Information form for children (8-11 years)

**Title of the study:** **Enter the simple title of the study here**

Hello,

You are invited to take part in a clinical study. This is scientific research that is done to find out what effect new medications have on your disease. You and your parents or guardian can decide together if you want to participate in this study. If you do not understand something or want to know more about the study, you can always ask your doctor or other persons of your choice.

# Why am i invited to take part in this study?

We invite you to participate in a study with XXX because XXXX.

# WHAT TREATMENT WILL I receive IN THIS STUDY?

Geef hier een eenvoudige beschrijving van de studie en de behandeling.

# Which tests will be done for the study?

During the study there are tests on your blood. Via these samples the doctors want to test the effect of the medication XXX. These tests would also be done if you did not join the study and received another treatment for your disease. No extra pricks are therefore required for the study.

All samples taken for the study will be given a code so they do not mention your name. This way they can be stored for XXX years and later be used for further research into your disease. You can ask to have the collected samples destroyed at any time without having to give a reason for this.

All data we collect about you will be coded, so no one outside the study team will know your name. The data we collect about you may also be used for later research on your disease.

# WHAT HAPPENS IF YOU DO NOT WANT TO PARTICIPATE IN THE STUDY?

If you do not want to participate in the study or if your parents do not want you to participate in the study, you can say this to your doctor. Your doctor and the nurses will not mind if you don’t want to take part. The doctor will then look with you how your disease will be further treated according to the current standard.

You can always ask questions about the study at any time.

# To whom can you ask questions?

If you have any questions about the study during your treatment or if there are any problems, you can always talk to your parents or guardian, the nurses and your doctor:

Name and phone number of your doctor:

…………………………………………………………………………………………………

…………………………………………………………………………………………………

**ASSENT FORM FOR CHILDREN (8-11 YEARS)**

**First and last name of the participant**:………………………………………………

I have read and understood the information form for children aged 8 to 11 and I received a copy.

I received an explanation of the study and have been able to ask all my questions.

I understand that information about me and my disease will be collected and that this information will also be used for future research about my disease.

I understand that my information will only be seen by the people who have the right to see it.

I understand that it is my choice to participate in the study and that I can stop participating in the study at any time without giving a reason.

|  |  |  |
| --- | --- | --- |
| Tick the box "YES" if you agree; if not, please tick the box "NO" | | |
| I agree to participate in the following parts of the study: | **YES** | **NO** |
| 1. I will let the doctor know if I notice unexpected symptoms. |  |  |
| 1. I agree that I will be administered the medication XX of the study. |  |  |
| 1. I agree that my samples are examined and kept for further study. |  |  |
| 1. XXXX |  |  |

|  |  |  |
| --- | --- | --- |
| Name and first name of the participant | | Date |
| Name of the doctor\* | Signature | Date |

2 copies must be completed. The original is kept by the investigator in the hospital for a period of at least 25 years, the copy is given to the participant.

\*Tick by the doctor if agreed

|  |  |
| --- | --- |
| I declare that I have provided the necessary information regarding this study (the nature, the purpose, and the foreseeable effects) orally and a copy of the information document to the participant. |  |
| I confirm that no pressure has been exerted on the participant to allow him/her to participate in the study and I am prepared to answer any additional questions. |  |