**GUIDELINES FOR DRAFTING AN INFORMED CONSENT FORM**

**[ONLY IN CASE OF MINORS UNDER 16, OR IN CASE OF PEOPLE NOT ABLE TO EXPRESS CONSENT INDEPENDENTLY]**

**By the Ethics Committee of the Department of Human Sciences,**

**University of Verona**

Below are outlined the directions and examples for drafting an informed consent form for people under the age of 16 or for persons unable to express their consent independently. For people within either of these two categories, consent must be provided by either the parents for minors under the age of 16 or by a caregiver or guardian who holds the power to provide legal consent.

Please use clear and concise language when filling out the consent form.

It is specified that the following is shown for illustrative purposes.

Researchers and people who exercise parental authority are reminded that the child has the right to be heard, to express his/her opinion and to be involved in all the situations that concern him/her, beyond the fact that the signatories of the informed consent are the parents or the holder of parental responsibility.

Rules of international law - as well as the Italian Constitution - specify these rights and emphasize that States must promote and support the participation of children at all levels. These include:

• the UN Resolution on the Rights of the Child, called Omnibus Resolution, adopted by the UN in 1989,

• the European Strasbourg Convention for the Exercise of Children's Rights 1996,

• the Oviedo Convention of 1997,

• the Fundamental Charter of European Union Rights proclaimed in Nice in 2000.

• the Italian Constitution, especially articles 2, 3, 13, 32.

**INFORMED CONSENT – Information form**

Dear Parents/legal representative,

this study aims to investigate... [BRIEFLY DESCRIBE THE RESEARCH SUBJECT: Example: the social attitudes of school-age children]. The project manager[[1]](#footnote-1) is ... [NAME], ... [ROLE] at the Department of Human Sciences of the University of Verona. The person(s) in charge of data collection is/are ... [NAME(S) AND ROLE(S)]

**We are asking for your permission to allow** [PLEASE WRITE THE NAME FOR WHOM THE CONSENT FORM IS BEING PROVIDED FOR; e.g. your child] take part in the research. Before giving your consent, it is advised to carefully read the following information regarding the objectives and methods of the research. Take time to read all the information and please do not hesitate to ask for further information, if needed.

***What is the objective of this research?***

The objective of this research is ... [PLEASE SPECIFY THE OBJECTIVE OF THE RESEARCH IN A CLEAR AND CONCISE WAY, USING APPROPRIATE LANGUAGE. For example: check if the vision of educational materials leads to the development of more positive attitudes towards different social groups].

***Why were you contacted?***

[PLEASE SPECIFY IN A CLEAR AND SIMPLE WAY THE INCLUSION CRITERIA FOR THE RESEARCH PROJECT.] For example “To carry out this study we are requesting the participation of ... [SPECIFY THE CHARACTERISTICS OF PARTICIPANTS. Example: all children of second and fifth grade of primary school XX]”.

***Do you have to give your consent?***

Participation in research studies should be on a voluntary basis, so you can always refuse to give your consent. If you decide to accept, you will have to sign a consent form stipulating your willingness to participate in the research project and also for the use of the data that you provide for [PLEASE WRITE THE NAME FOR WHOM THE CONSENT FORM IS BEING PROVIDED FOR; e.g. your child] collected by the research team during the project. You can withdraw your consent at any time, without any negative consequence, and without any obligation to specify your reasons.

***What do the participants have to do?***

[THIS SECTION ALLOWS THE PARTICIPANT TO UNDERSTAND WHAT HE/SHE WILL BE ASKED TO DO IF HE/SHE AGREES TO PARTICIPATE. THEREFORE, ALL TASKS REQUIRED FOR THE PARTICIPANTS SHOULD BE IN WRITTEN FORMAT, SPECIFYING TIMES AND PLACES AND ANY OTHER RELEVANT INFORMATION]

Example: Children will be shown a documentary (TITLE) that illustrates the similarities between all animal species, including humans. This video aims to make it easier for children to understand and appreciate the whole animal world and it should also encourage more favorable attitudes towards children belonging to different social or ethnic groups.

Under the guidance of NAME SURNAME, they will be asked to perform some simple tasks. Children will be randomly divided into two groups; the TITLE video will be shown to both groups, but at different times. The research will be carried out in two sessions one week apart from each other, which will take about 10 and 20 minutes, respectively. For methodological reasons, some children will also be shown a video not related to the animal world, entitled "XXX", concerning the recycling of waste.

***Is the identity of the participants protected?***

The data will be treated according to the articles of the European Regulation UE n. 679/2016 and of D.L. 196/2003 as specified in D.L. 101/2018 concerning personal data protection regulation. The data controller is Università degli Studi di Verona, Via dell’Artigliere n. 8, IT37129, Verona (e-mail: privacy@ateneo.univr.it, PEC: ufficio.protocollo@pec.univr.it, tel. +39 045.8028777). Further information about processing and protection of personal data can be found on the website https://www.univr.it/it/privacy, with reference to the parts concerning the data processing and protection for people involved in research activities.

The data will be collected exclusively for aims related to scientific research. All the collected information will be kept safely and strangers will not be able to have access to the data. The information that could be useful to identify the participants will be removed to guarantee the anonymity of the data. The project manager will be responsible for ensuring that these requirements have been met.

***Do the participants run risks?***

[SPECIFY THE TYPE OF RISKS]

Example: There are no physical risks arising from participation in this study. However, if your child feels uncomfortable at any point during their participation or if they ask to stop, it will be the responsibility of NAME SURNAME to immediately end the data collection.

***What are the benefits of participation?***

[SPECIFY THE TYPE OF BENEFITS]

Example 1: The information deriving from your child's participation will help us to understand if viewing the TITLE video produces more favorable social attitudes, contributing to the construction of a more harmonious coexistence among children of different social groups.

Example 2: There aren’t direct benefits. However, also thanks to his/her participation, it will be possible to deepen the knowledge of the dynamics and/or processes inherent to the area under investigation (specify). This could, in turn, be useful for the redesign and/or for improvement of existing training models and/or training practices (of intervention, etc.).

***Is it possible to know the results of the research?***

[SPECIFY HOW THE RESULTS ARE COMMUNICATED]

The results of the research will be published through both scientific and other channels. At the end of this study, you will be invited to attend an information meeting that will be held specifically to share the results with participants. In any case, the results will be disseminated in an aggregated manner and never in a way that allows a participant to be identified.

***Who can I contact for further information?***

[WRITE NAME, SURNAME, PHONE NUMBER AND EMAIL OF THE SCIENTIFIC RESEARCH MANAGER AND OF THE REFERENCE PERSON INSIDE THE DEPARTMENT IN WHICH THE RESEARCH IS CARRIED OUT, IF APPROPRIATE]

Example 1: If you have any questions or concerns about this research, you can contact ...

***If I decide to take part in the research, what are my rights?***

It is your right to decide to withdraw your consent and suspend your participation in the research at any time. No legal rights will be lost by signing the consent form. Furthermore if you have any questions about your rights while participating in this research, or if you have any doubts, suggestions or if you would like to talk more about the research with others (other than the researchers involved), you can contact [NAME SURNAME], a member of the Ethics Committee at the Department of Human Sciences of the University of Verona, at the following number [TELEPHONE NUMBER] or you can write to the following email address: [EMAIL ADDRESS OF THE MEMBER OF THE ETHICS COMMITTEE].

Thank you for your cooperation.

[NAME AND SURNAME OF THE MAIN RESEARCHER]

Date and place

# Example of form for signing consent

***Consent for the child’s participation to the research***

***(BOTH PARENTS HAVE TO SIGN THIS FORM)***

I read (or someone has read to me) the information outlining this form and I am aware that I was asked to give consent for my child’s participation in an intervention-research project. I had the possibility to ask questions and to receive satisfying answers. I voluntarily agree that my child can participate in this study.

No legal rights will be lost by signing this form.

|  |  |  |  |
| --- | --- | --- | --- |
| **SURNAME AND NAME OF THE PARTICIPANT**  **IN CAPITAL LETTERS** |  |  | |
| **SURNAME AND NAME OF THE PARENT 1**  **IN CAPITAL LETTERS** |  | **SIGNATURE OF THE PARENT 1** | |
| **SURNAME AND NAME OF THE PARENT 2**  **IN CAPITAL LETTERS** |  | **SIGNATURE OF THE PARENT 2** | |
| **OR SURNAME AND NAME OF THE LEGAL GUARDIAN IN CAPITAL LETTERS** |  | **SIGNATURE OF THE LEGAL GUARDIAN** | |
|  |  | **Date and time** |  |

***Consent for data treatment***

I agree to the treatment of the data derived from my child’s participation.

|  |  |  |  |
| --- | --- | --- | --- |
| **SURNAME AND NAME OF THE PARTICIPANT**  **IN CAPITAL LETTERS** |  |  | |
| **SURNAME AND NAME OF THE PARENT 1**  **IN CAPITAL LETTERS** |  | **SIGNATURE OF THE PARENT 1** | |
| **SURNAME AND NAME OF THE PARENT 2**  **IN CAPITAL LETTERS** |  | **SIGNATURE OF THE PARENT 2** | |
| **OR SURNAME AND NAME OF THE LEGAL GUARDIAN IN CAPITAL LETTERS** |  | **SIGNATURE OF THE LEGAL GUARDIAN** | |
|  |  | **Date and time** |  |

I explained the research to the participant or his/her legal representative before requesting the signature(s) above. There are no parts not filled out in this document. A copy of this form has been delivered to the participant or his/her legal representative.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | |  |
| **SURNAME AND NAME OF WHOM HAS OBTAINED CONSENT IN CAPITAL LETTERS** |  | **SIGNATURE OF WHOM HAS OBTAINED CONSENT** | |  |
|  |  | **Date and time** |  | |

**Note: a copy of this signed form must be delivered to the participant.**

1. This is not a student, even in the case of a person collecting data for the purpose of his/her degree project. This is generally the main researcher (Principal Investigator - PI). [↑](#footnote-ref-1)