**INFORMED CONSENT TO THE STUDY WITH MINORS**

(to be signed by the Parents)

**STUDY TITLE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**INFORMATION SHEET FOR THE PARTICIPATION OF MINORS**

Dear parents,

We would like to request the involvement of your daughter/son in a study. It is your right to be informed about the purpose, characteristics and ways of conducting the study, so that you can make a free and informed decision on whether to agree or not to the participation of your daughter/son. We invite you to carefully read what is reported below. The researchers 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?**

The general purpose of this study is [[1]](#endnote-1)

The purpose of this study is neither to reveal the intellectual level nor check the ability of your daughter/son.

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

The study will be conducted as …….

**Why are we proposing the participation of your son/daughter in the Study[[3]](#endnote-3)?**

**Is it mandatory to take part in the study?**

Participation is completely voluntary. Moreover, if at any time, you and/or your daughter/son should change your minds, you are free to withdraw consent to participation without having to provide any explanation.

**What are the steps required for your daughter/son to take part in the study?**

Participation in the study involves the provision of detailed information to you and your daughter/son about its characteristics, risks and benefits. At the end of the information phase, you can agree to your daughter/son taking part in the study by signing the informed consent form. It is important that your daughter/son also agrees to take part in the study. Only after you have expressed your consent in writing can your daughter/son actively take part in the proposed study. If your daughter/son is older than 12 years, a dedicated Informed Consent document is provided.

**What will happen if you agree to the participation of your daughter/son in the study? What will she/he 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 deriving from the study[[6]](#endnote-6)?**

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

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

Should information emerge from the study that is potentially useful for the health of your daughter/son (i.e. results compatible with a difficulty in a psychological or learning area), you can express the choice of being informed or not in the section "Expression of informed consent”.

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

**How will the personal data of your daughter/son be used?**

The data collected will be used in anonymous and aggregate form, in such a way as to make it impossible to trace the data of individuals, for thesis work and/or scientific publications, in agreement 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 agree to your son/daughter taking part in the Study. Therefore, the names of the minors who have taken part in the study will never be used, nor will information be provided that could allow them to be identified.

**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, as parents, have the right to receive a copy of it.

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

## Thank you for your availability and help

**DECLARATION OF THE INVESTIGATOR**

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

I also declare that I have provided the parent of the participant with the information sheet.

|  |  |  |  |
| --- | --- | --- | --- |
| SIGNATURE OF THE INVESTIGATOR |  | Date |  |

*(name of the investigator in capital letters)*

**INFORMATION SHEET SIGNATURE OF THE PARENTS**

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

|  |  |  |  |
| --- | --- | --- | --- |
| SIGNATURE OF THE PARENT |  | Date |  |

|  |  |  |  |
| --- | --- | --- | --- |
| SIGNATURE OF THE PARENT |  | Date |  |

***EXPRESSION OF INFORMED CONSENT***

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

Name and Surname of the minor taking part in the study ………………………………………………….

We, the undersigned

* Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Surname \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Surname \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

as parents/guardians of the aforementioned participant,

* Declare that we have received exhaustive explanations regarding the request for our daughter/son to take part in the experimental study in question and enough information regarding the implicit risks and benefits of the study, in accordance with what is reported in the information sheet attached herewith.
* Declare that we have been able to discuss these explanations, being able to ask all the questions that we deemed necessary and having received satisfactory answers in that regard.
* We have also been informed of the right to withdraw consent for the participation of our daughter/son in the trial at any time and our right 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 we have been provided (select the chosen option):

I, the undersigned ……………………………………………………. as parent/legal guardian

*(Parent/guardian J)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 🞎 | AGREE | 🞎 | DO NOT AGREE | To the participation of my daughter/son in the study  |
| 🞎 | AGREE | 🞎 | DO NOT AGREE | To audio-video recording [[8]](#endnote-8) |
| 🞎 | WISH | 🞎 | DO NOT WISH | To be informed of any results useful for the health of my daughter/son 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 PARENT

 PLACE, DATE SIGNATURE OF THE INVESTIGATOR

I, the undersigned ……………………………………………………. as parent/legal guardian

*(Parent/guardian K)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 🞎 | AGREE | 🞎 | DO NOT AGREE | To take part in the study |
| 🞎 | AGREE | 🞎 | DO NOT AGREE | To audio-video recording [[10]](#endnote-10) |
| 🞎 | WISH | 🞎 | DO NOT WISH | To be informed on any results useful for the health of my daughter/son deriving from the study[[11]](#endnote-11) In the event you wish to be informed, indicate a contact telephone number: |

 PLACE, DATE SIGNATURE OF THE PARENT

 PLACE, DATE SIGNATURE OF THE INVESTIGATOR

 Notes:

* In the event one of the parents is unable to sign, the parent present, by signing this document, accepts the responsibility of properly informing the other parent.
* In the event there is only one parent or legal guardian, a single signature will be enough.
1. *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 you, your son/daughter and the investigator are aware of the trial procedure and the group to which they belong ....)* [↑](#endnote-ref-2)
3. *…. (indicate the inclusion criteria… trying to translate them in layman's terms*

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

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

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

*(Or alternatively) The possible disadvantage …* [↑](#endnote-ref-5)
6. The study brings the following direct benefits for the participant ........................ Moreover, the study will enable knowledge to be increased in the field ….

*(Or alternatively) The study does not bring direct benefits for the participant. However, the study will enable knowledge to be increased in the field ….* [↑](#endnote-ref-6)
7. The Investigator will ask you to provide some personal data, such as … *(specify the personal data that will be collected ... the minor’s 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. 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)
10. (if envisaged) [↑](#endnote-ref-10)
11. (if applicable). [↑](#endnote-ref-11)