**INFORMATION SHEET FOR PARTICIPATION IN A CLINICAL TRIAL**

 **- MINORS AGED BETWEEN 6 AND 11 YEARS -**

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| --- |
| **Indicate the title of the study** |
| **Indicate the facility-context of the study** |

Dear ..............................................,

the doctors have asked your parents for permission to let you participate in a clinical study. This document aims at briefly explaining what is a clinical study and in particular what is proposed to your parents. It will be for them to decide, but it is worthwhile that you are informed. We have provided your parents with a document similar to this one, only much more complex.

We have thought about the questions you are likely to ask, and we have provided answers that we hope will clear up your doubts. Of course, you can ask the doctor in charge any other questions to have a better understanding.

Your parents will examine the document and receive all the clarifications from the doctor. Afterwards, if they decide that it is good for you to take part in the study, they will be required to sign a document called “declaration of informed consent”.

What is this clinical study for?

*[Adapt the description to what you intend to test: Existing drug? New drug? New technology?]*

Example for a new drug:

We would like to evaluate whether it may be useful to include in the therapies the drug called XXXXXXX *(please specify in detail)*. Studies performed so far have shown that this drug works safely even in children *(if applicable)*. However, more studies are needed to better define how and at what doses it works in children.

What we expect from the study:

*[Explain the rationale of the study in simple and concise terms, clearly identifying the aim of the study]*

Example for a new drug:

the investigational drug increases the chances of recovery (or: is more effective / is more tolerated / has fewer/delayed side effects) than those currently in use, etc.

What will happen to me during the study?

*[Indicate experimental and/or standard treatment. Indicate* *the planned tests and examinations]*

Example for a new drug:

Participation in the study is not that different from the care you have already been receiving.

First of all, you will undergo some tests to verify that you can really take part in the study.

If this is the case, you will be prescribed a medication, which you will need to take as directed by your doctor and under your parents’ guidance.

At regular intervals you will undergo examinations and check-ups during which the doctor will ask you to give him indications on how you feel.

How long will the study last?

*[Indicate the duration of the study]*

The study we propose will last …………. months, during which you will be in constant contact with the center where the clinical study is being performed.

Will I have any benefit from participating in the study?

*[Indicate the expected benefits from participating in the study, also with reference to the progress of scientific knowledge]*

Example for a new drug:

Doctors think that this experimental treatment is more useful against your disease than the treatments known to date, [in particular for…. (specify benefits?)], but at the moment there is not yet evidence of this. However, we know that the information gathered in this study will help doctors learn more about this new treatment, and this information could help children with your own disease in the future.

Am I taking risks in participating in the study?

*[Indicate the potential adverse effects related to the trial, drugs and procedures that will be used]*

All medical practices involve risks, even those you are already doing.

In particular, in this case ………… (please specify).

However, you will always be under control, as you already are now. For your part, immediately report to your parents any discomfort you may have, such as headaches, stomach pains, nausea. Doctors will help you get better.

Can you explain it better?

*[Solicit further questions from the minor]*

You can ask the doctors any questions you may have. They will do their best to give you clear and simple answers.

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We hope that what you have read and heard was enough to get you a fairly clear idea of ​​a clinical trial. Now all you need to do is talk about it with your parents.

