TEHRAN UNIVERSITY OF MEDICAL SCIENCES

Office of IC-TUMS Vice Dean for Research Affairs

Participant Consent Form

1-Does your research need a completed informed consent form?
2-Does your research include participants with no legal rights or participants who are unable to make decisions?
(Such as: Children, Mentally disabled patients, Psychotic patients, Patients with low level of consciousness.)
3-According to your answer to the above questions, who is going to complete this form?
a) Research subject:
b) Alternative option: (someone with the authority and capability of completing this form)
c) Both:

PARTICIPANT/PATIENT' CONSENT:

1- I,_____, have been explained about the ***purpose & objectives*** of this research and I am aware of them. The purpose& objectives are as follows:

_____

_____

2- I understand that my participation in this study is voluntary, and I freely agree to participate in this study.

3- I have been assured that if I decide to reject the offer of participation in this study, the decision will not affect my legal rights, medical care, or any treatment in any way.

4- I understand that if I reject the offer of participation in this study, I will receive the usual treatment which involves the following benefits and risks:

_____

_____

_____

5- I understand that I may choose to withdraw at any time by informing the research project manager, and my withdrawal would not affect my legal rights, medical care, or any treatment in any way.

6- **Type of involvement**. My involvement in this study would be as follows:

_____

7- **Possible benefits obtained**:

_____

8- **Possible risks and side effects** :

_____

9- I have been assured that the records of this study will be kept private. Any sort of report, which may be published, will not include any personal information of mine.

10- I acknowledge that the ethical committee is allowed to access my personal information in order to protect my rights.

11- I understand that there is no cost for me to be in this research study or for medical treatments/interventions which are applied.

12- I have been provided with the name, phone number, and address of a contact person whom I can contact in case of any questions/problems. The name and contact number are as follows:

Name: _____

Phone number(s):_____
Address: _____

13- I understand that if I experience medical problems or injuries as a result of being in this study, it will be the project manager's responsibility to compensate for the injuries and pay for the care or treatment that I will need.

14- I understand that if I have any complaints or concerns about this research, I can contact the TUMS Ethical Committee at 6th floor, TUMS Headquarter, Keshavarz Boulevard, Tehran, Iran (Tel: 81633626, 81633613).

15- After signing this form, a copy of it will be given to me for my records and future reference.

16- I may get dismissed from the study by the project manager at any time for the following reasons: (1) it is in my best interests (e.g. side effects or distress have resulted), (2) I have failed to comply with the study rules, or (3) the study sponsor decides to end the study.

I acknowledge I have read and *understood the contents of this form*, and have been given full opportunity to discuss the implications of this consent. *I give my consent to participate* in this study.

Participant/patient's Signature:_____ Date: _____

Project Manager:

I have read and *understood the contents of this form,* and agree to fulfill all the responsibilities and to preserve my client's rights as stated in this form.

Participant/patient's Signature:_____ Date: _____