

**1993**

**BAŞKENT UNIVERSITY**

**CLINICAL RESEARCH ETHICS COMMITEE**

**INFORMED CONSENT FORM FOR CLİNİCAL RESEARCH ON CHILDREN**

DEAR BROTHER/ SISTER

*We have invited you here to get permission on your participation to the clinical study that we are planning. This document presenting the study to be conducted in detailed is prepared for you. You are free to participate or not to participate in this study. Participation in research is voluntary. If you have problems with understanding this document, you may ask for help from your mother/ father/ legal representative or us, any time you need. You can ask for any time and help you need to make a decision on this matter*

***Important Note: It should be kept in mind that all the parts in italic or in parenthesis serving as explanatory information for researcher should be eliminated while the form is being prepared.***

**1. NAME OF STUDY**

*The title should be included in this part. If the title contains medical jargon, it should be explained for the volunteer in parenthesis.*

*Example:*

*Detection of Respiratory Alkalosis in Children Presenting to Hospital with Febrile Convulsions. (Detection of respiration related alkalosis in blood in children presenting to hospital with febrile spells)*

**2. NUMBER OF PARTICIPANTS**

*(This number should be the same as the number mentioned in materials and method section of the clinical research form. Criteria for choice of number should be explained together with the biostatistics pre-assessment document in the clinical research application form.*)

The anticipated number of children to participate this study is ………… .

**3. DURATION OF PARTICIPATION TO STUDY**

*(The duration of procedure to be performed should be written. (e.g. minutes, hours) If follow up is planned after data collection, this period should also be indicated.)*

The predicted duration of your participation to this study is …… .

 **WHY ARE WE CONDUCTING THIS STUDY ON CHILDREN?**

 The subject of this study directly concerns children.

 The subject of this study is a clinical condition that can only be investigated in children.

The subject of this study needs confirmation of, validity of data obtained from research done in adults, in children

 This study does not carry a significant predictable risk for children’s health but it should be kept in mind that it will not provide direct benefit to children.

**4. AIM OF THE STUDY**

*(Aim of the study should be clarified in a way the volunteer will understand, without using medical terminology, an example may be found in the consent form for adults)*

The aim of this study is;

**5. CRITERIA FOR PARTICIPATION TO THE STUDY**

 *(The criteria for participation in this study should be explained addressing to the mother/ father/ legal representative. Age, gender, special situations should be written in detail.An example may be found in the consent form for adults)*

You should meet following criteria in order to participate this study:

**6. STUDY METHOD**

*(Method of the study should be written addressing to the mother/ father/ legal representative. At this point all the steps included in scientific terminology in the clinical studies application form should be explained thoroughly in a way that the volunteer will understand. Medical language should be changed to public language, also; expressions like “ml, cc” should be explained as “tea spoon, table spoon etc.”.)*

*Example 1: “…For research purposes, an MRI will be performed which takes approximately… minutes. …”*

*Example 2: “ … You may be allocated to either the study group or the control group. This selection will randomly be made…”*

*Example 3: “… You will be given 1 mL (tea spoon) of the medication named … through his/her vein. …”*

*Example4: “…If you are in the study group his/her blood will be drawn 24 hours after the spell, if he/she is in the control group his/her blood will be drawn at time of presentation to hospital…1*

Treatments/ interventions/ tests/ procedures that will be applied to you are as follows;

Details of planned treatments and procedures;

**7. RULES AND CONDITIONS TO FOLLOW DURING THE STUDY, CIRCUMSTANCES THAT WILL RESULT IN EXCLUSION**

 *(This part should be addressed to the mother/ father/ legal representative. Responsibilities such as being compliant with the study plan and advises of the researchers, not using a medication other than that advised by the researchers, informing the researchers on any situation where you are obliged to take a medication should be explained)*

………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

Medications/ food/ herbal supplements of which the usage is known to be inconvenient together should definitely be indicated

………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**8. POSSIBLE BENEFITS EXPECTED FROM THE STUDY**

*(In cases where medical benefit is expected of study, the benefits should clearly be specified. Otherwise; the possibility that there may not be a personal medical benefit despite the potential of using results obtained from this study for benefit of other people, the sole scientific purpose of the study and unlikely expectation of direct benefit of the volunteer or a change of course in treatment should be clearly written.)*

*Example:*

*“… This study is expected to elucidate why we see spells in some children with fever while we do not in others. Our study is solely of scientific purposes. Direct personal benefit or a change in course of your treatment is not expected from this study. However the results obtained from this study will contribute to treatment planning of patients like you, diagnosed with the same condition. …”*

**9. POSSIBLE RISKS TO ARISE FROM THE STUDY**

*(E.g.: Pain, fainting (rarely), bruising, infection at entry site of the needle (rarely), clotting or prolonged bleeding are possible risks of drawing blood. Possible side effects, adverse effects, hypersensitivity reactions of the planned medications/interventions/procedures should be explained. It should be added that all the precautions are taken against a possible problem.)*

……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

We will take all the precautions against a possible problem.

**10. LIABILIY AND RESPONSIBILITY IN ANY DAMAGE ARISING FROM THE STUDY**

In case you suffer from harms caused by the study, cost of the necessary treatments will be covered by ……………………… . *(name of the university etc. should be indicated)*

**11. CONTACT PERSONS FOR EMERGING PROBLEMS DURING THE STUDY**

During course of the study, you may reach related doctor any time of the day using the contact information provided below, in order to inform researcher in charge in advance, to obtain additional information about the study, to report a problem related to the study, to report an adverse affect or other disturbances concerning the study.

**Address and telephone number of the doctor that can be reached 24 hours a day:**

**……………………………………………………………………………………………**

**Work: ………………… Cell:**……………..(*It is obligatory to fill, work number only is not sufficient)*

**12. COVERAGE OF THE EXPENSES AND PAYMENTS**

No payment will be requested from you for your participation in this study or to serve as resource for the study. No payments for any kinds of tests, physical examinations, other expenses of the study, in addition to the tests necessary for your disease will be requested from you or the private or official institutions you are covered by.

**13. INSTITUTION SUPPORTING THE STUDY**

The institution supporting the study is ……………….. .

**14. PROVIDING OF INCENTIVES OR REWARDS FOR PARTICIPANT OR NOT**

When you participate this study, obligatory expenses will be covered by the study’s grant but other than that; no additional financial contribution will be made to you or to your legal representatives.

**15. CONFIDENCIALITY OF INFORMATION**

During the course of the study, medical information obtained will be stored using a code number dedicated to you. All of your personal medical information will be kept confidential. Results of the study will be used only for scientific purposes. Even if the study is published, your identification information will not be disclosed. However, when needed, observers of the study, inspectors, ethics committees, official authorities will be able to reach your medical information. You will also be able to reach your medical information whenever you wish. *(If the treatment is blind, volunteer should be informed that his/her personal information could be reached only after the data analysis is done)*

**16. EXCLUSION CRITERIA**

In case you are not compliant with the treatment regimen, you skip the study program, or suffer an unwanted affect related or unrelated to the study etc.; your doctor may chose to exclude you from the study without your permission. This will not cause a change in your treatment.

Even in the case you are excluded from the study, your medical information can be used for scientific purposes.

**17. ALTERNATIVE TREATMENTS OTHER THAN THE TREATMENT THAT WILL BE USED IN THE STUDY**

Alternative treatment options offered for the same diagnosis as yours, that you will not be getting as needed by the study protocol are listed below (if present) together with their advantages and adverse effects.

Medication/ProcedurePotential Advantages Potential Side Effects

……………………………………………………………………………………….

………………………………………………………………………………………………….……………………………………………………………………………………………………………………………………………………………………………

**18. REJECTING TO JOIN THE STUDY/ DROPPING OUT**

You may talk to your mother and father and consult them. We do not have a time limit for your decision process, if you need time to think and decide, we may wait for you. We will explain this study to your mother/father/legal representative and ask for their permission. Even if your mother/father/legal representative accepts your participation to this study, you will make the final decision. Participating in this study is entirely up to your wish. You may reject to participate in this study.

You may leave any time during course of the study without showing an excuse.

In case you refuse to participate or withdraw, your decision will not cause any change in the course of your treatment.

In case you withdraw or are excluded by the researcher, medical information obtained from you may be used for scientific purposes.

**19. SHARING OF NEW INFORMATION AND SUSPENSION OF THE STUDY**

During the course of the study, all the new information and results, negative and positive, will be shared with you and your legal representative. There results may affect your willingness to continue the study. In this case you may ask for the suspension of the study until you reach a final decision.

***(Declaration of the Participant/ Patient/ Mother-Father/ Legal Representative)***

I was informed that a clinical research will be conducted by dear doctor ………….., at …………. University School of Medicine, Department of ………….. / ………………. Research and Training Hospital ……………. Clinic. Above information concerning the study is explained. Following these information I was invited to join such research as “participant” (volunteer).

If I am to participate in this study, I believe that my personal information that must remain confidential between my doctor and me will be handled with great care and respect. I was given assurance that my personal information will be protected meticulously as the study results are being used for educational and scientific purposes.

I may withdraw from the study without showing a particular reason during the course of the study. *(I am aware of the fact that it is appropriate for me to notify in advance that I am withdrawing in order not to put the researchers in a difficult position)* Also I may be excluded from the study by the researcher on condition that medical status is not harmed by any means.

I do not assume any financial responsibility for the expenditure of the study. I will not receive any payment.

In case a medical problem emerges caused by study procedures, I am given assurance that all the necessary medical interventions will be made. It is explained that I will not be put under financial burden concerning these medical interventions.

I am not obligated to participate in this study and I may not participate. I am not facing a compelling attitude about my participation in the study. If I refuse to participate in this study, I know that it will not cause any harm to my relationship with my doctor or to my medical care.

**APPROVAL TO PARTICIPATE IN THE STUDY**

I have read and verbally listened to the 6-page text concerning information that needs to be given to my mother/ father/ legal representative before starting the study. I have listened to the related explanations. I have asked all the related questions I have to the researcher. I have understood all the verbal and written explanations made, in detail. This process is in my mother/ father/ legal representative ‘s knowledge. At least one of my legal representatives accompanied me during this process. I was given sufficient time to decide on whether I wish or do not wish to participate in the study.

Under these circumstances, I authorize the conductor of the study to review, transfer and process my medical information and I voluntarily accept the invitation to participate in the above-mentioned study under no force or pressure. I was given a signed copy of this form.

I know that I will not loose rights provided by local law by signing this form.

I was given a signed and dated copy of this form.

|  |  |
| --- | --- |
| VOLUNTEER | SIGNITURE |
| NAME, SURNAME |  |  |
| ADRESS |  |
| TELEPHONE NUMBER |  |
| DATE |  |

|  |  |
| --- | --- |
| LEGAL REPRESENTATIVE (if present) | SIGNITURE |
| NAME, SURNAME |  |  |
| ADRESS |  |
| TELEPHONE NUMBER |  |
| DATE |  |

|  |  |
| --- | --- |
| RESEARCHER | SIGNITURE |
| NAME, SURNAME and DUTY |  |  |
| ADRESS |  |
| TELEPHONE NUMBER |  |
| DATE |  |

|  |  |
| --- | --- |
| ATTENDANT OF THE INSTITUTION THAT WITNESSED THE PROCESS OF OBTAINING CONS[[1]](#footnote-1)ENT FROM THE BEGINNING UNTIL THE END | SIGNITURE |
| NAME, SURNAME and DUTY |  |  |
| ADRESS |  |
| TELEPHONE NUMBER |  |
| DATE |  |

1. [↑](#footnote-ref-1)