**Model of Consent to Research (minors aged 8-12 years)**

**THE TITLE OF THE RESEARCH**

**THE LOCATION OF THE RESEARCH**

**THE NAME AND SURNAME OF THE HEAD OF THE RESEARCH *(RESEARCHER)***

**Read this text with your mother or father!**

Describe the purpose of the study.

**As part of our study, we will ask you to...**

Describe what the child will do in the research. Be specific, but check that your description is written in a way that a child can understand.

**The research will take place in** (the location of the research), **and is paid for by**...(the title of the project, donor). **The research is being conducted for the purpose of** (e.g. a dissertation, a PhD, a scientific project).

**Your participation in the research is voluntary and you may withdraw it at any time.**

**The doctor/researcher who is conducting this research will not receive any money for the research.** If any remuneration is to be paid, it is necessary to state the source and the amount of financing.

**INFORMATION ABOUT THE RESEARCH**

The subject and aims of the study, why it is begin conducted, how long it will last (write a short passage about the research which all subjects can understand regardless of their level of education). Point out whether the research is being conducted on one or two groups of subjects. If there are two groups of subjects, state the reason for this research (e.g. comparison of two forms of treatment for arterial pressure or blood sugar, comparison of two diagnostic tests, methods etc.) Point out that the subjects will be allocated randomly to one of those groups (like when tossing a coin).

Will there be only one meeting (visit) between the subject and the researcher, or several?

What is expected of the subjects?

At the single meeting (state what will be done)

In the case of repeated meetings, state:

E.g., the number of visits to the doctor, the number of times e.g. blood samples will be taken, or US tests conducted...

(During this research, you will come to visit for tests twice a week/five times in the next five months, that is, once a month, etc.)

You must give a description:

(of the visit at the beginning of the research: learning about the research and procedures, tests, analyses. Then you will be given medication, continue with your current therapy, US diagnostics will be conducted, they will be monitored etc.)

A visit after e.g. two weeks, a month etc.... (point out if the same procedures will always be conducted at each visit). If not, point out the differences between e.g. the first and third visits.

***Special note for genetic research:*** *Describe precisely each genetic test that will be performed and why it will be performed.*

Will it be necessary for the subjects to stay in the hospital during the research, or is it sufficient for them to visit an out-patients clinic?

**RISKS AND BENEFITS**

**Taking part in this study will not cause you any harm. On the other hand, it will not help you in any way. We hope that it will help us find out more about children.**

Using language that this age group can understand, describe the risks and what you will do to reduce the risks. Consider explaining the risks using examples that a child can identify with. Limit your explanation to one or two sentences. Do not over emphasise the advantages.

Confidentiality: Use this section to describe how you will keep the participants' data private and confidential. This may include a short statement about how you will collect and store data ...

The following text may be used as a model for a common scenario when collecting data:

**Your answers to our questions and samples (such as blood) that we collect during this study, will be kept secret. Your name will not be used and it will be kept secret, and no one who reads about our research will know that it is you. We keep things closed so only trained laboratory workers can see them.**

**Through the researcher, you have the right to access all the data collected about you. You can look for their corrections if they are incorrect during the research / after the end of active participation in the research. (IMPORTANT!!! here please choose one of two options because this depends on the type of test that would not affect the results of the research).**

**You have the right to a complaint in the way that you deal with your information.**

**You do not have to take part in this study.**

**You may end your participation in this research at any time.**

**If you want to stop being part of this research, tell the person who is testing you (the person's name). If you decide to stop before we have finished, all the answers you have already given will be destroyed. There is no penalty for stopping.**

**If you have any questions about this research, ask:**

(the name and surname of the person and their telephone number)

**I agree to participate in the research described above.**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**

**You will be given a signed form like this to keep for yourself.**

IMPORTANT NOTE!

In order for us to know precisely which level of education this text is intended for, it is necessary to calculate the SMOG formula for Croatian

**SMOG (Croatian) = 2 + √(number of words with 4 or more syllables)**

The result we obtain is the number of years of formal education (from first grade elementary school upwards) which a person must have to be able to read with understanding the text of the consent we have drawn up.

For this text, the number must be: 2.