***Office of IC-TUMS Vice Dean for Research Affairs***

***Participant Consent Form***

**Research Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Project Manager’s Name: Contact Number:**

**Participant’s Name: Contact Number:**

*Dear participant,*

You are invited to participate in a research with the above mentioned title, and you are free to accept or decline this invitation. You may ask the research team members your questions, and may consult anyone you wish about your participation. Before signing this form, please make sure you have read it thoroughly and understood its contents.

**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:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. I understand that my participation in this study is voluntary, and I freely agree to participate in this study. 2. 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. 3. 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:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. I understand that I may choose to withdraw from participation 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. 2. **Type of involvement**. My involvement in this study would be as follows:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. **Possible benefits obtained**:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. **Possible risks and side effects** :   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. 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. 2. I acknowledge that the ethical committee is allowed to access my personal information in order to protect my rights. 3. I understand that there is no cost for me to be in this research or for medical treatments/interventions which I will receive. 4. 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***   1. 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. 2. 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). 3. After signing this form, a copy of it will be given to me for my records and future reference. 4. 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 the above mentioned participant’s rights as stated in this form.  Participant/patient’s Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |