Dear investigator, this sample form is just for your information and the original form should be completed online in the Pajooheshyar when submitting the project.

Dear investigator:

Please consider the following points when developing your informed consent form:

1) The informed consent form should be based on the research information in a non-specialized and understandable language for low literate participants (fifth grade).

2) You can change the sentences of this form in order to make the text more fluid and understandable, but the logical routine for presenting the information should be the same as this form.

3) For each individual article, please note the explanations given as comments.

4) In this text, if the participant is a child or the person lacking the decision making capacity, the word "I", should be changed to " the child" or "the person under my guardianship", and when the words "I " refers to the concenter, it should be changed to the "legal guardian /parent".

5) After finalizing the form and before sending it to the Ethics Committee, please clear the explanations and comments.

6) It is suggested to give the form to couple of ordinary people before submission, to review the meaning of the content, and then, improve the text.

University's Ethics Committee in Research

The consent form for participation in the project. . . .

Commented [I1]: Write the research title here

Dear Sir/Madam

Hereby, you are invited to participate in the above-mentioned research. Information about the research is provided in this sheet and you are free to participate in this research or not.

You do not have to make an immediate decision, and you can ask your questions from the research team or consult with anyone you like. Before signing this form, please make sure that, you have understood all the information in this form and all of your questions have been answered.

Investigator

1. I understand that, the aims of this study are:

2. I am aware that, my participation in this study is completely voluntary. I have been assured that, if I do not participate in this study, I would not be deprived from the routine diagnostic and therapeutic care that I receive and my therapeutic relationship with the treatment center and the physician would not be affected.

3. I know that, even after agreeing to participate in the study, I can withdraw from the project after informing the research conductor, and my withdrawal from the study will not deprive me from the usual health care services that I am receiving.

4. My collaboration in this study is as follows:

5. The possible benefits of my participation in this study are as follows:

6. The possible risks, possible harms and complications of my participation in this study are as follows:

7. If I do not want to participate in the study, I will be provided with a routine treatment plan which its benefits and harms are as follows:

8. I am aware that, the researchers keep my information confidential and are only allowed to publish the general and collective results of this study without mentioning my name and detail.

9. I know that, the Ethics Committee in Research can access my information to make sure my rights have been preserved.

10. I understand that, the costs of study's interventions (as follow) will not be on me.

11. Ms. / Mr. ..... is introduced to me to answer my questions and I was told that, whenever I had a problem or question regarding participation in the above mentioned study, I can talk to him/ her and ask for guidance.

His/ her address and phone number is:

- Address: ....
....
- Landline phone No: ....
- Mobile phone No: ....

Commented [I2]: Do not write the exact proposal's aims. Write in such way that it would be understandable for people. Explain the aims of the research for the participants.

Commented [I3]: Here, with simple language, explain that:
- What kind of intervention they are going to have
- What type of information you want from them
- What type of paramedical intervention are they going to receive
- Sample size
- How long their collaboration is going to last in this study
- During this time, how many time should they attend the project, what intervals
- How long do they spend time during each attendance?
- What activities should they do between each attendance?
- What do you follow them up?
- Inform them if they are being placed in one of the groups randomly.

Commented [I4]: Explain the benefit that, the participant can have such as possible cure of their disease, better diagnosis, etc

Commented [a5]: Possible harms or the probability of them

Commented [a6]: So the participants can better evaluate the benefits or consequences of their participation

Commented [I7]: Name of the person who can provide the participants with information about the project

12. I know that, if I develop any physical or mental problem during and after the research as a result of my participation in this study, it will be the responsibility of investigator to pay for the treatment and compensation.

13. I know that, if I have a problem or objection from the research conductors or process, I can contact the Ethics Committee of the Tehran University of Medical Sciences, (situated at Keshavarz Blvd, Qods St., sixth floor, Research & Technology Management, the Secretariat of the Ethics Committee, headquarters building of Tehran University of Medical Sciences, Phone no: 81633626 and 81633613) and address my problem either verbally or in writing.

14. This informed consent form has two copies, and after signing the form, a copy will be given to me and the other copy will be given to the research conductor.

I…… have read and understood the above items, and based on that, I declare my informed consent to participate in this research.

Signature of the participant

Hereby, I ..... consider myself bound to comply with the obligations in this form, and I strive to protect and preserve the rights and safety of the participant in this research.

Signature of the investigator