Participant Information Sheet/Consent Form
Parent/Guardian

Royal North Shore Hospital

Study Title:		A Randomized, Double-Blind, Placebo Controlled, Phase 3 Study Assessing the Efficacy and Safety of L-carnitine Supplementation to Treat Muscle Fatigue and Weakness in children with neurofibromatosis 1
Short Study Title:		**S**upplement **Tr**eatment **E**valuation of L-car**N**itine for Muscle Fati**g**ue and Weakness in Children with Neurofibromatosis **T**ype 1 (**STrENgT**h)
Project Sponsor:	**Global**	Children's Tumor Foundation, USA
	Local	Royal North Shore Hospital, Clinical Genetics
Coordinating Principal Investigator/Principal Investigator:		Associate Professor Yemima Berman
Location:		Royal North Shore Hospital

Part 1 What does my participation involve?

1. Introduction

Your child is invited to take part in this research project called L-Carnitine for Children with NF1. This is because your child has, or your child's doctor thinks your child a condition called Neurofibromatosis Type 1 (NF1) and muscle weakness. The research project is testing a new treatment for muscle fatigue and weakness brought about by NF1. The new treatment is called L-carnitine. L-carnitine is a supplement available over the counter.

As parent/guardian/legally authorized representative, consent from you is sought for your child's participation in the study. Participation in this research is voluntary. If you do not wish your child to take part, they do not have to. Your child will receive the best possible care whether they take part or not.

If you do decide for your child to participate, you will have to sign this consent form prior to any study procedures. By signing it you are telling us that you:

- Understand what you have read
- Consent your child to take part in the research project
- Consent your child to have the tests and treatments that are described
- Consent to the use of your child's personal and health information as described.

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

2 What is the purpose of this research?

The purpose of this research project is to test a new treatment (called L-carnitine) for children who have muscle weakness and NF1. NF1 is an autosomal dominant genetic condition occurring in approximately 1 in 3000 births. It affects the soft tissue, skin, nervous system, and bone.

Adults and children with NF1 are challenged by reductions in lean tissue mass, global muscle weakness, problems with fine and gross motor functioning, express higher levels of physical and cognitive fatigue, and report a low self-concept for physical and sporting abilities. While the impact of NF1 on muscle appears variable, for some individuals it can be a major concern and reduce their quality of life. Early studies have found that NF1 deficiency can lead to accumulation of intramyocellular lipid (fat in the muscle) featuring long-chain fatty acids. L-carnitine is an amino acid derivative that plays a crucial role in the metabolism of fats in the body. It is involved in the transport of long-chain fatty acids into the mitochondria, where they can be broken down and used for energy.

L-carnitine has been used in the acute and long-term treatment of people with disorders of organic acid and fatty acid metabolism, i.e. propionic acidemia (PA); methylmalonic acidemia (MMA); isovaleric acidemia (IVA); and medium chain acyl-CoA (MCAD) deficiency. In the USA, L-carnitine was approved by the Food and Drug Administration (FDA) in 1992. It is considered a cheap, safe, and effective therapeutic measure for these conditions. L-carnitine is available as an over-the-counter supplement and used to treat muscle fatigue in healthy individuals (PMID: 34842765)

The study medicine (L-carnitine) may help in managing the physical limitations associated with muscle weakness or fatigue in NF1. This research study will check how safe and effective L-carnitine is in children from 8-12 years of age with NF1.

L- carnitine has been studied in a clinical trial for children with NF1 and been found to be safe (PMID: 34155781). L-carnitine is an experimental treatment for muscle weakness and fatigue in NF1 children and can only be used for research in this case. This means that it is not an approved treatment in Australia in managing muscle weakness and fatigue. However, L-carnitine is used and approved in the world, for treatment of systemic carnitine deficiency and is widely used in people with other medical conditions.

This research is being conducted by the Department of Clinical Genetics, Royal North Shore Hospital and sponsored by the Children's Tumor Foundation, USA.

3 What does participation in this research involve?

Study Design:

1. This study is a randomized, double-blind, placebo-controlled study, which means all participants will be assigned to two different treatment groups, you, your study doctor, and the study team will not know what treatment you are getting. This study includes treatment periods, which are outlined and further described below in detail:
2. Overview of Study Periods:
3. Screening Period: including baseline functional and clinical assessments (from 1 to 2 weeks).
4. Day 1 to Week 12: L-carnitine or Placebo dosing (12 weeks).
5. Washout Period: Break from dosing period (1 week).
6. Week 13 to Week 25: Crossover Period (12 weeks).
7. Follow Up (2 weeks)

1. Screening Period:

The study starts with a Screening Period. During this time, you will sign this consent and your child will complete screening assessments to see if he/she will meet participation requirements.

The following screening activities may be performed to see if he/she meets all study participation criteria.

- Information about your child (such as age, race, ethnicity, and gender) and information about his/her medical history (including current and past medical conditions and surgical history) will be collected.
- Measurement of vital signs (blood pressure, heart rate, breathing rate, and temperature).
- Height and weight will also be measured.
- Blood may only be drawn from one of his/her veins for standard safety tests and if the study doctor believes that it is necessary to do so.

2. Day 1 to Week 12:

In this period, he/she will be randomly assigned to either the L-carnitine or placebo and will commence on treatment. A placebo is any treatment that has no active ingredients, such as a sugar pill. In this study, your child has a 50% chance to get the placebo.

He/she will be given a wearable device (actigraphy device) to wear on the wrist or waist throughout the study. The wearable device will record how active he/she is by counting the total daily steps when worn. The device should be always worn unless showering. If he/she wish, he/she may also remove the device during sleep. The device is water resistant but not waterproof. He/she may wear it when swimming but please avoid getting soap or cleaning products on it. It should also not be worn in a sauna or hot-tub. Further instructions will be provided as he/she is enrolled in the study.

This period is 12 weeks long. During this time, he/she will have face-to-face and telephone consultations with the study doctor and you or he/she will be asked to complete questionnaires and measures to assess his/her muscle strength.

3. Washout Period:

There will be a 1-week washout period, and at this time you and he/she are given a choice whether he/she would like to participate in the crossover study.

4. Week 13 to Week 25:

This period is a 12-week long treatment extension wherein he/she will be given L-carnitine treatment. Similarly, he/she will have face-to-face and telephone consultations with the study doctor and will be asked to complete questionnaires and measures to assess his/her muscle strength.

5. Follow Up:

This will be the final study visit and treatment completion.

Study Activities and Time Commitment

The assessments and procedures described in this section will be done only after he/she have agreed to take part in this study and you signed this consent form in his/her behalf.

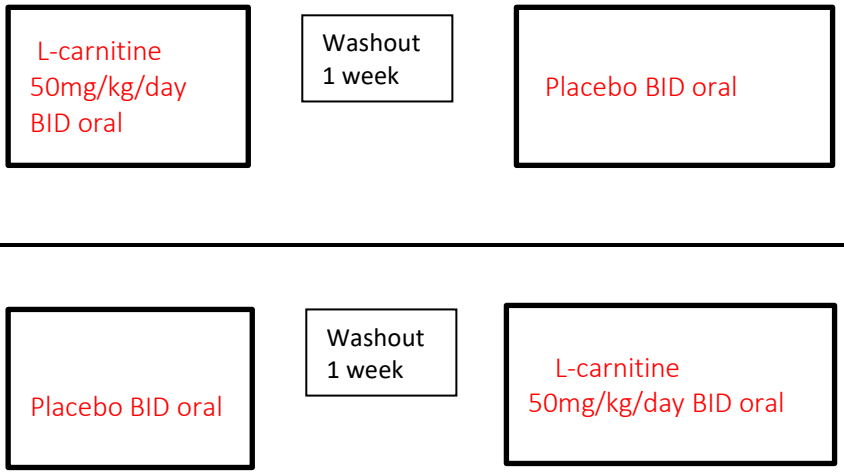
- The *Screening Period* may be up to 14 days.
- The *Day 1 to Week 12 will* take about 3 months and could include 2 visits to the study center. This is the *main part of the study* where he/she will be taking the study drug and the team alongside will monitor for effectiveness and tolerability of the medication.
- If you and he/she choose to continue in the *Crossover Study Period*, he/she will have 3 additional face-to-face visits to the study center and a few telephone visits over 12 weeks.

Face-to-face clinic visits will take approximately 1 to 1.5 hours. You and your child also receive a telephone check-in from the study team to see how he/she are doing with the treatment and report

any issues he/she may have had and medications he/she are taking. They will also ask he/she took the L-carnitine or placebo doses, as instructed, and whether he/she missed or skipped any doses.

It is important that you and he/she answer all the questions asked by the study staff honestly and completely. If anything about his/her condition changes during the study, you must tell the study doctor as soon as possible. As part of the study, he/she will be asked to complete a questionnaire during some study visits and a dosing diary daily. The questionnaire is called PedsQL used to indicate your health status. In the Dosing Diary he/she will enter the study medication, time, and date the study medication was taken.

Figure 1: Study Design



Week	14 to 0	1	6	12		13	19	25	27
Visit*	1	2	3	4		5	6	7	8
	Screening	Placebo or carnitine			washout	Crossover Swap to placebo/ carnitine		End of Treatment	Final Visit

* ± 3 days is allowable in all study visits

Early Termination Visit:

At any point in the study if you can decide to stop participating, he/she will be asked to come to the clinic for an Early Termination Visit as soon as possible.

Additional costs:

There are no additional costs associated with participation in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

However, taking part in this research may lead to additional costs to you, such as missed hours from work to attend the study visits. In addition, you will be responsible for all the costs linked with this study that are related to his/her regular medical care and are not covered by other payers (such as your health insurance provider).

You and your child will need to take time to attend the study visits, follow study instructions, and speak with the study center. This may take time out of your day from school or work.

Reimbursement:

You will be reimbursed for reasonable expenses incurred due to your child's participation in the study (for example: parking) up to the amount of $75 per visit. The reimbursement will be paid against the receipt of the invoice and corresponding support documentation.

Please speak to your study doctor about this before your sign this consent form.

What do I have to do?

As a participant in this study, your child and you have certain responsibilities. You will have to:

- Provide consent for your child to be a volunteer by reading, understanding, and signing this consent form.
- Attend all your child's study visits and participate in phone calls with him/her for check-ins with the study center.
- Provide a clear and extensive medical history for your child.
- Be certain that your child wears the actigraphy wrist or waist band
- Complete questionnaires to assess your child's health and how he/she is feeling.
- Tell the study doctor of any side effects or changes to your child's health or new medical problems your child may experience during the study.
- He/she must take the L-carnitine or placebo twice daily during the study as instructed by the study doctor.
- Complete clinical and functional assessments as required by the study and diligently wear the activity tracking devices provided to study participants.
- Keep L-carnitine or placebo in a safe location, out of reach of other children or anyone not taking part in the study.
    - Bring back your child's unused tablets to each visit.
- Let the study doctor know of any new medicines your child starts to take or changes in medicines he/she is already taking. This includes over the counter medicines like paracetamol, cold/cough medicine, supplements, and herbal supplements.

Other relevant information about the research project

Approximately 40 children who have NF1 will take part in this study.

Do I have to take part in this research project?

Your child's participation in this study is voluntary. Your child does not have to join this study to receive treatment for your NF1.

You may decide for your child to discontinue or to no longer take part in the study at any time for any reason. There will be no penalty or loss of benefits if your child and you decide not to take part in the study, or he/she then later decide to leave the study.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign as a parent/guardian and on behalf of your child, and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your child's routine treatment, your relationship with those treating you or your relationship with Royal North Shore Hospital.

What are the alternatives to participation?

Your child does not have to take part in this research project to receive treatment at this hospital.

The study doctor will discuss what other options for treatments are available to your child before you decide whether to take part in this research project. You can also discuss the options with your local doctor.

What are the possible benefits of taking part?

There will be no clear benefit to you or your child from his/her participation in this research.

Other possible benefits to others include ongoing and future development of L-carnitine which, if approved by regulatory agencies, may provide another treatment option for NF1.

What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. Your child may have none, some or all the effects, and they may be mild, moderate, or severe. Like all medicines, L-carnitine may cause side effects. This study may involve risks to your child that are currently unknown and unforeseeable.

However, in previous trials, no adverse events were seen in children aged 8-12 given a comparable dose of carnitine.

Please tell your study doctor if your child experiences any side effects. Contact information can be found on page 10 of this consent form.

Possible Side Effects of L-carnitine:

L-carnitine is approved by the Therapeutic Goods Administration (TGA), a medicine and therapeutic regulatory agency of the Australian Government, for L-carnitine deficiency caused by certain genetic diseases and other disorders. Like all medicines, L -carnitine may cause side effects. This study may involve risks to your child that are currently unknown and unforeseeable. Please tell your study doctor if your child experiences any side effects. Contact information can be found on page 10 of this consent form.
When taken by mouth, L-carnitine is likely to be safe for up to 12 months. It can cause side effects such as:

- Stomach upset
- Heartburn
- Diarrhoea
- Seizures
- Urine, breath, and sweat's fishy odour
- Hypothyroidism symptoms
- Potential emotional and psychological distress

There may be side effects of L-carnitine which are unknown at this time. Be sure to tell your study doctor if your child experiences any side effects during this study. If your child experiences any chest pain or are concerned by any side effects, you should seek immediately medical assessment.

What if new information arises during this research project?

Sometimes during a research project, new information becomes available about the treatment that is being studied. If there is new information available on L-carnitine during the study which may make you change your mind about taking part in the study, you will be informed of this new information without delay. If this happens, the study doctor will tell you about it and discuss with you whether you want your child to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your child's regular health care to continue. If you decide to continue in the research project, you will be asked to sign an updated consent form on behalf of your child.

Also, on receiving new information, your study doctor might consider it to be in your child's best interests to withdraw from the research project. If this happens, he/she will explain the reasons and arrange for your child's regular health care to continue.

Can my child have other treatments during this research project?

Whilst your child is participating in this research project, he/she may not be able to take some or all the medications or treatments he/she has been taking for his/her condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications he/she may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture, or other alternative treatments.

You should also tell your study doctor about any changes to these during your child's participation in the research project. Your study doctor should also explain to you, which treatments or medications need to be stopped for the time your child is involved in the research project.

What if I withdraw from this research project?

If you decide to withdraw your child from the project, please notify a member of the research team before you withdraw him/her. This notice will allow that person to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you or your child, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

If you decide for your child to no longer take part in the study, or your study doctor decides your child should no longer take part, you should contact the study personnel to perform the Early Termination and follow-up visits.

Your choice to take part or to stop taking part in this study will not affect your child's routine or regular treatment, your relationship with those treating him/her, or your relationship with the place where your child is getting treatment. You will still receive care for your child's condition and will not lose any benefits to which he/she is otherwise entitled.

Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The drug/treatment/device being shown not to be effective

- The drug/treatment/device being shown to work and not need further testing
- It is in your best interest,
- You are unable to take the study drug, or you choose not to,
- You do not follow the instructions you receive for taking part in the study.

If any of these happen, you will be offered all the planned tests and checks to be sure that you receive the most appropriate medical treatment.

What happens when the research project ends?

Participation in this research study does not guarantee your child's further access to L-carnitine, even if you believe it will help you. Please speak with your doctor about other treatments for your condition.

What will happen to information about me?

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about your child for the research project. Any information obtained in connection with this research project and for the future research that can identify your child will remain confidential and securely stored as described in this form. Your child's information will only be used for the purpose of this research project, and it will only be disclosed with your/your child's permission, except as required by law.

If you sign this form, we will collect your child's health information until the end of the research. We may collect some health information from your child's medical records even after your child finishes taking part in the research study. We may keep your child's health information forever in case we need to look at it again. We will protect your child's health information and keep it confidential as described in this form.

What personal data will be collected?

Your child's study doctor will collect the following personal data about your child as part of this study and store it in your child's medical records and the electronic case report form:

- Results, reports, and images from medical examinations
- Results and reports from tests and procedures
- Interviews and questionnaire responses
- Data about the effects of the study medicine
- Diagnosis and treatment of any side effects
- Your contact details, sex, age or date of birth, race, and ethnic origin (ethnicity)

This personal data must be provided in order to participate in this study.

Your child's study doctor will add your child's personal health data from his/her medical record into electronic study records called case report form. To protect your child's privacy, we will not put your child's name in the study records. We will use a code number instead of your child's name. This is how we will encode your child's personal health data. The study doctor will keep a list connecting the code number to your name. This list will not be shared with anyone not directly involved in the study. It will be accessible only to the study doctor and his/her study staff, and auditors, as required.

Your child's health records, and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Global Sponsor, Children's Tumor Foundation, USA, and the institution relevant to this Participant Information Sheet, Royal North Shore Hospital or as required by law.

By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above. We may publish the results of this study in academic journals, on the Internet, or at educational meetings. We will not use your child's name or directly identify your child in any publication or in any teaching materials. Some academic journals may need limited access to your child's encoded personal data. This allows them to verify the study results and to make sure the study meets the journal's quality standards.

Journals may also require that the results from this study be available to other researchers for other research projects. If the results from this study are provided to other researchers for this purpose, your child will not be directly identified. If we remove anything that could identify your child, such as destroy the code list or remove your child's code from the data (anonymized), the anonymized data can be shared without your/your child's further consent.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this website at any time. The posting of this study on an International Clinical Trials Registry Platform is also a requirement of the Australian National Statement on Ethical Conduct in Human Research 3.1.7. In accordance with relevant Australian and/or or New South Wales privacy and other relevant laws, you/your child have the right to request access to the information collected and stored by the research team about your child. You/your child also have the right to request that any information with which you/your child disagree be corrected. Please contact the research team member named at the end of this document if you/your child would like to access your information. In certain cases, you/your child can request that the use of your child's personal data is limited or to have your child's personal data erased however the Sponsor may be required to keep certain data until after the study has been completed.

Complaints and compensation

If your child suffers any injuries or complications as a result of this research project, you should contact the study team as soon as possible and your child will be assisted with arranging appropriate medical treatment. If your child is eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

Who funding the research?

This research project is being conducted and funded by the Childrens' Tumor Foundation, USA Company and the Department of Clinical Genetic, Royal North Shore Hospital, Northern Sydney Local Health District. You will not benefit financially from your involvement in this research project even if, prove to be of commercial value to the Sponsor.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the Sponsor, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

Royal North Shore Hospital will receive a payment from the Children's Tumor Foundation, USA for undertaking this research project. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Royal North Shore Hospital

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2023). This statement has been developed to protect the interests of people who agree to participate in human research studies

Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on [phone number] or any of the following people:

Clinical contact person

Name	Nanette Lacson
Position	Clinical Trials Manager
Telephone	02 9926 4775
Email	nanette.lacson@health.nsw.gov.au

If you experience distress, please contact

Name	Claire Wong
Position	Genetics Counsellor
Telephone	02 9463 1560
Email	claire.wong@health.nsw.gov.au

If you experience distress, you can also call at any time:

Name	Lifeline Australia
Telephone	131114
Web	https://www.lifeline.org.au

NF1 Support Groups:

Name	Children's Tumor Foundation, US
Address	697 Third Avenue, Suite 418, New York, NY 10017
Telephone	1800-323-7938 or +12127470004
Web	https://www.ctf.org/contact/

NF1 Support Groups:

Name	Children's Tumour Foundation Australia
Email	info@ctf.org.au
Telephone	02 9713 6111
Web	https://www.ctf.org.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	NSLHD Research Office
Position	NSLHD Research Governance Officer
Telephone	02 9926 4590
Email	NSLHD-Research@health.nsw.gov.au
REGIS Reference Number	2024/STE00040

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	NSLHD Human Research Ethics Committee
HREC Executive Officer	NSLHD Ethics Officer
Telephone	02 9926 4590
Email	NSLHD-Research@health.nsw.gov.au
REGIS Reference Number	2024/STE00040

Local HREC Office contact (Single Site -Research Governance Officer)

Name	NSLHD Research Office
Position	NSLHD Research Governance Officer
Telephone	02 9926 4590
Email	NSLHD-Research@health.nsw.gov.au

Consent Form - *Parent/guardian providing consent*

Study Title:		A Randomized, Double-Blind, Placebo Controlled, Phase 3 Study Assessing the Efficacy and Safety of L-carnitine Supplementation to Treat Muscle Fatigue and Weakness in children with neurofibromatosis 1
Protocol Number:		**S**upplement **Tr**eatment **E**valuation of L-car**N**itine for Muscle Fati**g**ue and Weakness in Children with Neurofibromatosis **T**ype 1 (**STrENgT**h)
Project Sponsor:	**Global**	Children's Tumor Foundation, USA
	Local	Department of Clinical Genetics, RNSH
Coordinating Principal Investigator/Principal Investigator:		Associate Professor Yemima Berman
Location:		Royal North Shore Hospital

Declaration by Parent/Guardian

I have read the Participant Information Sheet (Parent/Guardian), or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my child's doctors, other health professionals, hospitals, or laboratories outside this hospital to release information to Royal North Shore Hospital concerning my child's disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had the opportunity to read the information, to ask questions, and have had all of my questions answered to my satisfaction.

I freely agree for my child to participate in this research project as described and understand that my child is free to withdraw at any time during the study without affecting my child's future health care.

I consent my child's primary doctor (also known as my general practitioner, or GP) being informed of my child's participation in the study.

I understand that I will be given a signed copy of this document to keep.

Name of Parent/Guardian (please print) _____

Signature _____ Date _____

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness* to informed consent is required.*

Name of Witness* to Parent/Guardian's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project; its procedures and risks and I believe that the participant and parent/Guardian have understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team or an associate investigator with medical qualification must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation – *Parent/guardian providing consent*

Study Title:		A Randomized, Double-Blind, Placebo Controlled, Phase 3 Study Assessing the Efficacy and Safety of L-carnitine Supplementation to Treat Muscle Fatigue and Weakness in children with neurofibromatosis 1
Protocol Number:		**S**upplement **Tr**eatment **E**valuation of L-car**N**itine for Muscle Fati**g**ue and Weakness in Children with Neurofibromatosis **T**ype 1 (**STrENgT**h)
Project Sponsor:	**Global**	Children's Tumor Foundation, USA
	Local	Department of Clinical Genetics, RNSH
Coordinating Principal Investigator/Principal Investigator:		Associate Professor Yemima Berman
Location:		Royal North Shore Hospital

Declaration by Parent/Guardian

I wish my child to withdraw from participation in the above research project and understand that such withdrawal will not affect my child's routine treatment, my child's relationship with those treating him/her or my child's relationship with Royal North Shore Hospital.

Name of Parent/Guardian (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project, and I believe that the participant/parent/guardian has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

†A senior member of the research team or an associate investigator with medical qualifications must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.