Government of Western Australia
Department of Health

TELETHON KIDS INSTITUTE

Participant Information Sheet/Consent Form - Parent/Guardian, Participant (if able)

Perth Children's Hospital/ Telethon Kids Institute

Title	**Developing Clinical Predictors of Disease Progression in Children with Neuromuscular Disorders to Prevent Future Respiratory Failure**
Short Title	**Clinical Predictors of Respiratory Failure in Paediatric Neuromuscular Disorders**
Protocol Number	**2015185**
Project Sponsor	**Princess Margaret Children's Hospital**
Coordinating Principal Investigator/ Principal Investigator	**Dr Andrew Wilson** **Dr Adelaide Withers, Prof Graham Hall, Dr Peter Rowe**
Associate Investigators	
Location	**Perth Children's Hospital**

Part 1 What does participation involve?

1 Introduction

This is an invitation for you and the child in your care to take part in this research project, Developing Clinical Predictors of Disease Progression in Children with Neuromuscular Disorders to Prevent Future Respiratory Failure because the child in your care has a neuromuscular disorder.

This research project is aiming to identify problems with breathing during sleep because of muscle weakness by using various tests, and to see whether we can diagnose this problem earlier than if we rely on asking about symptoms alone. We hope that by earlier diagnosis and treatment of muscle weakness during sleep, we can prevent future lung failure.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want the child to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not the child can take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you do not wish for the child to take part, they do not have to. They will receive the best possible care whether or not they take part.

If you decide you want the child to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to the child taking part in the research project
• Consent to the child having the tests and research that are described
• Consent to the use of the child's personal and health information as described.

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

2 What is the purpose of this research?

Children with neuromuscular disorders have weaker muscles, and this can affect their breathing. This is especially a problem while they are asleep as the muscles relax. Difficulty breathing during sleep can cause oxygen levels to drop and carbon dioxide levels to rise during sleep – this is called hypoventilation. Hypoventilation is often the first sign that lung function is worsening, and can be a signal to doctors that more treatment is needed for the breathing muscles. If hypoventilation is not treated, muscle weakness can progress, eventually leading to lung failure.

There is treatment available for hypoventilation, called non-invasive ventilation or NIV. NIV is a mask worn over the nose during sleep, which helps the breathing muscles to work better, gives them a rest and raises oxygen levels while lowering carbon dioxide levels. NIV has been show to improve lung function, prolong life and improve quality of life in people with neuromuscular disorders.

Unfortunately, it is very difficult to identify when hypoventilation starts. The best test is with a sleep study – this requires an overnight stay in hospital, is an expensive test and not easily available at all places.

Currently we rely on asking about symptoms a person might have when they have hypoventilation to let us know when a sleep study is required. The problem is, the symptoms of hypoventilation are vague, may not be present or may be present because of another problem that is not hypoventilation. It is very difficult to detect when hypoventilation occurs just by asking about symptoms. The main aim of this study is to use other tests (such as lung function testing) to see if we can detect hypoventilation earlier than just asking about symptoms. This would allow us to treat hypoventilation with NIV much earlier, and possibly prevent or slow the progression to lung failure.

Currently we do not know the best way to detect hypoventilation when it begins, particularly in children. If we could find a better method, it could be very useful in treating people with neuromuscular disorders and potentially slowing the onset of lung failure. This study will also

allow us to collect information about lung function that will allow us to design clinical trials in the future, which may also help improve lung function in children with neuromuscular disorders.

The results of this research will be used by the study doctor Adelaide Withers to obtain a masters degree by research at Curtin University.

This research has been initiated by the study doctors, Dr Adelaide Withers, Dr Andrew Wilson and Professor Graham Hall.

This research has been partially funded by The Muscular Dystrophy Association of Western Australia (MDAWA) and Duchenne Parent Project Netherlands (DPP NL).

3 What does participation in this research involve?

All children between the ages of 0-18 with a neuromuscular disorder that potentially affects breathing muscles and could be treated with NIV will be invited to participate. Potential participants will be identified from the list of children who already attend the Neuromuscular Clinic at Perth Children's Hospital. To avoid missing any eligible participants, we will be cross checking the clinic list with Rocky Bay. We will also send a letter to the neurology doctors who work at Perth Children's Hospital to ask if they have any patients with neuromuscular disorders who would be eligible to participate but are not currently seen at the Neuromuscular Clinic. Eligible participants will be invited to participate by a letter in the mail, and will be asked verbally at the Neuromuscular Clinic by Dr Withers. Dr Withers will also call you before the clinic appointment to ask if you have any questions and if you are interested in participating.

Participants and/or their guardians who agree to participate in the study will be asked to sign a consent form on behalf of yourself and the child participating. Dr Withers, the study doctor, will explain and discuss the consent form with you and the participant if appropriate. Dr Withers will ask you to sign the consent form. If the child is old enough, Dr Withers will also ask them to sign a consent form as well. No part of the study will be done until consent is obtained.

During the study period of 12 months from the time of enrolment, we will be conducting a number of tests and asking you and the child (if able) to complete some questionnaires. The total amount of time the participant is enrolled in the study is 12 months, and consists of 4 visits 3 months apart (which we feel is a clinically appropriate interval between visits). The *vast majority* of tests that will be conducted and information collected during the regular attendance at the Neuromuscular Clinic will not be different to the tests and information that is normally collected at the Neuromuscular Clinic. The participant may have to attend for extra visits outside of the Neuromuscular Clinic, for example if they require a sleep study (explained below). In addition, although some of the tests (such as multiple breath washout and 6-minute walk test), are performed in some centres, we do not currently perform these tests in our clinics, so the clinic visits may take a little longer than usual. We may arrange another time for your child to complete some testing if they get tired during clinic. Please note that not all participants will be required to perform extra tests depending on their underlying diagnosis.

After the participant is enrolled, Dr Withers will review the participant's medical file to see whether the participant is already using NIV.

IF THE PARTICIPANT IS ALREADY USING NIV, Dr Withers will collect previous lung function results, sleep study results and information about hospital admissions for the 12 month period prior to the start of the participant using NIV from the medical files. The participant will then have information collected for a 12 month period in 3 monthly intervals as described below.

IF THE PARTICIPANT IS NOT USING NIV, they will be booked for an overnight sleep study in the sleep lab at Perth Children's Hospital. Once the sleep study is complete, the participant will have information collected for a 12 month period in 3 monthly intervals as described below. At the end of the 12 month period, the participant will have another sleep study to see if they have developed hypoventilation.

If the initial sleep study shows that the participant has hypoventilation and needs treatment with NIV, this will be discussed with you and the participant, and treatment initiated if appropriate.

DATA COLLECTION

Information will be collected every 3 months for the 12 month period the participant is enrolled in the study. Most of the information will be collected at the Neuromuscular Clinic, however if you have difficulty attending the clinic or your child becomes tired alternative arrangements can be made. The majority of information collected and tests performed are not different to what normally occurs at the Neuromuscular Clinic.

At each visit, we will collect the following;

1. Lung function testing (if the participant is able to do lung function and is old enough) – this might include blowing into a tube, taking deep breaths, breathing slowly for several minutes at a time, coughing into a tube and sniffing through a tube. This will be done in the respiratory lab. Most of these tests would be performed regardless of whether the participant is enrolled in the study, however one test will only be performed if your child is participating in the study. This takes about 20-30 minutes and is done just before the participant attends the clinic.
2. Information regarding the general health of the participant, snoring, sleep, chest infections, hospital admissions, antibiotic use. This information would be collected regardless of whether the participant is enrolled in the study. This is collected during the clinic visit, which usually takes between 30-60 minutes.
3. Motor function testing with various tasks such as walking (including a 6-minute walk test if able), standing up, climbing, using the hands. This testing will be performed by a physiotherapist or a doctor and the majority would be tested regardless of whether the participant is enrolled in the study. This is collected during the clinic visit, which usually takes between 30-60 minutes.
4. Information regarding the quality of life and mood of the participant and the main carer. These questions can include how you and your child have been feeling, any worries or concerns you may have and how your family is coping. This will be collected with a short questionnaire that can be completed by you, the participant (if able) or Dr Withers can ask you the questions and fill out the answers if you prefer. This will be done in the waiting room or in a spare room while you are waiting in the Neuromuscular Clinic, and will take between 5-10 minutes.

If the participant has more tests ordered by a doctor for clinical reasons such as a spine x-ray, an ECHO (heart ultrasound) or blood tests to look at bone health, this information will be collected however the participant will NOT be asked to do these tests for the purpose of the study. Some of the information about hospital admissions and antibiotic use may be collected from the participant's medical file.

There are no costs to the participant to participate in the study, nor will you or the participant be paid. If you and/or the participant are given assistance to attend the Neuromuscular Clinic, this will continue to occur. If assistance with transport to a sleep study is required, this can be arranged.

This research has been approved by and will be monitored by the Child and Adolescent Health Service Ethics and Research Governance Committee.

The participant will be required to attend the Neuromuscular Clinic on 4 occasions during the 12 month period, and may be required to have 2 sleep studies in the 12 month period. Participation is voluntary and the participant can choose to withdraw from the study at any time. If the participant chooses to withdraw, no reason needs to be given.

Access to the participant's medical records at Perth Children's Hospital, previous test results and sleep studies will be required. This information will be accessed only by Dr Withers. None of the information will be recorded with video or audio taping except that which is normally recorded during a sleep study.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

4 What does the participant have to do?

To participate in this study, the participant and the main carer need to attend the Neuromuscular Clinic and have lung function tests done at the clinic. Some extra information will be collected by questionnaire. We will try to avoid extra attendances at the clinic apart from two sleep studies which may be required if the participant is not using NIV. We may arrange another time for your child to come back if they become tired during the testing.

There are no lifestyle, dietary or other restrictions for participants. Participants should continue to take their usual medications and there are no restrictions on using any medications. The participant can still donate blood.

There are no restrictions on participating in this study, however you and the participant are free to withdraw from the study at any time for any reason.

5 Other relevant information about the research project

We expect approximately 60-75 participants to be enrolled in this study via Perth Children's Hospital. This is small initial study and in the future it is likely this study will be expanded to include any more participants – this may include other sites within Australia and also sites in other countries such as the USA. This study involves a number of researchers from Perth Children's Hospital and Telethon Kids Institute, and involves the staff from the Department of Respiratory and Sleep Medicine and the Department of Neurology at Perth Children's Hospital.

All participants will be enrolled into the same study pathway. There is no control group.

6 Does the child have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for the child to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw them from the project at any stage.

If you do decide that the child can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether the child can or cannot take part, or take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them or relationship with Perth Children's Hospital.

7 What are the alternatives to participation?

The child does not have to take part in this research project to receive treatment at this hospital. If the participant does not enrol in the study, this does not affect the treatment they will receive. All children with neuromuscular disorders will continue to receive the same standard of medical care at the Neuromuscular Clinic regardless of whether or not they participate in this study.

8 What are the possible benefits of taking part?

Although your child may not directly benefit from participation in this study, we hope the findings will benefit other children with neuromuscular disorders.

9 What are the possible risks and disadvantages of taking part?

This research does not involve interventional treatment, so it is unlikely that side effects caused by participation in this study would occur. Participants would not be given extra or different medications as a direct result of this study, however they will continue to have standard clinical care.

If hypoventilation is identified on the initial sleep study (if required), the participant may start using NIV. This would only be in discussion with the carer and the participant if it was felt that NIV would benefit the participant. Use of NIV may cause side effects. The participant may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If they have any of these side effects, or are worried about them, talk with the study doctor. The study doctor will also be looking out for side effects of NIV.

There may be side effects of NIV that the researchers do not expect or do not know about and that may be serious. Tell the study doctor immediately about any new or unusual symptoms.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, the doctor may need to stop the treatment. The doctor should discuss the best way of managing any side effects with you.

Most people who use NIV have no side effects and tolerate it without any problems.

Occasionally people find NIV uncomfortable or don't like the way the mask feels on their face. This can often be solved by using a different mask or adjusting the NIV machine. If the participant has any problems with using NIV they should alert the study doctor so that this could be addressed. A participant will never be forced to use NIV if they find it too uncomfortable.

Sometimes using NIV can cause the nose to feel dry in the mornings. This is often easily treated with using a humidifier with the NIV (which would be supplied at no cost) or nose sprays. Rarely, the nose can become dry and bleed, which can be treated with moisturisers. Sometimes NIV would need to be stopped for a few days to let the nose recover – this would not affect the lung function. If the participant has any problems with a dry nose they should alert the study doctor so this can be addressed.

Some people find NIV causes red marks on their face in the mornings, especially if used for long periods overnight. In most cases the red marks cause no discomfort and fade within 1-2 hours after waking up. This is usually easily treated by inserting small cushions in the NIV mask or adjusting the head straps. If the red marks do not improve, long term use of NIV can cause ulcers or pressure sores to develop on the forehead, nose or cheeks. This is uncommon and can nearly always be prevented by using cushions in the mask, adjusting the head straps or using more than one mask on different nights. If the participant experiences any problems with redness or ulcers please notify the study doctor so that this can be addressed.

When NIV is used for long periods of time (several years or more) in young children, this can rarely put pressure on the bones of the face and teeth, which may cause the shape of the face bones to change. This can also affect their teeth. This is a rare problem that is mostly seen in children who start using NIV from a very young age (less than 5) and use NIV for more than 16 hours per day. The risks of this occurring must be balanced with the risk of not using NIV and having hypoventilation progress – this can eventually lead to lung failure and death. This is why there is always a discussion of the risks and benefits of using NIV before treatment starts. IF THE PARTICIPANT starts using NIV as a result of a sleep study performed in this research study, there will be a detailed discussion of the risks and benefits of using NIV with the carer and the participant before any NIV is started. When NIV is started there is careful monitoring of the growth and shape of the skeleton of the face, and the NIV user may be referred to the Craniofacial Clinic at Perth Children's Hospital and/or The Dental Department to allow closer monitoring to avoid this problem.

It is possible that participation in this study may uncover a medical problem (hypoventilation) of which the participant was unaware. If this were the case, steps would be taken as described above to support, explain and treat the hypoventilation. Diagnosis of hypoventilation should not affect future insurance.

Treatment with NIV and/or any side effects of NIV will be at no cost to the participant and will be provided by Dr Withers via the Department of Respiratory and Sleep Medicine at Perth Children's Hospital.

If the participant becomes pregnant during the research project, you should advise her study doctor immediately. The study doctor may withdraw her from the research project and advise on further medical attention should this be necessary.

If the participant and/or carer becomes upset or distressed as a result of participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to the participant's test samples?

Participants will NOT have blood or tissue samples taken for the purposes of this study. If blood samples are taken for a clinical reason (such as bone health) the results may be collected for this study. In this case, the samples will be collected and stored for a period of time by the PathWest Pathology Lab at Perth Children's Hospital, and disposed of by the PathWest standard procedures.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the study doctor will tell you about it and discuss with you whether you want the participant to continue in the research project. If you decide to withdraw the participant, the study doctor will make arrangements for their regular health care to continue. If you decide the participant is to continue in the research project, you will be asked to sign an updated consent form.

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

12 Can the participant have other treatments during this research project?

Whilst the participant is taking part in this research project, they should continue to take all of the medications or treatments they have been taking for their condition or for other reasons. It is important to tell the study doctor and the study staff about any treatments or medications the participant may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the study doctor about any changes to these during participation in the research project.

13 What if the participant is withdrawn from this research project?

If you decide to withdraw the participant from this research project, please notify a member of the research team before withdrawal.

If you do withdraw consent during the research project, the study doctor and relevant study staff will not collect additional personal information from the participant, 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 the participant withdraws will form part of the research project results. If you do not want them to do this, you must tell them before the participant joins the research project.

14 Could this research project be stopped unexpectedly?

It is unlikely that the research project would be stopped unexpectedly, however if new information became available during the study period regarding identification or treatment for hypoventilation, it is possible that the project would be stopped. The study doctor would contact you in this case and explain the reasons for stopping the study.

15 What happens when the research project ends?

At the end of the study, the participant would continue to attend the Neuromuscular Clinic as they did prior to the study.

A report outlining the results and findings of the study will be provided to participants. We anticipate this would be in the form of an information evening/seminar and all participants and carers would be invited to attend.

It is likely that results of this study will be published in medical journals in the future.

Part 2 How is the research project being conducted?

16 What will happen to information about the participant?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about the participant for the research project. Any information obtained in connection with this research project that can identify the participant will remain confidential.

Data collected will be de-identified with each participant assigned a code number. Participants will have their unique medical record unit number attached to their data, so will be re-identifiable. The database will be kept on the study doctor's computer which is stored in a locked office with swipe access. The computer is accessed by a password lock. The participant's information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Any written questionnaires will be kept in a locked box in a locked office with swipe card access. The data will be stored for a minimum of 15 years as per the NHMRC Guidelines.

If data is transferred to a database for future use (such as the Treat NMD National Database this will ONLY OCCUR WITH YOUR PERMISSION AND CONSENT.

Information about the participant may be obtained from their health records held at this and other health services, for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, except with your permission. Confidentiality will be maintained by removing all identifiers and using the participant's code number for data presentation.

In accordance with relevant Australian and/or Western Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about the participant. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access the participant's information.

Any information obtained for the purpose of this research project that can identify the participant will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

If the participant suffers any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If the participant 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.

If there are any complaints from participants and/or carers in regards to the staff involved in this study and data collection, please inform the study doctor or one of the other doctors listed for this study.

If required, the Medicines Australia compensation guidelines will be made available to you.

18 Who is organising and funding the research?

This research project is being conducted by Dr Adelaide Withers, Dr Andrew Wilson, Professor Graham Hall and Dr Peter Rowe. Dr Adelaide Withers is the primary investigator/study doctor. This research project is being partially funded by Muscular Dystrophy Association of Western Australia (MDAWA) and the Duchenne Parent Project Netherlands (DPP NL).

The Curtin University may benefit financially from this research project if, for example, the project assists The University to obtain approval for a new treatment.

Neither you nor the participant will benefit financially from involvement in this research project even if, for example, the knowledge acquired from this study prove to be of commercial value to Curtin University.

No member of the research team will receive a personal financial benefit from the participant's involvement in this research project (other than their ordinary wages).

There are no conflicts of interest to declare.

19 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 Children and Adolescent Health Services.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 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 the participant has any medical problems which may be related to involvement in the project (for example, any side effects), you can contact the principal study doctor via Perth Children's Hospital switchboard on 9340 8222 or any of the following people:

Clinical contact person

Name	Dr Adelaide Withers
Position	Chief Investigator/Study Doctor
Telephone	Perth Children's Hospital switchboard on 6456 2222
Email	Adelaide.Withers@health.wa.gov.au

For matters relating to research at the site at which the participant is taking part, the details of the local site complaints person are:

Complaints contact person

Name	The Director of Medical Services
Position	Director, Medical Services , Perth Children's Hospital
Telephone	Perth Children's Hospital Switchboard on 6456 2222
Email	

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	Princess Margaret Children's Hospital Governance and Ethics
HREC Executive Officer	Dr Mark Salmon
Telephone	Perth Children's Hospital switchboard on 6456 2222
Email	Mark.Salmon@health.wa.gov.au

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

Name	Princess Margaret Children's Hospital Governance and Ethics
Position	Dr Mark Salmon
Telephone	Perth Children's Hospital switchboard on 6456 2222
Email	Mark.Salmon@health.wa.gov.au

Consent Form – Parent/Guardian, Participant (if able)

Title	**Developing Clinical Predictors of Disease Progression in Children with Neuromuscular Disorders to Prevent Future Respiratory Failure**
Short Title	**Clinical Predictors of Respiratory Failure in Paediatric Neuromuscular Disorders**
Protocol Number	**2015185**
Project Sponsor	**Princess Margaret Children's Hospital**
Coordinating Principal Investigator/ Principal Investigator	**Dr Andrew Wilson** **Dr Adelaide Withers, Prof Graham Hall, Dr Peter Rowe**
Associate Investigators	
Location	**Perth Children's Hospital**

Declaration by Parent/Guardian

I have read the Participant Information Sheet 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 have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to the child participating in this research project as described and understand that I am free to withdraw them at any time during the project without affecting their future health care.

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

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

Name of Child (please print) _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

Signature of Participant (if able) _____ Date _____

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 parent/guardian of the participant has understood that explanation.

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

Signature _____ Date _____

† A senior member of the research team 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

Title	**Developing Clinical Predictors of Disease Progression in Children with Neuromuscular Disorders to Prevent Future Respiratory Failure**
Short Title	**Clinical Predictors of Respiratory Failure in Paediatric Neuromuscular Disorders**
Protocol Number	**2015185**
Project Sponsor	**Princess Margaret Children's Hospital**
Coordinating Principal Investigator/	**Dr Andrew Wilson**
Principal Investigator	**Dr Adelaide Withers, Prof Graham Hall, Dr Peter Rowe**
Associate Investigators	
Location	**Perth Children's Hospital**

Declaration by Parent/Guardian

I wish to withdraw the child from participation in the above research project and understand that such withdrawal will not affect their routine treatment, relationship with those treating them or relationship with Perth Children's Hospital.

Name of Child (please print) _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

If consent for withdrawn is given verbally, please indicate here:

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 parent/guardian of the participant has understood that explanation.

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

Signature _____ Date _____

† A senior member of the research team 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.