**Model for Consent to Research (for minors aged 13-17 years)**

**THE TITLE OF THE RESEARCH**

**THE LOCATION OF THE RESEARCH**

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

**Dear ...,**

**Please read this text together with your parents or guardians before you decide to take part in this research. Your parents or guardians will give permission for your participation in this research, but it is necessary for you to give your consent to this research and to understand what the research is about.**

Describe the purpose of your study.

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

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

(N.B. scientific research may be open and blind. Therefore the type of research must be mentioned here. For instance, the research is open, single blind, double blind; it must be mentioned if the subjects receive remuneration for taking part in the research).

**The research will take place in** (the location of the research), **and is financed 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 at any time.**

**The physician/researcher who is conducting this research will not receive any financial remuneration.** 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 being 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/a total of 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. Further, you will be given medication, continue with existing therapy, ultrasound diagnostics will be conducted, you 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?

**INCIDENTAL FINDINGS**

***Special note for genetic research:*** *If incidental findings arise which indicate a serious genetic disease, it must be emphasized what you will do as the researcher.*

**RISKS AND BENEFITS**

**If you participate in the study, you may find it uncomfortable if/when...**

Describe the risks and what you will do to minimize the risks, but do this in a way that a minor can understand. Consider explaining the risks using examples which a minor can identify with. If there are no risks, then state: **We do not believe that this study involves any risks.**

**If you participate in this study, there will be no benefit for you at all (or there will be some benefit for you).** Please limit the part about benefits to one or two sentences. AVOID UNREALISTIC EXPECTATIONS!

**Confidentiality:**  Use this section to describe how you will keep the participants' data private and confidential. This may include a short statement about how data will be collected, stored and used in this study.

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

**The information you provide during this study will not be available to the public. Your name will not be used, and the list linking your code name with your real name will be destroyed after all the data have been collected, so no one who reads about our study will know that it is you. We keep things closed so that only the researchers can see them.**

**Through the researcher you have the right to access all the data collected about you and to ask for their corrections if incorrect during the research / after the 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 you deal with your information, and you can refer it to the responsible body for enforcing privacy protection laws.**

**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 taking part in this research, tell the researcher. If you decide to stop before we have finished, all the answers you have already given and all the materials taken from you (blood etc.) will be destroyed. There is no penalty for stopping or refusing to take part in the research.**

**WHO APPROVED THIS RESEARCH?**

State who approved this research: the Ethics Committee of the health institution, the Ethics Committee of the School of Medicine of the University of Zagreb

**QUESTIONS ABOUT THE RESEARCH AND CONTACT INFORMATION**

For any other questions about the research itself, you can talk to *(who? the name and surname of the person, telephone number, e-mail).*

If you become ill or suffer any injury during this research, please talk to the researcher (*who? the name and surname of the person, telephone number, e-mail).*

I agree to participate in the research described above.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_
You will be sent this form for your own records.

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: 6.