**INFORMED CONSENT TO THE STUDY**

(adults)

|  |
| --- |
| STUDY TITLE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **INFORMATION SHEET FOR PARTICIPATION**  |

Dear Sir/Madam,

We would like to ask you to take part in a study. It is your right to be informed about the purpose and characteristics of the study so that you can decide in an informed and free way whether to take part or not. We invite you to carefully read what is reported below. The investigators involved in this project are willing to answer any questions you may have:

|  |  |
| --- | --- |
|  | (Study manager) |
|  | (name) |  | (telephone no.) |
|  |  |  |  |
|  | (Investigator) |  |  |
|  | (name) |  | (telephone no.) |

**What is the purpose of this study[[1]](#endnote-1)?**

**How will the study be conducted[[2]](#endnote-2)?**

The study will be conducted as …….

**Why are we asking you to take part[[3]](#endnote-3)?**

**Are you obliged to take part in the study?**

Your participation is completely voluntary. Moreover, if you should change your mind and wish to withdraw, you are free to do so at any time without having to provide any explanation.

**What are the steps required to take part in the study?**

Participation in the study involves the provision of detailed information about its characteristics, risks and benefits. At the end of the information phase, you can agree to take part in the study by signing the informed consent form. Only after you have expressed your consent in writing can you actively take part in the proposed study.

**What will you be asked to do[[4]](#endnote-4)?**

**What are the possible risks and disadvantages of the study[[5]](#endnote-5)?**

**What are the possible benefits that could be derived from the study[[6]](#endnote-6)?**

The study brings the following direct benefits for the participant ........................ Moreover, the study will enable knowledge to be increased in the field ….

*(In the case of test/procedure with diagnostic power...)*

**What will happen if, during the study, information emerges that concerns your health?**

Should information that is potentially useful for your health emerge from the study, you can express your choice to be informed or not in the section “Expression of informed consent”.

**How is the confidentiality of the information guaranteed[[7]](#endnote-7)?**

**How will your personal data be used?**

The data collected will be used in an anonymous and aggregate form, in such a way as to make it impossible to trace the data of single individuals, for thesis work and/or scientific publications, in accordance with what is laid down in the “Authorisation for the processing of personal data for scientific purposes”, which you will sign separately if you decide to take part in the study.

**Other important information**

We inform you that the study will be conducted in compliance with the ethical principles laid down in the “Helsinki Declaration” and in the “Convention on Human Rights and Biomedicine” (Oviedo Convention).

We also inform you that this study has been approved by the Ethics Committee of the University of Milano-Bicocca.

The original of the Informed consent form signed by you will be retained by the manager of this study, while you have the right to receive a copy of it.

During the study, you can contact the investigator or the study manager for any information.

## We thank you for your availability

**DECLARATION OF THE INVESTIGATOR**

I declare that I have provided the participant with complete information and detailed explanations about the nature, purposes, procedures and duration of this research project. I also declare that I have provided the participant with the information sheet.

|  |  |  |  |
| --- | --- | --- | --- |
| SIGNATURE OF THE INVESTIGATOR |  | Date |  |
| Name of the investigator (*in capital letters)* |  |
| **INFORMATION SHEET SIGNATURE**  |  |

I declare that I have received information that has made it possible for me to understand the research project, including in the light of the additional clarifications requested by me. I confirm that I have been given a copy of this information document.

|  |  |  |  |
| --- | --- | --- | --- |
| SIGNATURE |  | Date |  |

***EXPRESSION OF INFORMED CONSENT***

Participant’s initials \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I, the undersigned \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* Declare that I have received exhaustive explanations regarding the request to take part in the experimental study in question and enough information regarding the inherent risks and benefits of the study, in accordance with what is reported in the information sheet attached herewith.
* Declare that I have been able to discuss these explanations, asking all the questions that I deemed necessary and receiving satisfactory answers in that regard.
* I have also been informed of my right to withdraw from the research at any time and to have free access to the documentation regarding the trial and the assessment expressed by the Ethics Committee.

Therefore, in the light of the information with which I have been provided:

I, the undersigned \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 🞎 | AGREE | 🞎 | DO NOT AGREE | To take part in the study |
| 🞎 | AGREE | 🞎 | DO NOT AGREE | To audio-video recording [[8]](#endnote-8) |
| 🞎 | WISH | 🞎 | DO NOT WISH | to be informed about any results that would be useful for my health deriving from the study[[9]](#endnote-9)*.* In the event you wish to be informed, indicate a contact telephone number: |

 PLACE, DATE SIGNATURE OF THE PARTICIPANT

 PLACE, DATE SIGNATURE OF THE INVESTIGATOR

1. The general purpose of this study *is to investigate* …………….., *is to analyse ………..* [↑](#endnote-ref-1)
2. *(specify and explain the study design:*

*i.e. The study will be conducted as …open-label…. parallel…. double-blind….;* ***Open-label study*** *means that both you and the investigator are aware of the trial procedure and the group to which you belong....)* [↑](#endnote-ref-2)
3. *…. (indicate the inclusion criteria… trying to translate them in layman's terms*

 *i.e. if the inclusion criteria cover adults who practise competitive sport, they can be told the following: “Because the study is aimed at adults who play football….)* [↑](#endnote-ref-3)
4. *The trial/research project procedure involves..........*

*The overall duration of the trial will be around ……*

*You will be asked to …* [↑](#endnote-ref-4)
5. There are no known risks ….

*(Or alternatively) The possible disadvantage …* [↑](#endnote-ref-5)
6. *(Or alternatively) The study does not bring direct benefits for the participant. However, the study will enable knowledge to be increased ….* [↑](#endnote-ref-6)
7. The investigator will ask you to provide some personal data, such as … *(specify the personal data that will be collected ... your initials, gender, date of birth....)*

This information, as with the data that emerge during the study, are important for the proper conduct of the study. The confidentiality of all the information will be guaranteed...

*(specify in what way.... i.e. by de-identifying the data. De-identification means… By assigning a numerical code)* [↑](#endnote-ref-7)
8. (*if envisaged*) [↑](#endnote-ref-8)
9. (*if applicable)* [↑](#endnote-ref-9)