

**MAGnesium NEbuliser Trial In Children (MAGNETIC) - A randomised, placebo controlled study of nebulised magnesium in acute severe asthma in children**

**ISRCTN81456894**

**A study to determine the usefulness of nebulised magnesium sulphate in the management of acute severe asthma in children**

You are being asked for your permission for your child to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or you would like more information on. Thank you for reading this.

**What is the purpose of this study?**

Children with bad asthma usually receive salbutamol (ventolin) mixed with ipratropium bromide (atrovent), commonly used drugs for treating asthma attacks, through a nebuliser when they come into hospital suffering from a severe asthma attack. We wish to investigate whether adding magnesium sulphate to nebulised salbutamol (ventolin) and ipratropium (atrovent) is helpful in children. We know that using magnesium can be beneficial in adults by helping to relax muscle in the airways, which tightens during an asthma attack. This treatment is sometimes given to adults directly into the bloodstream (intravenously), but we would like to see if magnesium is useful when delivered through a nebuliser mixed with salbutamol and ipratropium. This is because using a nebuliser is less invasive than using a needle and because the medication is inhaled direct to the airways where it is useful. Studies have been done in adults and it has been shown that mixing magnesium sulphate and salbutamol and using them in a nebuliser is safe.

**Why has your child been chosen?**

Your child has been asked to take part because they are having a severe asthma attack. We will be recruiting approximately 500 children from approximately 20-25 hospitals in the UK.

### **Does your child have to take part?**

No, taking part is completely voluntary. It is up to you and your child (if they can) to decide whether to take part. If you decide to take part you and your child are still free to withdraw at any time without giving a reason. This will not affect the standard of care your child receives.

### **What will happen if my child takes part?**

Your child will receive nebulised salbutamol and ipratropium as usual. However instead of mixing the salbutamol and ipratropium with normal saline, in this study it **may** be mixed with magnesium sulphate. This study is randomised, which means that whether your child receives nebulised magnesium or not is decided by chance, just like tossing a coin. It is also double blind, which means that neither you nor the doctors and nurses looking after your child will know whether your child has received the nebulised magnesium or not. However, the doctors will be able to find out which treatment they are receiving if they need to.

Your child will have three nebuliser treatments, each around twenty minutes apart. Between each treatment, a doctor or nurse will perform a quick exam to see if their symptoms have improved. We plan to give all three nebulisers even if their symptoms get better or worse (as long as the doctor thinks it is safe). This is so we can compare them with other children in the study. After the final nebuliser and assessment, we will continue to monitor your child for a further 3 hours to see what further treatment, if any, they go on to receive (as long as they remain in the hospital). In the event your child is admitted, we would also like to know how long they spend in hospital and what treatment they have

We will contact you 4 weeks after your child leaves hospital to check how they are doing, and so assess if attending hospital has affected you or your child's daily life. To do this, we would like to send you some questionnaires to fill in through the post. We would like your consent for us to pass on your contact details (address and telephone number) to the Medicines for Children Research Network Clinical Trials Unit (Institute of Child Health, University of Liverpool, Royal Liverpool Children's Hospital, Eaton Road, Liverpool, L12 2AP, <http://www.liv.ac.uk/mcrn/clinical.htm>). They are co-ordinating the study and will organise to send you the questionnaires.

### **What are the side effects of taking part?**

A pilot study has been performed using inhaled magnesium in children and it was found to be safe. We know that when given intravenously (directly into the blood), magnesium occasionally causes facial flushing (a reddening of the skin which can make you feel warm), and small drops in blood pressure. This is because it widens some of the small blood vessels near the surface of the skin, which also allows heat to escape. We do not expect this to be a problem in this study because the magnesium will be delivered directly to the airways by the nebuliser, and not all around the body.

### **What are the possible disadvantages and risks of taking part?**

We do not think there are any disadvantages or risks in taking part. Your child will receive the same standard of care regardless of their participation, and doctors and nurses will follow the same guidelines as they do for all children with severe asthma attacks.

### **What are the possible benefits of taking part?**

If we are able to prove that adding magnesium sulphate will lead to quicker and better relief of asthma symptoms, this may lead to new ways of treating children with bad asthma attacks in the future.

### **What if something goes wrong?**

If you have a concern about any aspect of this study, you should speak to <<PI name>>, who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure. Details can be obtained from the hospital.

In the event that something goes wrong and your child is harmed during the research study there are no special compensation arrangements. If your child is harmed and this is due to someone's negligence then you may have grounds for legal action against <<NHS Trust>>, but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

### **Will my child's participation in this study be kept confidential?**

All information which is collected about your child during the course of the study is considered confidential and giving the information to anyone else (called third parties) is not allowed. However, as we mentioned earlier, we would like to have your permission to forward your contact details (address and telephone number) to the Medicines for Children Research Network Clinical Trials Unit (MCRN CTU). The MCRN CTU is co-ordinating the study and will be responsible for sending out the follow-up questionnaires approximately 1 month after your visit to hospital; they will also receive a copy of your signed consent/assent forms. The MCRN CTU, based in the University of Liverpool, is a registered data controller with the Information Commissioners Office and will ensure that you and your child's confidentiality is preserved.

We would also like your permission to use some information collected about your child on admission. This will include details of their current asthma medication, and assessments about the severity of their attack that will be kept in their medical notes. We have to collect this information to check that your child is suitable for the study, and because we do not want to delay treatment by doing repeat examinations.

### **What happens with the results of the research study?**

Once the research is completed we would aim to present the findings to national and international asthma meetings, and to publish it in medical journals.

**Who is organising and funding the research?**

The research is being organised through and co-ordinated by the Medicines for Children Research Network Clinical Trials Unit. It is sponsored by Cardiff University and funded by the NHS Health Technology Assessment (HTA) programme.

**Who has reviewed the study?**

The study has been reviewed by and received a favourable opinion from the North West Multi-Centre Research Ethics Committee.

**Contact for information**

If you have any queries about the above, please contact <<contact details>>. For further information or independent advice on taking part in research projects, you can contact <<contact details>>

**THANK YOU FOR READING THIS INFORMATION SHEET.**

**WE HOPE YOU FOUND IT USEFUL.**

**MAGnesium NEbuliser Trial In Children (MAGNETIC) - A randomised, placebo controlled study  
of nebulised magnesium in acute severe asthma in children.**

**ISRCTN81456894**

*Please  
initial*

1.	I confirm that I have read and understand the information sheet dated 18/01/2008 (version 2.0) for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, and without my care/my child's care or legal rights being affected.	
3.	I understand and accept that information collected on admission will be used to assess my child's eligibility and that this information will form part of the data collection for the study.	
4.	I understand that relevant sections of any of my child's medical notes and data collected during the study may be looked at by the clinical trial staff from the Medicines for Children Research Network Clinical Trials Unit, responsible individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my child's records.	
5.	I agree to my child's GP being informed of my child's participation in this study.	
6.	I agree for a copy of this form to be sent to the MCRN CTU	
7.	I agree to release my contact information (address and telephone number) so that the MCRN CTU can organise the 4 week follow-up.	
8.	I agree to take part in the above study.	

\_\_\_\_\_  
Name of Patient

\_\_\_\_\_  
Name of Parent

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

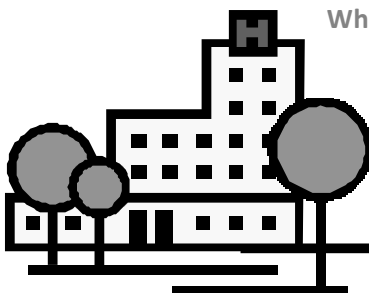
*When completed, 1 MCRN CTU; 1 for researcher site file; 1 for patient, 1(original) to be kept in medical notes*

**MAGnesium NEbuliser Trial In Children (MAGNETIC) - A randomised, placebo controlled study of nebulised magnesium in acute severe asthma in children.**

ISRCTN81456894

**Information Sheet for a Young Person with a Bad Asthma Attack**

This information sheet is intended to be shown/read to the child by their parent/guardian.



**What is happening to me?**

You have been brought to the hospital because you have been having trouble breathing. While you are here we are asking if you would like to take part in a test called a 'study'.

We would like to tell you about this.

Your mummy and daddy talked to the doctors and nurses and said it was OK for you to take part in the study.

The doctor will be giving you medicine to help you get better, but as part of the study, we would like to give you an extra medicine, if that is OK with you. By taking part, you will help us find out how good the extra medicine is



**How will the doctors and nurses give the medicine to me?**

The medicine will be given as a mist through a mouthpiece or mask. All you have to do is try and breathe as normally as you can. We will add the extra medicine at the same time.



### What will the medicine do to me?

We hope that the medicine might help you to get better more quickly. Other people have had the medicine and were OK.



### Who is looking after me?

The doctors and nurses will look after you while you are being given the medicine.

### What will the doctor and nurses do?

The doctors and nurses will be checking that you are OK by listening to your chest and heart to see how hard it is for you to breathe.

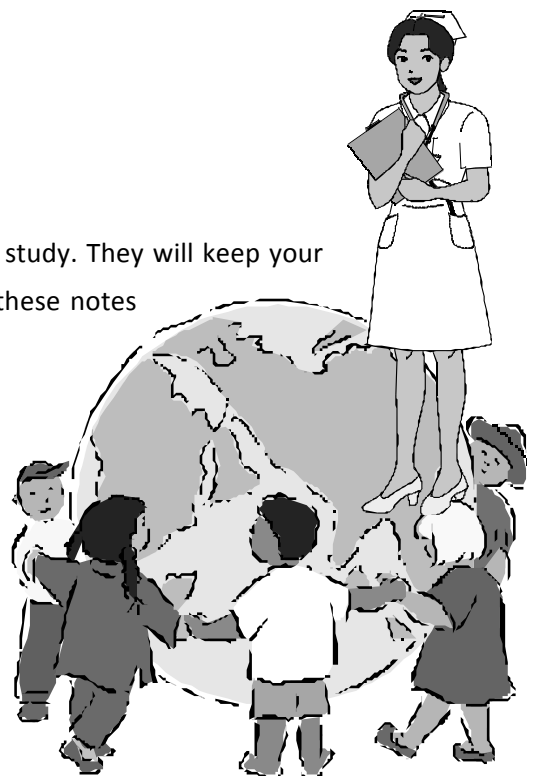


### How long will the study go on for?

We would like to give you the medicine 3 times. This will take an hour. You will need to stay in hospital until the doctors think you are well enough to go home.

### What else will happen in the study?

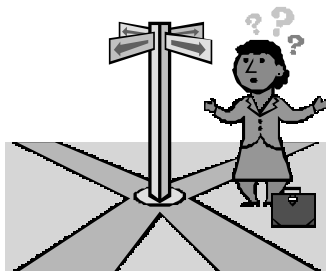
The doctors and nurses will write down notes about you for the study. They will keep your name secret so that only people at the hospital will know that these notes are about you.



### Why is the study being done?

We hope that the study will help children who have the same problems as you.

### Do I have to do the study?



No – not all. It's up to you. Just say if you don't want to carry on. Nobody will mind, and you will still be looked after.

If you do, you will need to write your name (if you can) on the form that comes with these sheets.

Thank you for taking the time to read this information sheet to your child. Please ask questions if you need to, or ask your child if they would like to ask any questions.



**MAGnesium Nebuliser Trial In Children (MAGNETIC) - A randomised, placebo controlled study of nebulised magnesium in acute severe asthma in children**

**ISRCTN81456894**

Child (or if unable, parent on their behalf)/young person to circle all they agree with:

Have you read information (or had it read to you) about this project? **Yes / No**

Has somebody else explained this project to you? **Yes / No**

Do you understand what the project is about? **Yes / No**

Have you asked all the questions you want? **Yes / No**

Have you had your questions answered in a way you understand? **Yes / No**

Do you understand it's OK to stop taking part at any time? **Yes / No**

Are you happy to take part? **Yes / No**

If any answers are 'no' or you **don't** want to take part, do not write your name

If you **do** want to take part, please write your name and today's date below. Your parent or guardian must also write their name here to if they are happy for you to do the project. The doctor or nurse who explained this project needs to sign as well. Thank you.

\_\_\_\_\_  
Your Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent's Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

*When completed, 1 copy for MCRN CTU; 1 for researcher site file; 1 for patient, 1 (original) to be kept in medical notes.*

**MAGnesium NEbuliser Trial In Children (MAGNETIC) - A randomised, placebo controlled study of nebulised magnesium in acute severe asthma in children.**

**ISRCTN81456894**

**Information Sheet for a Young Person with a Bad Asthma Attack**

We thank your Mum or Dad for helping you to read this information

**What is a study? Why is this study being done?**

A research study is what you do when you want to learn about something or find out something new. It can help doctors and nurses and other people in the hospital find out which medicines can help children get better. This study is to see if a medicine called magnesium sulphate helps you get better more quickly than if you had a placebo medicine. A placebo medicine is a dummy liquid and will look the same as the magnesium, but contains no medicine.



**Why have I been asked to take part?**

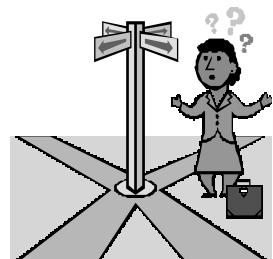
You have been asked because you are having a bad asthma attack.

**Did anyone else check the study is OK to do?**

Before any study is allowed to happen, it has to be checked by a group of people called an Ethics Committee. The Ethics committee is a group of experts and ordinary people who look at studies very carefully to decide whether they are OK to do. The North West Multi-Centre Research Ethics Committee have looked at this study and decided it is OK.

**Do I have to take part?**

No- not at all, it's up to you. Just say if you don't want to take part; nobody will mind. If you do take part, you will need to write your name on an 'assent form'. This form is to say that you understand the study and what will happen if you take part. You will be given your own copy of the form to keep, as well as this information sheet.

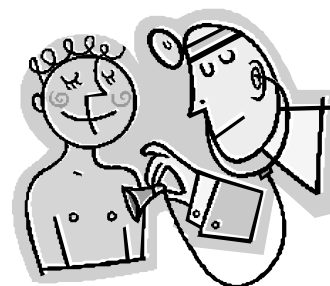


### What will I need to do and how long will it take?



Half of the children in the study will be given magnesium sulphate and the other half will be given the placebo medicine. You will not be able to choose which one you get, or be told which one you are taking. Your doctor and nurse will not be told which one you are taking, but they can find out if they need to.

We would like to add the magnesium sulphate or placebo to medicines we use you to help you get better. To do this we mix them together in a machine called a nebuliser, which turns medicines into a mist that you can breathe in through a face mask or mouthpiece. We plan to give you the medicine three times, and each time the nebuliser will last for 10-15 minutes. A doctor or a nurse will check soon after each nebuliser to see if you have gotten any better, any worse, or stayed the same.



After we have finished giving the medicine, we will want to keep an eye on you for another few hours and a doctor or nurse will keep checking to see if you are OK.

We would like to ask your parents some more questions about a month after you have left the hospital. To do this we will send them some forms to fill in; we have one for you to fill in as well, and your parents can help you do this.

### Will the medicine upset me?

Sometimes medicines upset our body and if this happens we call them side-effects. Magnesium sulphate has been given to lots of adults and children before for different reasons and has been found to be very safe. In some people having more magnesium in their body make them feel a bit warmer than normal and might make their face go a little red. We don't think this will be a problem in the project and the doctors and nurses know it might happen.



### Will joining the study help me?

We cannot promise that, but if the medicine helps you get better more quickly we will be able to tell people who will be able to help other children.

### Is there another sort of treatment I can have instead?

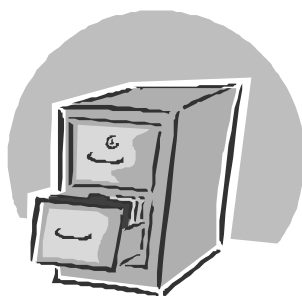
As well as having magnesium sulphate or placebo, you will also be getting other medicines called Salbutamol and Ipratropium Bromide in the nebuliser. These are



the medicines that most children will have for a bad asthma attack, and if you do not have our medicine you will still be able to have these.

### Who will know that I am in the study?

The doctors and nurses who normally take care of you will know. So will the study nurse and pharmacist.



### How will the information about me be kept private?

Everything you tell us is private. The only time we would ever tell somebody what you have said is if something made us worry about you. All information collected for this study will be kept safely on computers or paper records. Of course, you can tell your family and friends about the study if you want to.

We cannot promise that the project will help you, but the information we collect might help treat other young people who have problems with asthma. We hope to write about this project in special reports to let other people know what we found out.

### What happens if there is a problem with the study?

If you think there are any problems with the study or if you have any worries about it you can tell your parents. You can also tell the study nurse and they will do their best to answer your questions. If you are still worried, your parents will probably be the best people to talk to.



### What if I don't want to do the study anymore?

If you would like to stop at any time, just tell your parents, doctor or nurse. They will not be cross with you and will not change the way you are looked after. Your doctor will choose which treatment is best to use instead.

### What will happen to the results of the study?

We will write reports for the doctors and nurses who see children with asthma problems. The results will be written in special magazines (scientific journals).



### What shall I do now?

Now you have read about the study you need to think about whether you want to join in or not.

### Who can I contact for more information?

If you have any questions at all, at any time, please contact <<contact details>>

**Thank you for reading; we hope the information was useful**

**MAGnesium Nebuliser Trial In Children (MAGNETIC) - A randomised, placebo controlled study of nebulised magnesium in acute severe asthma in children**

**ISRCTN81456894**

Child (or if unable, parent on their behalf)/young person to circle all they agree with:

- Have you read information (or had it read to you) about this project? **Yes / No**
- Has somebody else explained this project to you? **Yes / No**
- Do you understand what the project is about? **Yes / No**
- Have you asked all the questions you want? **Yes / No**
- Have you had your questions answered in a way you understand? **Yes / No**
- Do you understand it's OK to stop taking part at any time? **Yes / No**
- Are you happy to take part? **Yes / No**

If any answers are 'no' or you **don't** want to take part, do not write your name

If you **do** want to take part, please write your name and today's date below. Your parent or guardian must also write their name here to if they are happy for you to do the project. The doctor or nurse who explained this project needs to sign as well. Thank you.

\_\_\_\_\_  
Your Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent's Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

*When completed, 1 copy for MCRN CTU; 1 for researcher site file; 1 for patient, 1 (original) to be kept in medical notes.*

**MAGnesium NEbuliser Trial In Children (MAGNETIC) - A randomised, placebo controlled study of nebulised magnesium in acute severe asthma in children.**

**ISRCTN81456894**

**Information Sheet for a Young Person with a Bad Asthma Attack**



We are inviting you to take part in some research. Before you decide if you want to join it's important to understand why the research is being done and what it will mean for you. Please read this leaflet carefully and if you can, talk it over with your family, or the doctor or nurse.

Please ask us if there is anything that is not clear or if you would like more information.

Thank you for reading this.

**Why are we doing this research?**

Children and young people with bad asthma attacks are treated with a medicine called salbutamol (ventolin) mixed with ipratropium bromide (atrovent) through a nebuliser, which helps them to breathe more easily. The nebuliser is explained in more detail later.



Adding another medicine called magnesium sulphate to the salbutamol nebuliser may also help. We would like to know whether adding magnesium sulphate to the nebuliser is better than a placebo medicine. A placebo is a medicine that looks like the active medicine (in this case magnesium sulphate) but doesn't actually contain any medicine.

**What is the medicine being tested?**

The medicine we are testing is called magnesium sulphate. Magnesium is normally found in your body and is helpful in a number of ways. One of the ways is that it can help to relax muscle. We would like to see if the magnesium will help to relax the muscle in your airways that tightens up during an asthma attack.

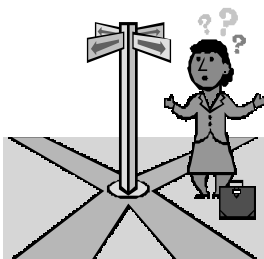
The magnesium sulphate used in this project has been especially made. Half the children will be given the magnesium and half will be given the placebo medicine. You will not be able to choose which medicine you take and will not know which medicine you are taking. Your doctor and nurse will not know which medicine you are given, but they can find out if they need to.

We would like your help with this study. You will receive nebulised salbutamol and ipratropium as usual. However instead of mixing the salbutamol and ipratropium with normal saline (salt water), in this study it may be mixed with magnesium sulphate.

### Why have I been asked to take part?

You have been chosen because you are having a bad asthma attack. This project will involve around 500 children in the UK.

### Do I have to take part?



No- not at all. We only want people to take part if they would like to. If you decide not to, don't worry, it won't change how you are looked after. If you decide to take part and then change your mind, that's OK as well- you can stop at any time and don't have to say why if you don't want to.

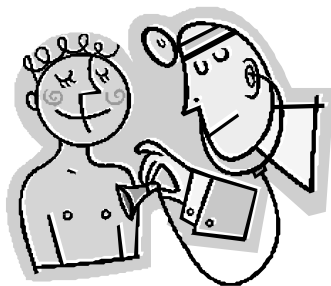
If you agree, we will ask you to write your name on a form called an 'assent form'. This is to say you understand the project and what will happen. You will be given your own copy to keep as well.

### What will happen to me if I take part?

If you take part, the magnesium sulphate or placebo medicine will be added to the nebuliser, along with the other medicines we mentioned earlier. The nebuliser is a machine that turns the medicines into a mist that you can breathe through a mask or mouthpiece. After about 20 minutes, a doctor or nurse will do a quick exam of your chest to see if you have gotten any better. You will then receive the nebuliser twice more in the same way. After the final nebuliser we will keep checking on you to see if you get better.



You may keep getting other nebulisers or medicines, but these will not have the extra medicine from this project.



### What will I be asked to do?

Taking part in the study is very simple. Nearly all children who come to hospital with a bad asthma attack will have medicine through a nebuliser. The only difference is that for this project, the nebuliser will have magnesium sulphate or the placebo medicine in as well. Each nebuliser will last for around 10-15 minutes.

### What other treatment could I have instead?

All children who come to hospital with a bad asthma attack are treated depending on their age and how bad the attack is. If you do not take part in the study, you will get the same treatment as anyone else.

### What are the side-effects of the medicines and might I have some if I take part in the research?

Other projects have shown us that magnesium sulphate is safe to have through a nebuliser. We know that when some people have extra magnesium in their body, their face may go a little bit red and feel warm. We don't expect this to be a problem for most children in this project, but if it does happen, you don't need to worry- the effect will wear off quickly.



### Is there anything else to be worried about if I take part?

We don't think so. We would like you to have all three nebulisers of the project medicine even if you get a little better or a little worse. If you do not feel better after the nebulisers, you might need to have some different medicine. The doctor and nurses will decide if you need this and take good care of you.

### How will the information about me be kept private?

If you decide to take part in the project, you will be given a number that tells us who you are. We will not need to use your name, and so no-one will know the information is about you. We would like to give your name to people who are helping to run the project as they will want to ask your parents some more questions, if that is OK. They would also like to send you a questionnaire about your asthma to fill in.



### What are the possible benefits of taking part?

We cannot promise that the project will help you, but the information we collect might help treat other young people who have problems with asthma. We hope to write about this project in special reports to let other people know what we found out.



If you ask any questions at all, please ask <<contact details>>

**Thank you for reading; we hope the information was useful**



**MAGnesium Nebuliser Trial In Children (MAGNETIC) - A randomised, placebo controlled study of nebulised magnesium in acute severe asthma in children**

**ISRCTN81456894**

Child (or if unable, parent on their behalf)/young person to circle all they agree with:

- Have you read information (or had it read to you) about this project? **Yes / No**
- Has somebody else explained this project to you? **Yes / No**
- Do you understand what the project is about? **Yes / No**
- Have you asked all the questions you want? **Yes / No**
- Have you had your questions answered in a way you understand? **Yes / No**
- Do you understand it's OK to stop taking part at any time? **Yes / No**
- Are you happy to take part? **Yes / No**

If any answers are 'no' or you **don't** want to take part, do not write your name

If you **do** want to take part, please write your name and today's date below. Your parent or guardian must also write their name here to if they are happy for you to do the project. The doctor or nurse who explained this project needs to sign as well. Thank you.

\_\_\_\_\_  
Your Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent's Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

*When completed, 1 copy for MCRN CTU; 1 for researcher site file; 1 for patient, 1 (original) to be kept in medical notes*