**Request for the opinion of the Ethics Committee\***

***Form for trial with human beings or for study with human biological materials***

**A. Presentation of the project**

**A.1 Project title**………………………………………………………………………………………………….

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**A.2 Project manager (Attach curriculum)**…………………………………………………….………

**A.3 Other investigators involved, entities to which they belong, their addresses (Attach summary and targeted curricula)**

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**A.4 Study site(s)**…………………………………………………………………………….……………………

**A.5 Is the authorisation of other Entities required (for example, hospitals, schools, prisons) for access to the data or the involvement of participants? If yes, attach a copy of the authorisation letter………**………………………………………………………………………………………………………………

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**A.6 Does the study manager have enough time, equipment, facilities and suitable personnel to carry out the study? (Attach declaration, countersigned by the manager of the facility concerned)**

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**B. Information about the project**

**B.1 Sources of financing**

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**B.2 Expected start date of the study** ………………………………………………………………….…………..

**B.3 Expected duration of the study (in months)**……………………………………………………..…………

**B.4 Summary of the research project in Italian (schematic representation of the protocol, where appropriate)** ……………………………………………………………………………………………………...

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**B.5 Key words (at least 3) identifying the research project ........................................................**

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**B.6 Project description:**

**B.6.I Starting point and theoretical justification**……………………………………………………………………

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**B.6.II Objectives**………………………………………………………………………………………………………

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**B.6.III Proposed investigative methods**…………………………………………………………………………

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**B.6.IV Study design** ………………………………………………...…………………………………………………………………………..

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**B.7 Bibliographical references**…………………………………………………………………….…………………

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**C. Information about the participants**

**C.1 Which type of subjects will take part in the study?**

* Students
* Adults (aged over 18 years and able to express their consent)
* Children and young people aged less than 18 years
* Elderly (aged over 65 years and able to express their consent)
* Non-native Italian speakers
* Subjects with cognitive/mental impairment NOT able to express their consent
* Other persons whose ability to express their consent may be compromised (indicate the reason)
* Subjects with physical disability (specify the type)
* Institutionalised subjects (for example, prisoners, hospitalised patients etc.)
* Patients and/or clients recommended by doctors, psychologists or other categories of professionals
* It is not possible to determine the type of subjects (for example, conducted via the Internet)

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**C.2 Is it possible that some of the subjects are in a dependent position with regard to the investigator or one of its collaborators, for which reason it could be supposed that the expression of consent to take part in the study is not entirely freely given or given without any kind of pressure (for example, student/professor, patient/doctor, employee/employer)?**

**If yes, indicate the measures intended to be taken to prevent the possibility of the subject feeling obliged to take part in the study**…………………………………………………………………………………………………………

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**C.3 Inclusion/exclusion criteria of the participants in the study**

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**C.4 How will the information and the invitation to take part in the study be disseminated? (Attach a copy of any flyers or letters to be sent)** …………………………………………………………………….

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**C.5 Is any form of indemnity provided for healthy volunteer participants?** ..................................... .............................................................................................................................................................................

***N.B. The investigator is obliged to give notice of any changes to the methods of involvement***

**D. Risk and risk management**

**D.1 The study envisages**

* use of questionnaires (attach a copy)
* structured or semi-structured interviews (attach a copy of the questions that will be asked; where this is not possible, indicate the subjects that will be covered)
* in-depth interviews
* *focus groups*
* autobiographical stories
* diary keeping
* covert observation of the behaviour of subjects
* observation of the behaviour of subjects
* audio or video recordings of the subjects
* administration of stimuli, tasks or procedures and recording of behavioural responses, opinions or judgements
* administration of stimuli, tasks or procedures that the subject could find unpleasant, stressful, physically or psychologically distressing, both during and after the conduct of the study
* recording of eye movements
* use of TMS (*Transcranial Magnetic Stimulation*)
* immersion in virtual reality environments
* recording of evoked potentials
* administration of tests, questionnaires or trial protocols through the Internet (web, email)
* use of neuropsychological tests
* neuroimaging techniques
* the implementation of behaviour that could diminish the self-esteem of subjects, or cause embarrassment, regret or depression
* procedures that deceive subjects
* the administration of substances or agents (for example, medicines, alcohol), the collection of samples of human tissue or fluids (for example, blood tests), participation in a clinical trial
* other (specify) ………………………………………………………………………………………….

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**D.2 If the study involves the use of procedures that could be stressful or hazardous for the**

**participants, describe the nature of the risks and the consequences that can reasonably be expected**

**from the procedures used** ………………………………………………………………………………………

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**D.3 Is a specific insurance policy for civil liability envisaged in addition to that of the University?**

**If yes, attach a full copy of the insurance contract** ………………………………………

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**D.4 What measures are provided to deal with any complications or adverse reactions?** ………………

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**D.5 Is it expected that there may be benefits for those who take part in the study? What benefits?** …………………………………………………………………………………………………………………………..

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**E. Information and consent**

**E.1 Summary of the information procedure envisaged (interview, signature of consent, delivery of the results…)**

**E.2 Information Form and Declaration of Consent/Agreement of the participant and/or of the letter of the legal representative (parent, guardian, holder of parental authority) (attach a copy)**

**E.3 Which methods will be adopted for receiving expressions of doubts and answering to requests for clarification by subjects during the study?**...................................................................................................

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**E.4 If, for the implementation of the study, it would be methodologically impossible to inform the participants before the start of the trial of its objective, specify what will be the methods for the subsequent discussion of clarification** …………………………………………………………………………

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**E.5 In what way will participants be informed of the possibility of receiving, directly or**

**indirectly, any other information regarding their psycho-physical condition, should it become available during the study?** .........................................................................................................................

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**F. Anonymity and confidentiality of the personal data**

**F.1 Attach the information sheet and authorisation regarding the processing of personal data in accordance with the Legislative Decree of 30 June 2003, no. 196 (Code on the protection of personal data), the EU Regulation 679/2016 and the fulfilments in accordance with Legislative Decree 101/2018.**

**F.2 How will participants be guaranteed anonymity (for example, use of identification codes)?...…**

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**F.3 Should it be necessary to store the identification data of the participants, specify the reasons and the methods by which the subjects will be informed** ………………………………………………

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**F.4 What security measures will be adopted to ensure that the confidentiality of the data is respected?** …………………………………………………………………………………………………………

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**G. Storage and security of the data collected and of the results of the study**

**G.1 Who will have access to the data collected and to the results (even if intermediate) of the study?** ………………………………………………………………………………………………………………………………

**G.2 For how many years after the conclusion of the study will the data collected be stored?.................**

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**G.3 Indicate the storage methods of sensitive data (the person responsible for the correct storage and place where they will be stored)**………………………………………………………………..

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