e-Natureza VR: Affective Validation of Nature Images as a Complementary Resource for Promoting Well-being in Hospital Environment

INFORMED CONSENT FORM

Sao Paulo, Brazil
Approved in the first version in 01/22/2019

Human subjects protection review board number:

Hospital Israelita Albert Einstein Research Ethics Committee

64096816.9.0000.0071

INFORMED CONSENT FORM
Patient
Research title: “E-NATURE VR: EVALUATION OF THE IMPACT OF VIRTUAL REALITY DURING BREAST BIOPSY”

Name (participant): _____ Dear participant,

We would like to invite you to participate as a research volunteer entitled “E-NATURE VR: EVALUATION OF THE IMPACT OF VIRTUAL REALITY DURING BREAST BIOPSY”

The objective of this study is identify whether a video of nature in the virtual reality format may have any influence on you while you are doing the breast biopsy procedure.

INVOLVEMENT IN THE RESEARCH: By participating in this study, you can watch a video with 3D images of nature and answer some questionnaires to assess the symptoms while performing the breast biopsy, as well as your pain. You also fill in some data about age, education so you can characterize the participants in this research.

As a clinical study is concerned, you can be classified for both this intervention group and the control group. If you participate in the control group, you can answer the questionnaire, but not watch the video. If you are interested, after answering questions, we can show you the video.

We remind you that your participation is voluntary and you have freedom to refuse participating and may still stop responding at any time without any prejudice. In addition, you still have the right to keep one of the copies of the consent form. Whenever you want you can ask more information about the research. To do this, you can contact the researcher, by the means informed below, in this document.

RISKS AND DISCOMFORT: Your participation in this research presents minimal risks, perhaps only some embarrassment (shame) that some people feel when they are providing information about themselves or some discomfort in relation to virtual reality, being possible a slight dizziness, nausea or headache, and you can freely discontinue research if you wish.

RESEARCH CONFIDENTIALITY: All information collected in this study are strictly confidential. Your name will not be mentioned in any moment. All data will be analyzed together, ensuring the anonymity of the information. The results may be used in events and scientific publications.

BENEFITS: If you are drawn to the intervention group maybe the video will bring some sense of well-being for you during your chemotherapy session, but we do not know, so we are doing this study. If you are drawn for the control group we do not expect immediate and direct benefits for you for your participation, but the results will contribute to a new form of intervention that benefits patients in hospitals if show effective.

PAYMENT: You will not have any expenses for participating in this research. And nothing will be paid for your participation. However, if you want, you may have access to copies of the research reports containing the results of this study. To do so, you just have to contact the responsible researcher as follows:

Address of the person in charge of the research:
Name: Daniela Reis Dal Fabbro
Institution: Instituto Israelita de Ensino e Pesquisa Address: Av. Albert Einstein 627/700 - Block A - 2nd floor Contact Phones: (55 11) 2151- 1032

ATTENTION: To report irregular occurrences or to obtain information on the ethical aspects of the study, during their participation, please contact:

Research Ethics Committee of the Hospital Israelita Albert Einstein Av. Albert Einstein, 627/700 - Block A, 2nd ss / Morumbi - São Paulo – SP-
Tel.: (55 11) 2151-3729

To make a complaint, suggestion or compliment you can also contact the Customer Service of the institution by e-mail: sac@einstein.br or by Phone: (5511) 2151-0222

PARTICIPATION CONSENT AS A PARTICIPANT

I understand that I am free to accept or refuse to participate and that I can with draw my authorization and leave the study at any time. By signing this Informed Consent Form, I am not relinquishing my legal rights. I will receive a signed and dated copy of this Informed Consent Form.

Having fully understood of everything that was told me about my participation in the mentioned study and being aware of my rights, my responsibilities, the risks and the benefits that my participation implies, I agree to participate in it and for this I EXPRESS MY CONSENT WITHOUT FOR THAT I HAVE BEEN FORCED OR OBLIGED.

We thank you for your attention and participation and we make ourselves available for more information about the study at any time.

Date: _____ / ____ / ____

_____ _____
Participant’s Name and Signature Participant's Digital

_____
Name and Signature of the researcher applying the Term