**SITE LETTERHEAD**

**Model Patient INFORMATION SHEET AND ASSENT FORM**

**(For patients 7-11 years old)**

|  |  |  |  |
| --- | --- | --- | --- |
| Study title (lay): |  | | |
| Locality: | **XXX** | Ethics committee ref.: | **XXX** |
| Lead investigator: | **XXX** | Contact phone number: | **XXX** |

This guide is intended to display an example of the level of information and the language used to communicate the information to participants who cannot consent but can assent to participation.

**Why am I being asked to be in the study?**

* You have (condition/disease).
* There is a study drug that may help to XXXX
* In this study, we will find out how well it works and if it is safe.

Your mum, dad, or the person taking care of you and your study doctor will tell you more about being in this study.

Your study doctor is Dr. <name>, and <his, her> phone number is <number>. You can call <him, her> any time you have any questions.

**How will I take the study drug?**

The (condition/disease) medicine (called XXX) will be given to you through a small needle into a vein in your arm.

**How often will I take the study drug?**

You will take the study drug as instructed by the study doctor.

**What will happen if I agree to take part in this study?**

* You will come to the doctor’s office for an injection of XXX and then you can take the study medicine home to use. You will then return to the clinic about every 12 weeks. Sometimes your doctor may want to see you more often.
* Your mum, dad, or the person taking care of you will come with you.
* The nurse or doctor will also call you and your mom, dad, or the person taking care of you every month during the study to see how you are feeling.
* Your parent will need to use an electronic patient diary. The doctor or nurse will show him/her how to use it.

At your visit to the doctor:

* You will answer some questions about the things you do every day, like playing and riding a bike, or school work.
* The doctor or nurse will check you, see how much you weigh, and measure how tall you are.
* The doctor will check your arms and legs and see how well you can move them and bend them.
* You will have blood tests with a small needle in your arm.

**Do I have to be in the study?**

NO: You can choose if you want to be in this study or not. Also, you can change your mind at any time even if you have started the study. Even if your mum, dad or person taking care of you says YES, you can still say NO. If you decide not to be in the study, no one will be angry with you. All you have to do is tell your mom, dad or person taking care of you or your doctor that you don’t want to be in the study any more. You will still be treated for your XXXX

**Can the study drug make me feel sick?**

Sometimes, there may be changes in the way you feel or in what the doctor may see when you visit him/her. We don’t know about all the changes that can happen. Side effects are unwanted things that can happen to your body after you have taken the drug.

You should tell your mum, dad or person taking care of you, or other grown-up (like a teacher or friend), and the doctor right away if any of these things happen. (examples)

* You feel sick or hurt anywhere
* You think you are having a bleed
* It is hard for you to breathe
* It is hard for you to swallow (your tongue gets in the way)
* Your face is puffy
* You have itching (like a bug bite) and/or rash
* Your head hurts or you can’t see well
* Your arms or legs are hard to move and tingle
* Your arms or legs are puffy

You may need to go to the hospital for help. More serious side effects can include allergic reactions. Also, your body may make something called inhibitors that may affect the way the study drug works in your body and may increase your risk of having an allergic reaction to the study drug.

When a blood test is done, it may hurt or bleed a little bit where your blood is taken, leaving a small “black and blue” mark (bruise) on your skin.

Talk with your mum, dad or person taking care of you or doctor about any changes you feel. They have more information and can answer your questions or will ask the doctor for you.

**Will being in this study help me?**

The study drug may or may not help you. You may not need to have injections as often to control your (condition/disease). We hope we might learn things that may help people who have the same sickness as you.

**What if there is a problem?**

If you are worried about anything to do with the study, please ask your doctor or nurse who will do their best to answer your questions

Name: [Emergency number 24 hours]

**Who do I contact for more information or if I have concerns?**

If you, mum or dad or the person taking care of you have any questions, concerns or complaints about the study at any stage, you can contact:

*Name, position*

*Telephone number*

*Email*

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050  
Fax: 0800 2 SUPPORT (0800 2787 7678)  
Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

For Maori Health support please contact :

*Name, position*

*Telephone number*

*Email*

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

**SITE LETTERHEAD**

**MODEL ASSENT FORM FOR YOUNG PEOPLE**

**Assent for patients aged 7-11 years old**

|  |  |  |  |
| --- | --- | --- | --- |
| Study title (lay): |  | | |
| Locality: | **XXX** | Ethics committee ref.: | **XXX** |
| Lead investigator: | **XXX** | Contact phone number: | **XXX** |

Participant's Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Birth: \_\_\_\_\_\_\_\_\_\_\_

(Full Name in BLOCK CAPITALS) (Month/Year)

**Please circle all you agree with:**

Have you read this form (or had it read to you)? Yes/No

Has the study doctor explained this study to you? Yes/No

Do you understand what this study is about? Yes/No

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

Are you happy to take part in this research study? Yes/No

If any answers are **“no”** or you **don’t** want to take part, **don’t** sign your name!

If you **do** want to take part in this study, please write your name and today’s date below.

You will be given a copy of this signed form.

|  |
| --- |
| Participant’s Full Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Participant’s Signature for Assent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Statement of Person Obtaining Informed Assent  I, the undersigned, have fully explained the details of this research study to the participant named above.    Name of Person Conducting Assent Discussion (Print)    Signature of Person Conducting Assent Discussion Date |