SAINT-JOSEPH UNIVERSITY

UNIVERSITY CENTER FOR ETHICS (CUE)

The Committee for the Ethics of Research (CER)

The Committee for Ethics at Hôtel-Dieu de France Hospital (CEHDF)

**INFORMATION AND CONSENT FORM**

**Researcher :**

My Name is ………..………………………...………………….................... I am a ……………………………………….…

student at the Faculty of…………………………………………….………. at Saint-Joseph University of Beirut

**Research :**

I invite you to participate in my research project entitled: « ...................................................................... ..................................................................................................................................................................».

My research Supervisor is .................................................................................................................; email address..................................................................................... Phone..............................................

**The reasons behind the choice of the Volunteer:**

*Why have you chosen this specific volunteer?*

**Approval of the Ethics Committee:**

This project has received the approval of (*please indicate one of the two)*

The Committee for the Ethics of Research (CER)

The Committee for Ethics at Hôtel-Dieu de France (CEHDF)

**Terms and conditions of the research study**:

The present document provides you with information about the terms and conditions of this project. Should you require any additional information or explanation, please feel free to ask us for help. In order to decide whether or not you wish to be a part of this study, you are invited to read carefully each section. Please put your signature at the end of the form if your decision is positive.

**Purpose of the project**

*Do not copy and paste the objectives of the preliminary draft.*

Formulate the objectives in a coherent paragraph using simple sentences.

**Study approach**

*Explain in detail what is required of each volunteer: the number of visits, the location, the medical tests that will eventually be performed (if blood will be drawn, specify the volume of blood drawn, the number of samples), and any other constraint and obligations.*

*Specify the amount of time required to participate in the study.*

**Advantages and disadvantages that may arise from this study**

*Specify known, foreseeable risks and any benefits to the volunteer (E.g. This research poses no risk to your health. There is no direct individual benefit to you from taking part in it.(*

**Health Insurance**

*Does your study involve exposure to minor pain, discomfort, or injury from invasive medical procedures, or harm from possible side effects of drugs? If it is the case, specify the insurance company which will offer the coverage the volunteer might need in case of an accident.*

**Financial compensation**

*Be specific about the financial involved in your study (E.g. There is no financial compensation for your participation in this research project. Your collaboration in this research protocol will not entail any financial participation on your part. All costs related to the study will be covered by the study sponsor, etc.).*

**Volunteer's freedom and right to withdraw**

Your participation in this research project is completely voluntary. You may freely withdraw from it at any moment without having to justify your decision or suffer any prejudice whatsoever.

To access your data, to rectify them, to ask for their deletion, to exercise your right to limit the processing of your data, or for any question regarding the processing of your data, you can always contact us or my research director.

**Information confidentiality**

During your participation in this research project, I will collect and securely record, in a research file (computer and/or paper), information about you necessary for the proper conduct of the research project. This may include the following information: name, gender, date of birth, lifestyle habits, results of all tests, examinations and procedures you will undergo during this project, etc.

All information collected during the research project will be strictly kept confidential. In order to preserve your anonymity and the confidentiality of this information, you will be identified only by a code number. I will only use the data for research purposes in order to meet the scientific objectives of the project.

**Purpose of the treatment**

The data collected will only be used for this research project. It will not be communicated to any other entity. The legal basis for the treatment is your consent.

**Video recording and/or taking photographs**

*Please delete one of the two items which is not required for your research*

* This research does not involve taking any photo, or recording any audio or video.
* This research may require taking photos, or recording audios or videos. I would like to be able to use those, with your permission, for training purposes and/or scientific presentations.

Your recordings and photographs will be destroyed at the end of the project in a confidential manner. Please note that it is not necessary to consent to this section in order to participate in this project.

At any rate, feel free to tell me if I may

* take photos of you? Yes  No
* make audio recordings of you? Yes  No
* make video recordings of you? Yes  No
* use this material for training purposes or scientific presentations and to store it with your research data? Yes  No

**Data storage and destruction deadline**

I undertake to store all data collected during the research project in a secure and confidential location. Your personal data will be destroyed two years upon completion of the study. However, the results of the research will be retained and will not be deleted.

**Publication of data and data recording**

If you wish, you will be informed of the results of the research and the publications it may produce. Data from the research project may be published in scientific journals or shared with other people in scientific discussions. No publication or scientific communication will contain any information that could identify you.

**Subsequent studies**

It is possible that the results of this study may lead to further research. In such a case, do I have your permission to contact you and ask whether you would like to be part of this new study project? (check one of the two boxes) Yes  No

**Understanding the information**

Should you require any further information regarding the research, please feel free to contact the supervisor of my research. If you need more information about the project or some explanation regarding your rights and in case you encounter any conflict, you can always contact the University Center for Ethics (Phone: 01421000 - ext. 2229).

**Consent of the volunteer**

I declare that I have read the above research which has already received the approval of one of the two Ethics Committees, CER or CEHDF, mentioned on page one. I acknowledge that the project has been explained to me, that my questions have been answered, and that I have been given sufficient time to make a decision. I agree to take part in this research project under the conditions stated herein.

Name …………………………………………………………………………… Date…………………………………

Signature…………………………………………………………

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

*Delete the paragraph below if the research does not include minor volunteers.*

***If a volunteer is under the age of 18****, his or her legal guardian should also sign a consent by giving the following statement*

I consent, as the father/mother of Name: ……………………………………………………………………………………, to allow their participation in this research project under the conditions stated herein.

Guardian’s Name: …………………………………………………………………….. Date……………………………………

Signature………………………………………………………

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

**Researcher's Statement**

I certify that I have explained to the volunteer the purpose and conduct of the study. I have also answered all questions the volunteer may have, and I have made it clear that he or she is free to withdraw from the research project described above. I undertake with the research team to respect what has been agreed upon in the information and consent form and to provide a signed copy to the volunteer.

Name…………………………………………………………………..……… Phone……………………………………………

Email…………………………………………………………………………….Date………………………………………………

Signature………………………………………………………………………