**Patient INFORMATION SHEET AND ASSENT FORM**

**(For patients 6-12 years old)**

|  |  |
| --- | --- |
| Study title: | **(Creative Acronym)** |
| Sponsor: |  |
| Locality: | Auckland District Health BoardStarship Child Health | Ethics committee ref.: | XXX |
| Chief investigator: |  | Contact phone number: | XXX |

**![C:\Users\mmuldowney\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\JIG21LMM\smiling_doctor[1].jpg]()Invitation Paragraph**

We would like you to help us with our research study. Please read the information carefully and talk to your mum, dad or carer about the study. Ask us if there is anything that is not clear or if you want to know more. Take time to decide if you want to take part. It is up to you if you want to do this.

**Why are we doing his study?**

We would like to find out if a new medicine can help you and other children with (named condition). Because it is a new medicine, we do not know yet if it works (or other protocol design description)

##### Do you have to be in this study?

You don’t have to take part if you don't want to. You and your mum and dad or your carer, and whānau should talk about it. If together you decide not to take part, that’s OK.

(Optional)

But your parents/carer, and your doctor may think it’s important that you do take part. That’s because they think it might help you or your family in the future.

If there are things you are worried about, talk to your parents/carer and doctor. Tell them how you feel.

After you talk to them, your parents/carer will decide if you should join or not.

##### What will happen to you if you take part in the study?

##### The first time we meet, we will measure how tall and heavy you are. The doctor will check your heart and lungs. We will then (describe other screening procedures).

##### If it is okay for you to be part of the study, you will need to visit the doctor (describe the visit schedule). Each time you visit, the doctor or research nurse will ask you and your parents questions about your health.

##### (Optional RCT otherwise describe what will happen)

##### During the study, you will receive the new medicine, or a pretend medicine. The medicine is given into a blood vessel and will take about 1 hour. The doctors and nurses will check on you while you are receiving the medicine, they will also give you some games to play or DVDs to watch and a play specialst from Starship will visit you to see what other things you may like to do, or to talk about the treatment.

(Description of other intervention/s for drug delivery or bloods)

Your doctor may think it will be easier for you receive the medicine through a small device called a “port”. Ports are plastic tubes put under your skin into your chest, that gets put there during a small operation. You would be given medicine to go to sleep for the operation.

During the study we would like to do a blood test from your arm. If you are afraid of needles, we can give you some cream to numb your skin. You will also need to pee into a little cup, to check your urine.

You will still take the medicine you already have, even though you are having the new study drug for this study.

##### Could the new medicine make me feel sick?

When you take the new medicine, the medicine may make you feel sick. This does not always happen, but does happen sometimes. It is very important to tell your parent(s) or the person taking care of you and your doctor if you feel sick or if something feels wrong.

The doctor may give you something that may make the sick feeling go away or may stop giving you the new medicine.

##### Will taking part help you?

You may or may not feel better while you are taking part in the study. Taking part in the study will give new information about the study drug. It may mean a better medicine can be made for you and other people with your condition in the future. We might also find out things that will help other families like yours.

* **Will anyone know if you take part in this study?**

Your family and your doctor will know you are taking part. Some people from the study team will also know you are taking part. But no-one else.

You can talk to anyone you want about the project. You can ask any questions you have. But we won’t tell anyone else you are taking part.

If you decide to help then you will be given a special number.

##### The other people looking at your information will only know the number and not your name.

##### Who will answer your questions about the study?

If you want to know more ask Mum or Dad or carer as they have some papers with more about it. Or you can ask the doctor lots of questions.

* **What if there is a problem or something goes wrong?**

Tell us if there is a problem and we ill try and sort it out straight away. You and your mum, dad or carer can either contact the nurse or doctor looking after you.

If you agree we will also tell your family doctor (GP) that you are doing the study.

Your medical notes may also be looked at by other people who work at the hospital to check that the study is being carried our correctly.

All information that is collected about you during the study will be kept strictly private. You will be given a number which will be used instead.

Any information about you that leaves the hospital will have your name and address taken off so that you cannot be recognised from it, except for letters to your family doctor (GP).



Thank you

#### Assent Form

**6 to 12 years olds**

|  |  |
| --- | --- |
| Study title (lay): |  |
| Locality: | Auckland District Health Board | Ethics committee ref.: | XXX |
| Lead investigator: |  | Contact phone number: | XXX |

**DO YOU WANT TO TAKE PART IN THIS STUDY?**

**PLEASE tick** (**🗹**) **or have your parent tick for you**, **your answers to the questions**

 **YES NO**

* Have you read (or been read to) about the study?

* Has somebody else explained the study to you?
* Do you understand what this study is about?
* Have you asked all the questions you want?
* Have you had your questions answered in a way you understand?
* Do you understand it’s OK to say you don’t want to join –

or that you want to stop taking part, but that your parent/s

(or whoever looks after you) will make the final choice?

* Are you hapy to take part?

If you want to take part write your name and today’s date here. If you don’t like writing, you could add an X to the lines below to show you want to take part of not. Someone else can write your name and the date for you.

I agree\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to take part in this study.

I do not agree\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_to take part in this study.

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

Your signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Today’s Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Statement of person conducting assent discussion:**

* I have explained all aspects of the study to the participant to the best of his or her ability to understand.
* I have answered all the questions from the participant relating to this research.
* The participant agrees to be in the research.
* To the best of my knowledge, the participant’s decision to enrol is voluntary.

The study doctor and study staff agree to respect the participant’s physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

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Printed name of the person obtaining assent

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Signature of the person obtaining assent Date