SUBMISSION FORM FOR APPROVAL OF THE IBS ETHICS COUNCIL

Title of the project:	Click here to enter text.
Investigator/the proponent:	Click here to enter text.
Investigator/responsible:	Click here to enter text.
Contacts (e-mail):	Click here to enter text.
School:	Click here to enter text.
Department or research centre:	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 aspects (mark all those applicable):

Sample derived from vulnerable populations

Children and young people aged less than 18 years old. ☐

Persons with physical or psychological difficulties. ☐

Persons with relations of dependence with those responsible for the investigation (e.g., immediate superiors; asymmetry of power/status) or in the context in which the investigation is taking place (e.g., university; companies). ☐

Persons belonging to minority groups in situations of vulnerability and/or illegality. ☐

Significant risks for the participants

Collection of information on sensitive matters for the participants (e.g., traumatic experiences; physical limitations; psychological suffering).	☐
Inducement of states of physical discomfort (e.g., prolonged or very repetitive physical tasks) or psychological discomfort (e.g., anxiety; humiliation).	☐
Assignment of labels or categories with potentially negative consequences for self-concept (e.g., manipulation of perceived abilities; manipulation of situations of exclusion).	☐
Invasive activities (e.g., administration of substances; ingestion of food).	☐
Collection of human tissue, blood or other biological materials.	☐

Indicate if the study involves processing personal data:[1]

Yes	☐
No[2]	☐

IF YOU INDICATED THAT THE STUDY INVOLVES THE PROCESSING OF PERSONAL DATA, ATTACH THE QUESTIONNAIRE ON PERSONAL DATA PROCESSING

[1] Personal data is defined as any information, of any nature and in any format (e.g. voice recording or image), relating to an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier (e.g. an IP) or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

[2] If your study shall not involve the processing of personal data, i.e. you will collect and process exclusively anonymous data, the timing of the anonymisation process is fundamental.

The fact that a study does not report the individual answers of participants is not, in itself, an indicator that there is no personal data processing.

A study may be considered as never processing personal data only on the condition that the researcher does not have access to any records of personal data during collection and subsequent processing.

If anonymization of the data occurs at a later stage of data collection, for example, when the researcher makes an audio recording of an interview and later makes a transcript removing personally identifiable information, or when transferring the collected personal data to another database, the raw data is still personal and you should indicate "yes" in this question and also attach the questionnaire on personal data processing.

DESCRIPTION OF THE STUDY

RESEARCH PROBLEM AND RELEVANCE OF THE STUDY

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

Click here to enter text.

RESEARCH AIMS/QUESTIONS

Indicate the general and specific aims 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.

If personal data are processed, include information on:

i) The collected personal data, who the data subjects are and the planned processing;
ii) The legal grounds for the processing, if not by consent;
iii) The entity responsible for the processing (the data controller), if it is not Iscte or there is joint responsibility;
iv) The procedures and timings or periods of time established for pseudonymisation and anonymisation or destruction, as applicable. If there is

anonymisation, indicate the measures taken to reduce the risk of re-identification.

[up to 700 words]

Click here to enter text.

ATTACH AN ANNEX WITH THE MATERIALS TO BE USED DURING THE DATA COLLECTION

(When sending the submission, please attach the questionnaires, interview scripts or activity plans, record/observation grids, etc., all properly identified)

PARTICIPANTS

NUMBER, AGE AND ORIGIN OF THE PARTICIPANTS

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

Click here to enter text.

RECRUITMENT METHOD

Describe the participant recruitment method. [up to 100 words]

Click here to enter text.

INFORMED CONSENT AND DEBRIEFING

OBTAINING OF INFORMED CONSENT

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

Click here to enter text.

Indicate how the informed consent was obtained:

Document which the participant signs to give consent (e.g., study with face-to-face participation) ☐

Document/text which the participant reads before conveying her/his intention to participate (e.g., online study, via videoconference, etc.) ☐

If consent is not obtained face-to-face and personal data is collected, please explain how the participant's positive and explicit manifestation is recorded in a manner enabling its confirmation through evidence.
Click here to enter text.

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

Consent obtained through third parties assuring the rights of the participants, such as carers and main 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

Mark the elements included in the informed consent:

Identification of the study and investigator(s)/person(s) or entity(ies) responsible ☐

Description of the general aims 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 any need for justification	☐
Information on any risks, discomfort or other adverse effects associated with the participation	☐
Information on any benefits associated with the study and/or participation	☐
Information on any limits to confidentiality, when applicable	☐
Information on incentives to participation, when applicable	☐
Contact details in case the participant wishes to ask questions or make comments about the study	☐
Measures foreseen to deal with any negative consequences for the participants, when applicable	☐

If the study involves the processing of personal data, mark the elements included in the informed consent:

Identification of Iscte-Instituto Universitário de Lisboa as the data controller and/or other controllers if applicable	☐
The legal grounds for the processing (Article 6(1)(a) or Article 9(2)(a) of the GDPR)[3]	☐
The rights that the participant data subject may exercise before the Controller, the manner of doing so and who to address (rights of access, rectification, withdrawal of consent, and erasure)	☐
The right to submit a complaint to the Portuguese Data Protection Authority (CNPD)	☐
The period of retention of personal data (after which the data are destroyed or anonymised)	☐
If there is data processing by third parties (e.g. outsourcers) or subsequent use of personal data by other research teams, information about the purposes of the processing and identification of the third parties	☐

[3] Article 9(2)(a) is applicable to personal data that reveal racial or ethnic origin, political opinions, religious or philosophical beliefs, or union membership, and to the processing of genetic data, biometric data that unambiguously identify a person, data related to the health, sexual life or sexual orientation of a person. In all other cases, Article 6(1)(a) is applicable.

If applicable, the fact that there are transfers to a third party or international organisation outside the European Economic Area and the existence or not of an "adequacy decision". If there is no "adequacy decision", information on the transfers, the risks that could arise to the participants and the measures taken to mitigate these risks.	☐
Contact details of the Data Protection Officer	☐
If the data processing involves potential risks to the participants' rights and freedoms, the importance and foreseen consequences of this processing for the participants	☐
If personal data is not obtained from the participants, the origin of the personal data and whether they originate from sources accessible to the public	☐
If there is automated individual decision-making[4], including profiling referred to in Article 22(1) and (4) of the GDPR, provide useful information concerning the underlying logic, as well as the importance and foreseen consequences of this processing for the participant	☐

If other elements are included in the informed consent, indicate them:

Other elements	☐

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

Click here to enter text.

DELIVERY Of THE DEBRIEFING

Indicate how the debriefing was delivered:

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	☐

[4] Automatic individual decision-making occurs when decisions are taken about a natural person by technological means and without human involvement. This may be carried out even without profiling. For example, if the decision of a bank to grant a bank loan to a natural person is taken by an algorithm, without human intervention. If a person controls the final decision supplied by the algorithm, with effective power or ability to influence the final result, the decision may be considered not "exclusively" automated.

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

Click here to enter text.

ELEMENTS Of THE DEBRIEFING

Mark the elements included in the debriefing:

Expression of gratitude for the participation	☐
More specific information on the aims, 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 make comments about the study	☐
Means of obtaining subsequent information on the findings and conclusions of the study	☐
Means of obtaining information on the theme of the research, when applicable	☐
Measures foreseen to deal with any negative consequences for the participants, when applicable	☐
Other elements	☐

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

Click here to enter text.

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

Click here to enter text.

ATTACH AN ANNEX WITH 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 speech)

PROTECTION AND SECURITY OF THE PARTICIPANTS

SAMPLE DERIVED FROM VULNERABLE POPULATIONS

If the sample is composed of:

- Children and young people aged less than 18 years old;
- Persons with physical or psychological difficulties;
- Persons with relations of dependence with those responsible for the investigation or in the context in which the investigation 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 their participation is part of a curricular component, alternatives to participation should be given to obtain credits). [up to 100 words]

Click here to enter text.

RISKS ASSOCIATED WITH PARTICIPATION

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

- Collection of information on sensitive matters (e.g., traumatic experiences; physical limitations; psychological suffering);
- Inducement of states of physical discomfort (e.g., prolonged or very repetitive physical tasks) or psychological discomfort (e.g., anxiety; humiliation);
- Assignment of labels or categories in the experimental context with potentially negative consequences for self-concept (e.g., manipulation of perceived abilities; manipulation of situations of exclusion);
- Invasive activities (e.g., administration of substances);
- Collection of human tissue, blood or other biological materials;
- Or other activities which may be expected to imply significant risks for the participants.

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

Click here to enter text.

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

Click here to enter text.

DECLARATION OF RESPONSIBILITY AND ETHICAL CONDUCT

As investigator/person responsible for the study, I declare that:

All the information provided in this submission form is true;	☐
I shall seek to foresee all the risks that could arise associated with participation in the study, delineate strategies to minimise the risks, and define measures to deal with any negative consequences for the participants;	☐
I possess (individually or in the team) the necessary competences and resources to accomplish the project as it has been presented in this submission form;	☐
My conduct and my decisions in all matters related to this project shall take into account the provisions in the Code of Ethical Conduct in Research – Iscte-Instituto Universitário de Lisboa.	☐

Investigator/the proponent Name	Click here to enter text.
Date	Click here to enter text.
Investigator/the proponent Signature	

(Mandatory if applicable)

Principal Investigator/Supervisor Name	Click here to enter text.
Date	Click here to enter text.
Principal Investigator/Supervisor Signature	