

**1993**

**BAŞKENT UNIVERSITY**

**CLINICAL RESEARCH ETHICS COMMITEE**

**INFORMED CONSENT FORM FOR SCIENTIFIC RESEARCH**

**PLEASE READ CAREFULY!!!**

You have been invited to join a clinical study for scientific research. Before you accept being part of this study; you need to completely understand the reason why this study is conducted and make your decision freely after being fully informed on this study. This informed consent form has been specifically developed for you in order to explain the below mentioned study. Please read this form carefully. Should there be any points you do not understand even though it is explained in this form or you notice that this form is lacking please refer to your doctor and ask for clear explanations. You are free to choose to participate in or not to participate in this study. Participation to the study is **voluntary**. Before you sign this form, your doctor will give you time in order for you to think and freely decide after you have been fully informed on this study. No matter what your decision is, your doctor will continue to do his/her duty in all respects to assure and preserve your wellbeing.

***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 VOLUNTEERS**

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

The anticipated number of volunteers 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 …… .

**4. AIM OF THE STUDY**

*(Aim of the study should be clarified in a way the volunteer will understand, without using medical terminology.)*

*Example:*

The aim of this study is, “To determine which test will give a more accurate result in detecting extent of disease in patients diagnosed with uterine wall cancer etc …*”*

**5. CRITERIA FOR PARTICIPATION TO STUDY**

 *(The criteria for participation in this study should be explained addressing to the volunteer. Age, gender, special situations should be written in detail.)*

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

1. *You should be a woman aged between 25-35 y*
2. *You should have been diagnosed with uterine wall cancer according to a biopsy result*
3. *Surgery should be seen appropriate by your doctor,*
4. *You should have no allergies for medications used for doing an MR*
5. *You should have no problems with the MRI procedure*

**6. STUDY METHOD**

*(It is important that the method of the study is written clearly in a way the volunteer will understand. At this point all the steps included in scientific terminology in the clinic 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 your vein. …”*

**7. RESPONSIBILITIES OF THE VOLUNTEER**

 *(This part should be addressed to the volunteer. If present, following information should be included and written in bold: predictable risks for the embryo, fetus, neonate feeding with breastmilk; warning against getting pregnant, list of appropriate contraceptive methods for the study. For male volunteers, a warning for need of contraception for self and partner should be indicated if appropriate.).*

*Example:*

1. *You should be compliant with the study plan and advises of the researchers.*
2. *You should not use a medication other than that advised by the researchers. If there arises a situation where you are obliged to take a medication you should inform the researcher in charge.*
3. *If you get pregnant during the study, you should inform your doctor.*
4. *You should report any medical condition that bothers you to the researcher in charge. … etc.*

*(Medications/ food/ herbal supplements of which the usageis 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:*

*“… 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**

*(This part should be addressed to the volunteer. E.g.: Pain, fainting (rarely), bruising, infection at entry site of the needle (rarely), clotting or prolonged bleeding are possible risks of drawing blood. It should be added that all the precautions are taken 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**

*Example: No payment will be requested from you to participate in this study or to serve as resource for the study.*

*No paymentsforany 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 INSENTIVES OR REWARDS FOR VOLUNTEERS OR NOT**

When you join 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 personal 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 do not comply with the treatment regimen, you skip the study program, get pregnant 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 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 AdvantagesPotential Side Effects

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

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

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

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. In case you refuse to participate orwithdraw, 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 Represantative)***

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 5-page text concerning information that needs to be given to the volunteer before starting the study. I have asked all the related questions I have to the researcher. I have understood all the verbal and written explanations made, in detail. 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 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 GUARDIAN (if present) | SIGNITURE |
| NAME, SURNAME |  |  |
| ADRESS |  |
| TELEPHONE NUMBER |  |
| DATE |  |

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

|  |  |
| --- | --- |
| ATTENDANT OF THE INSTITUTION THAT WITNESSED THE PROCESS OF OBTAINING CONS[[1]](#footnote-2)ENT FROM THE BEGINNING UNTIL THE END | SIGNITURE |
| NAME, SURNAME and DUTY |  |  |
| ADRESS |  |
| TELEPHONE NUMBER |  |
| DATE |  |

1. [↑](#footnote-ref-2)