INFORMATION FORM

**FOR THE PARTECIPATION TO THE RESEARCH PROJECT**

**for ADULT Subjects**

**Title of the study:**

…………………………………………………………………………………………………………………...………………………………………………………………………………………………………………………

**PARTICIPATING INSTITUTIONS:**

…………………………………………………………………………………………………………………...………………………………………………………………………………………………………………………

**RESEARCH TEAM**

*Enter all names exactly as they are entered on the CERPS approval form*

…………………………………………………………………………………………………………………...………………………………………………………………………………………………………………………

**Dear Sir/Madam,**

We inform you that we are conducting a study entitled: ……………………………………………………, organized by …………………………………………………………………………………………………….

and financed by…………………………………………………………………………………………...…

For this reason, we propose you to participate in the study that will be conducted under the responsibility of Prof. ……………………………………

Before you decide whether to accept or refuse, we invite you to read carefully this document; whenever you wish to have further information and clarifications, you can refer to *………………….* (whose contact information are specified at the end of the document) who will dedicate all the time necessary to clarify any doubt, provided that you can address professionals involved in the conduct of the study at any time.

**Are you obliged to participate to the study?**

Your participation is completely voluntary. Moreover, if you change your mind and want to withdraw from the procedure at any time, you are at liberty to do so.

**Premises and aim of the study**

-*Aim*: The main aim of the study is ……………………………………………………………………...

…………………………………………………………………………………………………………………

*-Study design:* ……………………………………………………………………………………………...

-*Estimated duration of the Study*: …………………………………………………………………….....................

-*Number of participating subjects*: ……………………………………………………………………...................

**What will happen if you decide to participate in the study?**

The *procedure* involves:

……………………………………………………………………………………………………………………...

……………………………………………………………………………………………………………………...

……………………………………………………………………………………………………………………...

……………………………………………………………………………………………………………………...

……………………………………………………………………………………………………………………...

**What are the possible benefits linked to the participation to the study?**

……………………………………………………………………………………………………………………...

……………………………………………………………………………………………………………………...

……………………………………………………………………………………………………………………...

……………………………………………………………………………………………………………………...

……………………………………………………………………………………………………………………...

**What are the possible risks/side effects linked to the participation to the study?**

……………………………………………………………………………………………………………………...

……………………………………………………………………………………………………………………...

……………………………………………………………………………………………………………………...

……………………………………………………………………………………………………………………...

……………………………………………………………………………………………………………………...

**Further important information**

We inform you that the study will be conducted in accordance to the “Standards of Good Clinical Practice” in compliance to the ethical principles established at a national level by the Code of Ethics for the psychological research, approved in 2015 by the Italian Psychological Association (AIP, Associazione Italiana di Psicologia) and updated according to the GDPR norms in July 2022, and inspired by the “Declaration of Helsinki” at the international level and successive revisions (latest version in 2013) applied to research in the psychological field.

**Participation to the study**

Your participation is completely free and voluntary.

If you consent to participate, you will be asked to sign the ***Form of Informed Consent to the participation to the study and to data processing***, attached to the present document, before you start performing the procedure intended by the study.

Signing the attached module is aimed at ensuring that you have received complete information and that you have freely expressed your will to participate; such signature does not imply any commitment to continue the study from your behalf, it does not establish any contractual obligation, and it does not represent a waiver of your rights.

In case you decide to withdraw from the study, after having initially accepted, you can terminate your participation at any time by communicating it to the Study Director without any justification. The choice of non-participation, or withdrawal following initial acceptance, does not have any negative consequences and does not imply any disadvantage in your relationship with personnel assisting you. Whenever new data or findings that could influence your participation to the study are known, you will be immediately informed; moreover, the Study Director could withdraw you from the study if he/she considers that such choice responds to your best interest.

Financially, the participation to the study does not determine any kind of cost or any additional charge from your behalf.

We want to clarify that you are not asked to participate to this study to have clinical assistance, or to obtain personal benefits of diagnostic nature.

**PERSONAL DATA PROCESSING**

The researcher will ask you some personal data, such as [*Specify which personal data will be collected; e.g., personal data such as gender and date of birth, contact details, but also data concerning racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, sexual life or sexual orientation of the individual, genetic data, biometric data intended to uniquely identify a natural person*]. This information is important for a correct conduct of the study.

[*Optional – to be included if the processing of photos or videos is planned*] With reference to the images collected (photos or videos), where is possible, the person concerned will be ensured by obscuring somatic features.

Personal data collected during the conduct of the present study are confidential and will be treated in compliance of the legislation provided by the Regulation (EU) 2016/679 respect to the «Protection of natural persons about the processing of personal data», entered into force since 25th May 2018, and by Legislative Decree 06.30.2003 n.196 – The personal information protection code, as far as not abrogated by the entry in force of the aforementioned European Regulation.

Pursuant to this legislation, the Controller of the processing of your personal data will be the Catholic University of the Sacred Heart of Milan.

The legal basis for processing data is your consent for one or more specific purposes, without which you will not be able to participate in the study.

*Nature of data and processing modality*

Your personal information collected during the study are confidential and will be treated in compliance with the aforementioned legislation in force.

Data that have been given by you will be rendered unidentifiable, namely the collected material will be anonymized and will be unconnectable to the identity of the participant to the Study. This material will be analyzed and processed for the purpose of the scientific research only by personnel in charge of the conduct of the Study.

Data and research output, processed also with electronical instruments, could be spread in a strictly anonymous form in meetings, conferences, and scientific publications; however, your name or any other detail that could lead to your identification, will not be disclosed since data will be presented in aggregated form exclusively, namely with a modality that will not make identifiable subjects participating to the study.

Personal Data are processed manually, digitally and electronically applying logics strictly connected to the purposes and, in any case, to guarantee the security and confidentiality of the Data pursuant to laws in force. Data processing does not involve an automated decisional process, profiling included. Adequate security measures will be adopted in order to guarantee protection, security, integrity and accessibility of personal data.

Personal data will be preserved only for the time required for the achievement of the purposes for which they have been collected or for any other legitimate purpose connected to it, anyway within a minimum period of 5 years (pursuant to Art.17 of the Deontological Code of Italian Psychologists).

Personal data that will no longer be necessary, or a legal basis will not persist for their retention, will be irreversibly anonymized or safely destroyed.

*Data Transfer*

Your data may be communicated to public and private entities or Authorities, in order to comply with legal obligations or internal regulations of the University, as well as to IT services companies supplier authorized by the University or other partners involved into research, in order to complete the project activities.

These parties will carry out the processing of the data and will use them, as appropriate, in their capacity as Data Processors expressly appointed by the Data Controller in accordance with the law, or rather as autonomous Data Controllers.

The list of designated Data Processors is constantly updated and available at the University.

The management and storage of personal data where digitized will take place on servers located within the European Union. Should the data be transferred outside the European Union, the Data Controller hereby assures you that the transfer of data outside the EU will take place in accordance with the applicable legal provisions by entering, if necessary, into agreements that guarantee an adequate level of protection and/or by adopting the standard contractual clauses provided by the European Commission.

[*Optional, to be included where there is data transfer between entities participating in the project*] Specifically, your data will be transferred to [*specify entity*] in [*specify location*].

*Exercise of the rights*

The GDPR – EU Reg. 2016/679 requires and strengthens the personal data protection and processing in terms of the principles of fairness, lawfulness, transparency, protection of privacy and rights of the interested party with regard to his/her data.

You can exercise your rights from Art. 15-18 and Art. 20-21 of the GDPR – EU Reg. 2016/679 (access to your personal data, ask for their integration, update, rectification, cancellation, demand to their limitation, request for the portability, oppose to their processing) turning directly to the Manager of processing, alternatively through personnel in charge.

In case you withdraw from the study, further data about you will no longer be collected, notwithstanding the use of data that have been eventually already collected in order to determine the results of the study, without altering them.

For any possible complaints or reports about the data processing modality, it is advisable to turn to the Manager of the data processing.

You have the right to forward your complaints or reports to the Data Protection Authority (Autorità Garante per la protezione dei Dati, using the channels indicated at https://www.garanteprivacy.it

The University has also appointed its Data Protection Officer (D.P.O.) who can be reached at the email address: dpo@unicatt.it

The protocol of the study to which you are offered to participate, has been approved – along with the present document – by the Ethical Committee of the Psychology Department (CERPS, Commissione Etica del Dipartimento di Psicologia) of Università Cattolica del Sacro Cuore.

# *For further information, clarifications and communications you can contact Prof./Dr./Dra. ……………….………., to the email address* *……………………….….*

# *We thank you for your availability and your collaboration*

# INFORMED CONSENT FORM FOR THE PARTICIPATION TO THE STUDY AND FOR THE DATA PROCESSING

**Research Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

I the undersigned: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Surname and First Name of the participating adult subject in locked letters.

born in, on the: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Place and date of birth of the participating adult subject.*

residing at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, in street \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 on his/her behalf

 exercising the legal representation of Mr./Mrs. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

born in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ residing at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in street \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**i declare the following:**

1. In accordance with the Legislative Decree n.196/2003 and with the GDPR – EU Reg. 2016/679, having received appropriate information about the processing of personal data and in relation to what previously mentioned about the processing of such information, I express free consent to the collection, the processing and the communication of personal data for all the purposes and in all the modalities mentioned by the present document, by checking the following box.

□ GIVE CONSENT □ DO NOT GIVE CONSENT

1. [*Optional, to be included where there is processing of data belonging to special categories as referred to in Article 9 of the GDPR, e.g., health data, data concerning racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, sexual life or sexual orientation of the individual, genetic data, biometric data intended to uniquely identify a natural person*] Pursuant to Legislative Decree no. 196/2003 and GDPR - EU Regulation 2016/679, having received specific information on the processing of special categories of data and in relation to what is indicated regarding the processing of such information, I give my free consent, by ticking the box below, to the collection, processing, and disclosure of special categories of data concerning health status [*insert any different categories based on the project*] for all purposes and in the manner indicated in this information.

□ GIVE CONSENT □ DO NOT GIVE CONSENT

1. [Optional] In relation to any audiovisual recordings made in the context of the project, I give my free consent, by checking the box below, to the conduct of such activities. I declare that such recordings will be made free of charge and I prohibit their use in contexts that may damage my/my Represented's dignity and decorum.

 GIVE CONSENT  DO NOT GIVE CONSENT

1. [Optional] In regards to the aforementioned audiovisual recordings, I give my free consent, by checking the box below, to the use and publication in any form, including competitions, the internet, educational and/or scientific publications, etc.

 GIVE CONSENT  DO NOT GIVE CONSENT

[Optional - only in the case of audiovisual recordings] Providing consent is not mandatory, but refusal may prevent your participation/the Representative from participating in the study.

Place and date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**i also declare the following:**

1. I have read and understood the information form of which this module is an integral part;
2. I have had the possibility to ask questions by email and ask clarifications to Prof. \_\_\_\_\_\_\_ from whom I have received satisfying replies;
3. I have been shown in the information form the nature, the purpose and the duration of the study, the procedures that will be followed, the treatment required for the participants and the kind of collaboration that will be requested to them;
4. I have understood that the participation to the study is free and voluntary and that I can decide to withdraw / withdraw who I legally represent from the study at any time without being subjected to negative consequences and without my/his/her rights and my/his/her relations with involved personnel being compromised;

**In light of the above, I accept the offer to participate to the study described in the present document by signing.**

Place and date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# this part is reserved to the operator who presented the document

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

*Surname and Name in locked letters*

**i declare:**

1. to have explained to the person aforementioned in the information form the nature and purpose of the study, including the procedures that will be adopted and the kind of collaboration that will be requested;
2. not to have tried to influence or force in any manner the aforementioned person to induce him/her to manifest his/her consent to the participation to the study;
3. to provide to the aforementioned person a signed and dated copy of the present document.

Place and date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_