we hope the information from this research will help other kids who have NF1 and muscle weakness.

### Could bad things happen to me if I join this study?

In previous research studies using this medicine, children your age did not have any problems. However, there is still a very small chance that you may have:

- An upset tummy,
- It may smell fishy when you breath, or go to toilet,
- And some children with epilepsy may have high chances of seizures

### If I feel distress or worried, who can I call?

Please call Nanette Lacson, your study nurse at 0473 425 910 or Claire Wong, Genetics Counsellor, at 02 9463 1560.

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### To be completed by person obtaining verbal assent from the child/participant:

Do you understand what I am saying? Do you want to be in this research study?

Child's/Participant's response:  Yes

No

Check which applies below:

The child/participant is capable of understanding the study

The child/participant is not capable of understanding the study

|  |
|--|
| Name of the Child/Participant (please print) _____ |
|--|

|   |
|---|
| Name of Study Doctor<br>Obtaining the Assent (please print) _____ |
| Signature _____ Date _____  |