SUBMISSION FORM FOR ETHICAL APPROVAL

Title of the project:	Click here to enter text.
Applicant researcher:	Click here to enter text.
Principal investigator:	Click here to enter text.
Contact details (e-mail):	Click here to enter text.
Research team:	Click here to enter text.
Funding (if applicable):	Click here to enter text.
Submission:	First submission ☐ Re-submission ☐ Alteration ☐

CHECKLIST FOR ETHICAL ISSUES

Indicate if the study involves any of the following elements (tick all that are applicable):

Sample derived from vulnerable populations

- Children and young people less than 18 years old. ☐
- People with physical or psychological difficulties.\ ☐
- People who are in relations of dependence on those in charge of the research (e.g. line managers; asymmetries of power/status) or in the context where the research is taking place (e.g. university; companies). ☐
- People belonging to minority groups in situations of vulnerability and/or illegality. ☐

Significant risks for the participants

- Collection of information about sensitive subjects for the participants (e.g. traumatic experiences; physical limitations; psychological suffering). ☐
- Induction of states of physical discomfort (e.g. prolonged or very repetitive physical tasks) or psychological distress (e.g. anxiety; humiliation). ☐
- Attribution of labels or categories with potentially negative consequences for one's self-image (e.g. manipulation of perceived skills; manipulation of situations of exclusion). ☐
- Invasive activities (e.g. administration of substances; ingestion of food). ☐
- Collection of human tissue, blood or other biological materials. ☐

DESCRIPTION OF THE STUDY

RESEARCH PROBLEM AND RELEVANCE OF THE STUDY

Indicate the research problem and the relevance of the study, clarifying the original contribution it presents for the advancement of knowledge and/or other expected benefits for individuals or communities. [up to 200 words]

Click here to enter text.

RESEARCH OBJECTIVES/QUESTIONS

Indicate the general and specific objectives of the study, and/or the research question(s). [up to 150 words]

Click here to enter text.

METHOD

Explain the choice of research methods and describe all the procedures for the collection and recording of data, participation and tasks requested from the participants, interventions carried out, duration of the participation and frequency of the data collection. [up to 500 words]

Click here to enter text.

ATTACH THE MATERIALS TO BE USED FOR DATA COLLECTION

(When sending the submission, please attach the questionnaires, interview or activity scripts, registration/observation grids, etc., duly identified)

PARTICIPANTS

NUMBER, AGE AND ORIGIN OF THE PARTICIPANTS

Characterise the study participants with respect to the expected number, selection criteria, age cohorts and origin (i.e. recruitment context). [up to 100 words]

Click here to enter text.

METHOD OF RECRUITMENT

Describe the method of recruitment of the participants. [up to 100 words]

Click here to enter text.

INFORMED CONSENT AND DEBRIEFING

OBTAINING OF INFORMED CONSENT

Indicate the time and place of obtaining the informed consent, as well as any measures to overcome linguistic barriers (if existent). [up to 100 words]

Click here to enter text.

Indicate the means of obtaining the informed consent:

Document in which the participant signs her/his consent (e.g. study with participation in person) ☐

Document/text that the participant reads before conveying her/his intention to participate (e.g. online study) ☐

Oral explanation given to the participant before conveying her/his intention to participate (e.g. when personal identification could imply risks to the participant) ☐

Consent obtained through third parties who assure the rights of the participants, such as main carers or legal representatives ☐

If *through third parties*, please describe who will consent, and how the consent will be obtained [up to 50 words]:
Click here to enter text.

Other means or Not Applicable ☐

If through *other means* or *Not Applicable*, please describe/justify [up to 50 words]:
Click here to enter text.

ELEMENTS OF THE INFORMED CONSENT

Tick the elements that were included in the informed consent:

Identification of the study and principal investigator(s)	☐
Description of the general objectives of the study, number of sessions, estimated time and general features of the participation	☐
Voluntary nature of the collaboration, which includes the possibility of stopping the participation at any time without requiring justification	☐
Information about any risks, discomfort or other adverse effects associated to participation	☐
Information about any benefits associated to the study and/or participation	☐
Information about any limits to confidentiality, when applicable	☐
Information about incentives to participation, when applicable	☐
Contact details in case the participant wishes to ask questions or comment on the study	☐
Measures foreseen to deal with any negative consequences for the participants, when applicable	☐
Other elements	☐

If *other elements* were included, please describe [up to 50 words]:

Click here to enter text.

PRESENTATION OF THE DEBRIEFING

Indicate the means used to present the debriefing:

Document/text presented to the participant at the end of the participation	☐
Oral explanation given to the participant at the end of the participation	☐
Other means or Not Applicable	☐

If through of *another means* or *Not Applicable*, please describe/justify [up to 50 words]:

Click here to enter text.

ELEMENTS OF THE DEBRIEFING

Tick the elements that were included in the debriefing:

Thank you for the participation	☐
More specific information about the objectives, hypotheses, procedures and/or expected contributions of the study research, when applicable	☐
Clarification on deception in the research, when applicable	☐
Contact details in case the participant wishes to ask questions or comment on the study	☐
Means of obtaining subsequent information on the outcomes and conclusions of the study	☐
Means of obtaining information about the research topic, when applicable	☐
Measures foreseen for dealing with any negative consequences for the participants, when applicable	☐
Other elements	☐

If *other elements* were included, please describe [up to 50 words]:

Click here to enter text.

If you wish to clarify or justify any aspect related to the elements of the informed consent and/or debriefing, please describe. [up to 100 words]

Click here to enter text.

ATTACH THE INFORMED CONSENT AND DEBRIEFING DOCUMENTS

(When sending the submission, please attach the informed consent and debriefing documents/texts or in the case of oral explanation, the transcription of the direct discourse)

PROTECTION AND SAFETY OF THE PARTICIPANTS

SAMPLE DERIVED FROM VULNERABLE POPULATIONS

If the sample is composed of:

Children and young people less than 18 years old;

People with physical or psychological difficulties;

People in relations of inequality or dependence on those in charge of the research, or in the context where the research is taking place;

Or other populations that could be considered vulnerable (e.g. minority groups in situations of vulnerability and/or illegality).

Indicate the measures foreseen to ensure that participation is strictly voluntary (e.g. in the case of university students in which participation comprises a curricular component, alternatives to participation should be given for the obtaining of credits). [up to 100 words]

Click here to enter text.

RISKS ASSOCIATED TO PARTICIPATION

If there are potentially significant risks for the participants, such as:

Collection of information about sensitive subjects for the participants (e.g. traumatic experiences; physical limitations; psychological suffering);

Induction of states of physical discomfort (e.g. prolonged or very repetitive physical tasks) or psychological distress (e.g. anxiety; humiliation);

Attribution of labels or categories with potentially negative consequences for one's self-image (e.g. manipulation of perceived skills; manipulation of situations of exclusion);

Invasive activities (e.g. administration of substances; ingestion of food);

Collection of human tissue, blood or other biological materials;

Or other activities that could be expected and might imply significant risks for the participants.

Indicate the procedures foreseen to minimise risks and/or monitor the safety of the participants. [up to 100 words]

Click here to enter text.

Indicate the measures foreseen to deal with any negative consequences for the participants. [up to 100 words]

Click here to enter text.

STATEMENT OF RESPONSIBILITY AND ETHICAL CONDUCT

As the principal investigator responsible for the study, I state that:

All the information provided in this submission is true;	☐
I have tried to anticipate all the risks that might arise associated to participation in the study, delineate strategies to minimise the risks, and define measures to deal with any negative consequences for the participants;	☐
I have (individually or in the team) the necessary competences and resources to accomplish the project in the manner presented in this submission;	☐
My conduct and my decisions in all the mattes related to the present project will take into consideration the provisions of the Code of Ethical Conduct in Research – ISCTE-IUL.	☐

Name	Click here to enter text.
Date	Click here to enter text.
Signature	