**CERPS - Commissione Etica per la Ricerca in Psicologia**

***commissione.cerps@unicatt.it***

**Application form**

The documentation for approval must be submitted to the Ethics **Commission** for Research in Psychology (hereinafter referred to as CERPS) using exclusively the attached **Application** Form, which includes a specific list of questions that the Applicant must answer.

It is possible to reproduce the Form for electronic completion and printing. However, it is necessary to maintain the original form unchanged, both in terms of content and format, including all and only the questions provided by the original Form, whether they are directly relevant or not to the specific research subject to approval.

The form is structured in 7 sections:

1. GENERALPROJECT PRESENTATION
2. PROJECT INFORMATION
3. PARTICIPANT INFORMATION
4. RISK AND RISK MANAGEMENT
5. CONSENT AND INFORMATION FORM
6. ANONYMITY AND CONFIDENTIALITY
7. DATA COLLECTION AND SECURITY

**PREFACE**

The Ethics Committee for Research in Psychology (CERPS) provides guidelines and opinions **only** regarding research projects (mono- or interdisciplinary) on psychological topics and exclusively from proposers affiliated with the Department of Psychology at the Catholic University of the Sacred Heart.

Research projects submitted by doctoral candidates must have be submitted in combination with their faculty advisor.

1. **GENERAL PROJECT PRESENTATION**

A.1 **Project title**

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A.2 **Principal Investigator (identify only one PI including scientific area, institution, and contact information)**

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A.3 **Other investigators involved (including institution and contact information)**

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A.4 **Location(s) for data collection**

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A.5 **Are there already any ethical approvals provided by other project partner entities (e.g., hospitals, schools, prisons, companies, etc.) related to participant involvement or data access?** *If the answer is affirmative, please attach a copy of the authorization letter from the entity and specify why the applicant is also submitting this approval request to CERPS.*

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A.6 **Will the research site(s) where data will be collected utilize the reference Territorial Ethics Committee (CET)?**

If the answer is affirmative, please attach a declaration from the Scientific Directorate of the Institute (or the responsible party/parties of the Operating Unit/Department/Service where the data used in the research will be collected), specifying that the project does not require submission to their CET or, alternatively, that the evaluation by CERPS constitutes necessary-preliminary documentation for subsequent submission to the reference CET.

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A.7 **Is there already a University approval regarding GDPR compliance? YES/NO**   
*If the answer is affirmative, please specify the approval date and outcome.*

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**A.8 Does the PI have suitable equipment, facilities, and personnel to conduct the research?** (For example, in relation to the project's objectives, has the PI assessed that the researchers involved are appropriate for their required tasks; regarding the tools used, has the adequacy of equipment, usage context, and participant safety been verified, etc.; concerning the research environments, has the manager evaluated their suitability for conducting the activities, etc.? Please provide information to support a potential positive response to this question).

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**B. PROJECT INFORMATION**

B.1 **Estimated study start date (ongoing or already initiated projects will not be evaluated)**:

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B.2 **Estimated study duration (from the start to the data analysis) (in months)**

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**B.3 Has the project being funded?** YES NO

*If yes, please describe the funding source*

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B.3.I **Has the project been submitted for a grant proposal? If so, please provide the details of the call (title, Grant type, Institutions involved)**

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B.4 **Study summary (200 words maximum**)

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B.5 **Keywords (at least 3)**

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**B.6** **Project description**.

**B.6.I Provide the scientific background and the rationale for the study (400 words maximum).**

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**B.6.II** **Project aims (300 words maximum)**

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**B.6.III** **Methods and materials** (please attach all the instruments, including *questionnaires, interviews, recruitment materials, etc.*).

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**B.6.IV** **Study procedure (300 words maximum)**

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**B.7** **Most relevant references (max 10)**.

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**C. PARTICIPANT INFORMATION**

**C.1** **What kind of participants will be recruited?** *Multiple options could be selected*.

* Adults (18+, able to express consent)
* Minors (less than 18 years old)
* Older adults (65+, able to express consent)
* People who are not fluent in Italian
* People with cognitive deficits, unable to express consent
* Other people with a compromised ability to express consent (please state why) ………………………………………………………….
* People with a physical disability (please specify)
* People confined to a specific institution (e.g., hospital, prisoners)
* Students
* Patients, provided by physicians, psychologists, or other professionals
* Other (specify) ………………………………………………………….
* Unable to determine the subject characteristics (e.g., online recruitment; please explain)

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**C.2** **Is it possible that (some) participants may feel pressured to join the study, preventing the consent to be fully free? Examples include students of the PI or collaborators, or patients of a study physician. If yes, please indicate how you intend to ensure that the subject does not feel obligated to participate in the study**.

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**C.3** **List the participant characteristics (inclusion criteria) and the expected sample size (when applicable, indicate the statistical power)**.

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**C.4** **How will the information and the invitation to participate in the research be disseminated? (Attach a copy of any poster that will be used or a letter introducing the study that will be presented by a third party, for example, medical personnel presenting the study to patients)**.

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**C.5** **Will participants receive reimbursement, compensation, or incentives?**

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***N.B. Please note that the PI is obligated to communicate to CERPS any changes in the recruitment strategies.***

**D. RISK AND RISK MANAGEMENT**

**D.1** **Research methods include** (*it is possible to select more than one option*):

* Questionnaires (to be attached)
* Structured or semi-structured interviews (questions or investigated topics to be attached)
* In-deep interviews
* Focus groups
* Autobiografical narratives
* Diary keeping
* Behavioral observation of the subjects
* Behavioral observation of the subjects without them being aware
* Audio or video recording
* Stimulation, tasks, and procedures to record behavioral responses or opinions
* Eyes movements
* Biomedical instruments
* Virtual reality
* Questionnaires, test, or experimental protocols through the internet (web, email)
* Neuropsychological testing
* Clinical trials
* Drug or other substances administration; human tissues or fluids collection (e.g., blood analysis)

**Please specify the presence of procedures with a significant impact on risk management and participant discomfort, indicating if there are present:**

* Deception
* Behaviors or procedures that can embarrass the participants, or have a negative impact on their self-esteem
* Stimula, tasks, or procedures that the participant may find psychologically or physically upsetting, both during the study or after its end
* Other (specify)

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**D.2** **In case the study includes procedures that could be stressful or dangerous, describe the risks and possible consequences**.

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**D.3** **What will be communicated to the participants regarding the various stages of the research?**

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**D.4** **How do you expect to manage possible issues or adverse reactions**?

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**D.5** **Are the investigators experienced with the study procedures? If not, how will they be trained or supervised?**

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**D.6** **Does the researchers have any potential conflicts of interest? If yes, specify.**

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**D.7** **Do you anticipate that there may be benefits for those who participate in the research? If so, what are they?** (*The personal contribution to the research should not be considered a potential benefit*).

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**D.8** **Will there be an additional liability insurance (other than the one provided by UCSC)?**

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**E. CONSENT AND INFORMATION FORM**

**E.1** **Please describe the procedure of informed consent (briefing, consent signature, debriefing, …)**.

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**E.2** **Will the consent be written, oral, or obtained through a computer? If there is no written consent, explain why.**

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**E.3** **Attach the Information Form and the Declaration of Consent/Assent for the processing of participant data and/or the letter from the legal representative (parent, guardian, custodian) (for this, also see point F1).**

**E.4** **How will doubts and requests for information be handled by the research team?**

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**E.5** **If, for methodological reasons, it is not possible to inform the participants about the study's objective before the start of the experimentation, please specify the methods of the subsequent clarification interview.**

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**E.6** **How will participants be informed about the possibility of receiving, directly or indirectly, any other data related to their psychophysical conditions that may become available during the research?**

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**F. ANONYMITY AND CONFIDENTIALITY**

**F.1** **Attach the information and authorization regarding the processing of personal data** in compliance with the regulations set out in Regulation (EU) 2016/679 on the 'Protection of natural persons with regard to the processing of personal data,' which came into effect on May 25, 2018, and Legislative Decree 30.6.2003 no. 196 - Personal Data Protection Code, to the extent not abrogated by the entry into force of the aforementioned European regulation.

F.2 **Please specify below how the data will be collected (specify if anonymously or confidentially).**

**The data will be collected anonymously (the researcher will not have access to the participant's identity)**

**YES NO**

**The data will be collected confidentially (it is possible to assign a code to the participant during the research process, for example, to allow for the completion of pre and post-intervention questionnaires, but this code will be dissociated from the participant's identity during the data analysis phase)**

**YES NO**

**F.3 In case identifiable data should be conserved, specify why and how participants will be informed**.

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**F.4** **What security measures are in place to ensure the confidentiality of data is maintained?**

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**G. DATA COLLECTION AND SECURITY**

**G.1** **Who will have access to the data and to the results (including incomplete results)?**

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**G.2** **For how many years are the collected data estimated to be retained after the research's conclusion?**

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**G.3** **Will the data be disseminated in countries outside the European Union?** If yes, please specify who the project partner (reference entity) is and what agreements exist between our University and the non-EU partner (such as a convention). If possible, specify how an adequate level of data protection will be ensured.

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**G.4 Indicate the storing modality for sensible data (nominate the person responsible for the process and the storing location)**.

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**G.5** **CERPS certifies that every approved research project that is part of teaching or training has been approved by the Department Dean. A copy of the approval letter will be sent to the Department Dean**.

Signatures of Principal Investigator (as reported in A.2)

Location and date Signature

(readable)

Document checklist (checkmark for approval by the proposer):

* Application Form
* Informed Consent, Information Form, Data Protection Form
* Other attachments (*specify*):

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