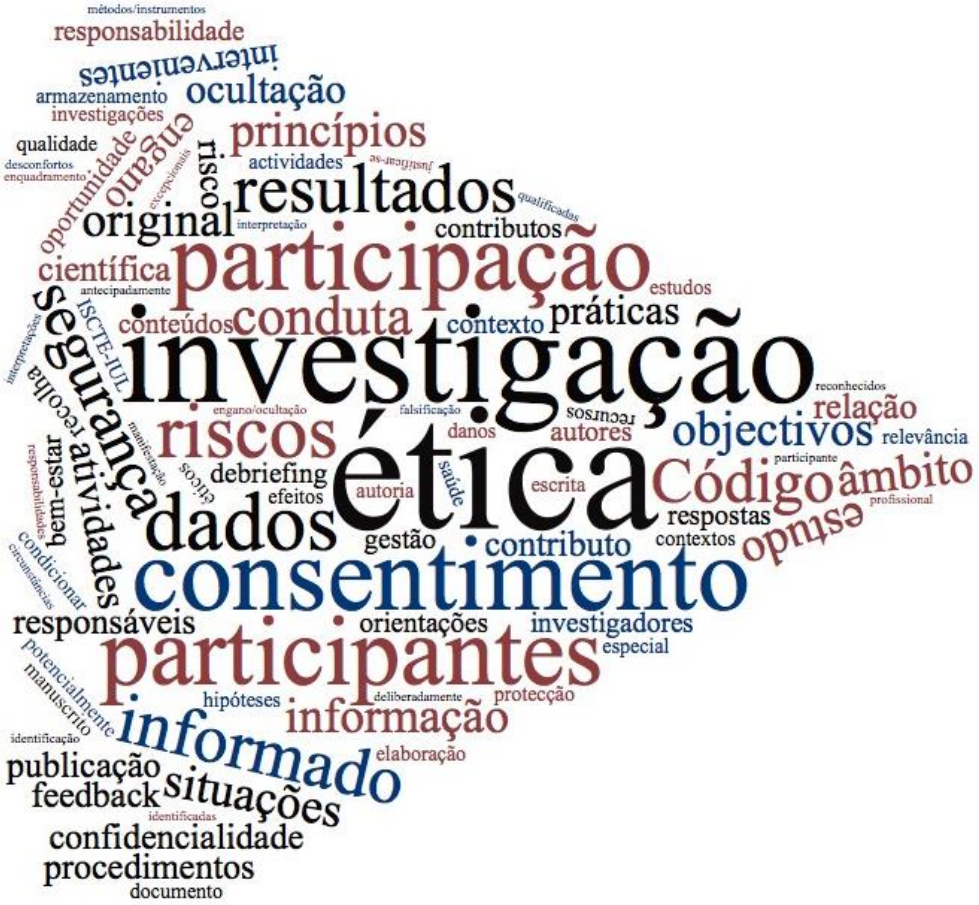
Ethics in Research

Best practices, best Science



CODE OF CONDUCT | GUIDELINE DOCUMENTS | TOOLS AND PRACTICAL MODELS | SUGGESTED ACTIVITIES

ISCTE-University Institute of Lisbon

CODE OF ETHICAL CONDUCT

Code of Ethical Conduct in Research – ISCTE

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1. OVERVIEW

1.1. The present Code seeks to promote compliance with ethical standards in research conducted within ISCTE, and arises in the general context of the mission and duties of the Ethics Committee of ISCTE-IUL (Order number 7095/2011; *Diário da República*, 2nd series, number 90, dated 10/06/2011). More specifically, the Code conveys a series of principles and guidelines whose objectives are to: (1) protect the dignity, safety and wellbeing of the participants; (2) preserve the safety and

reputation of the researchers; and (3) promote the quality of the research as a whole.

1.2. In the context of the present document, research is defined as all initiatives that seek to generate original knowledge through the application of scientific methodologies. The Code is applicable to all research activities with human participants developed within Schools, Departments, Research Centres, Institutes, associate entities and/or other organic units of ISCTE, by lecturers, researchers, students and/or other intervenors.

1.3. Although the Code is of a prescriptive nature, it emphasises the role of the autonomy, responsibility and self-regulation of the person conducting research, in accomplishing the principles and guidelines that it conveys. Thus, it is neither binding nor intends to replace critical reflection in the identification and resolution of ethical issues in research. Rather, the Code aims to inform and guide the action of all intervenors with responsibilities in planning, management and/or scientific disclosure.

1.4. Likewise, the Code is viewed as a document that should be continuously improved, moulding itself to the evolution of ethical requirements and preoccupations in scientific research. It is, therefore, open to the inclusion of suggestions of review and updating that are in line with all the objectives presented in its overview (see paragraph 1.1), focusing, as much as possible, on a parsimonious and careful selection of the contents to be included.

1.5. With respect to its structure, in addition to the present overview, the Code has a series of general principles that inform ethical conduct in research, a list of practical guidelines organised by relevant topics for ethics in research, and an annex with the sources used in the preparation of the document.

1.6. The provisions of the Code do not exempt, replace or override the consultation and knowledge of other guides and legislation of relevance at a national and European level, such as: the Charter of Fundamental Rights of the European Union; the Convention for the Protection of Human Rights and Fundamental Freedoms; Law number 67/98, of 26 October – Personal Data Protection Law (LPDP); the General Data Protection Regulation (GDPR) and Law 59/2019, of 8 August – Implementing Law, in the national legal system, of the GDPR;Law number 12/2005, of 26 January, relative to Personal genetic information and health information; Law number 125/99, of 20 April, relative to the Legal System for Scientific Research Institutions.

1.7. Likewise, the provisions of the Code and/or guides and legislation of relevance at a national European level do not exempt, replace or override the legal obligations of other countries, whenever the research is conducted in third countries.

2. GENERAL PRINCIPLES

Responsibility

2.1. Responsibility in relation to the impact of the research: on the participants, respecting self-determination and taking measures to mitigate any risks to health and physical and/or psychological wellbeing; on society, giving priority to activities with high potential relevance in social and scientific terms; and on the environment, mitigating harmful impacts and promoting the sustainable management of the available resources.

Honesty

2.2. Honesty in relation to the research process, ensuring the transparency and veracity of the procedures, data, results, interpretations and of any implications, recognising the contributions of third parties, and neither using nor concealing bad practices of research.

Reliability and rigour

2.3. Reliability and rigour in carrying out research activities, acting in a meticulous and careful form, attentive to details; and in the communication of results, reporting them in a correct, comprehensive and impartial manner.

Objectivity

2.4. Objectivity in the interpretations and conclusions, substantiating them on data and evidence that can be provided and is confirmable, obtained through replicable procedures.

Integrity

2.5. Integrity in the identification and manifestation of conflicts of interest, real and/or potential, and in compliance with all the ethical and legal requirements in relation to the respective research area.

3. PRACTICAL GUIDELINES

Relevance and quality of the research

3.1. The research activities should be planned and conducted according to the research questions/problems, so as to enable relevant additional knowledge on a particular topic, developing new methods/instruments with potential application or improving existing methods/instruments.

3.2. The relevance of the research can also be justified in situations of confirmed pedagogic-educational value for purposes of training and instruction of students,

researchers and/or other intervenors, even if the achievement of an original contribution in a given topic is not the principal focus of the activities.

3.3. Research that does not present any original contribution to the advancement of knowledge and/or to the capacity-building of individuals and communities is not considered ethical, as it constitutes a waste of resources (material and immaterial) and undermines the contribution of the participants.

3.4. Research carried out through studies lacking in validity and with serious methodological flaws is not considered ethical. Apart from wasting resources and undermining the contribution of the participants, it could give rise to erroneous data and results, whose dissemination could have possibly damaging implications.

Consent

3.5. No-one can be obliged or compelled to participate in a study. In the context of the informed consent, the participants should receive information that includes: (1) the general objectives of the study, estimated time and general features of the individual's participation; (2) the right to refuse participating in the study, and to stop the participation at any time; (3) any risks, discomfort or other adverse effects associated to participation; (4) any benefits associated to participation; (5) any limits to confidentiality (see *Confidentiality*, paragraph 3.15); (6) incentives to participation, when existent; (7) who to contact in case of wanting to ask questions or comment on the study.

3.6. The participants should not start participating in a study before having the opportunity to give their consent, in a free and self-determined manner.

3.7. When the participation is in person, preference should be given to obtaining informed consent signed by the participant, except in situations of disability (e.g. difficulties of literacy or motricity), or when personal identification could imply risks for the participant (e.g. studies involving participants with unlawful behaviours). In these cases, the participant can express her/his consent verbally or through a behavioural sign, which should be duly recorded.

3.8. For situations in which the participants are prevented from giving their consent, due to being limited in their self-determination (e.g. children and young people less than 18 years old; disabled patients; severe cognitive difficulties), the consent should be given previously by third parties that ensure respect for their rights, such as the main carers or legal representatives.

3.9. Consent given by third parties can only be obtained, apart from exceptional situations and justified, through the principle of the option of inclusion (opt-in; i.e. in being informed, explicit consent should be given for participation) furthermore, even if consent is given by third parties, the participant's manifestation of refusal should preclude her/his participation.

3.10. The collection of data in the context of a service or organisation should be preceded by formal authorisation on the part of the respective service or organisation. However, the obtaining of formal authorisation for data collection does not mean that the request for informed consent of the study's participants is not required.

3.11. Studies involving mere observation in public scenarios, where it is expected that one could be observed by others, do not require consent – provided that the observation does not imply additional risks to the participants, or the collection of information on their identity.

3.12. In situations where the obtaining of fully informed consent prior to participation could compromise the study's objectives, due to probable risk of constraining the answers and/or conduct of the participants, the guidelines relative to *Deception and concealment of information* (paragraphs 3.28 to 3.30) should be applied.

Confidentiality

3.13. All the information provided by the participants in the context of research should be treated confidentially and, when published, should not be identifiable.

3.14. In the context of research, only the personal data strictly that is necessary for carrying out the study should be collected. The information that identifies the participants in a unique form should be kept only for as long as necessary, and should be converted as soon as possible into anonymous data (e.g. anonymous identification code).

3.15. In research conducted with schools, hospitals, companies or any other public or private organisations, they should not be identified, unless previously agreed by all the parties.

3.16. The duty of confidentiality is not absolute and, under exceptional circumstances, can be overridden by the duty of protection in view of damage. In certain research contexts, it may happen that serious and credible threats are detected in relation to the safety of individuals in vulnerable situations and/or victims of public or semi-public crimes. In this regard, the persons responsible for the research should previously define the procedures to be followed in the event of encountering situations of this nature.

3.17. If the confidentiality and/or anonymity of the data cannot be assured, the participants should be informed of this possibility in the informed consent form.

Debriefing and feedback

3.18. At the end of participation in the study, the participants should be given the opportunity to access more specific information about the objectives, hypotheses,

procedures and/or expected contributions of the research (i.e. debriefing), complementing the more general information that may have been provided in the informed consent.

3.19. Where there is a risk of constraining the answers or conduct of other potential participants, due to contact or exposure, the debriefing can be provided at a later date, through contact details given freely for this purpose – provided that the postponement does not imply any foreseeable risks, discomfort or other adverse effects for the participants (see *Protection and safety of the participants*, paragraphs 3.22 to 3.27).

3.20. The participants should be offered the opportunity to obtain information about the results and conclusions of the study (i.e. feedback).

3.21. The duty to offer the participants a debriefing and the opportunity to receive feedback about the study's outcomes is applicable, in principle, to all research in which there is *Consent* (paragraphs 3.5 a 3.12) or *Deception and concealment of information* (paragraphs 3.28 to 3.30).

Protection and safety of the participants

3.22. Respect for the dignity, safety and wellbeing of the participants should be among the foremost considerations of any research. To this extent, the persons responsible for the research should consider all possible risks associated with participation.

3.23. The risks associated with participation may refer to real or potential damage to the physical or psychological health of the participants, discomfort, stress, offences to reputation, damage to family and interpersonal relations, damage to the economic, professional or academic situation, and/or any other factors manifestly contrary to the interests of the participants.

3.24. Where significant risks associated to participation are foreseen, the persons responsible for the research should previously define procedures for mitigation and management of the risks, placing them for consideration of the ethics committee.

3.25. Significant risks are understood to be all risks that do not fit in the strict definition of minimum risk. It is considered that the study is of a minimum risk when it is foreseen that it might imply, at the most, a very slight and temporary negative impact on the wellbeing of the participant.

3.26. Special attention should be paid to the existence of potentially significant risks in studies that involve: 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 in the experimental context with potentially negative consequences for self-image (e.g. manipulation of perceived skills;

manipulation of situations of exclusion); invasive activities (e.g. administration of substances); collection of human tissues, blood or other biological materials.

3.27. Likewise, special attention should be paid to the existence of potentially significant risks in studies with vulnerable populations, such as: children and young people less than 18 years old; people with physical or psychological difficulties; people in relations of inequality or dependence in relation to the persons responsible for the research, or in the context in which the research is taking place.

Deception and concealment of information

3.28. In situations in which the prior obtaining of fully informed consent could compromise the study's objectives, due to probable risk of constraining the answers and/or conduct of the participants, there could be justification for resorting to an incomplete explanation of the research objectives or hypotheses (deception).

3.29. The resorting to an incomplete explanation of objectives and hypotheses, referred to in the previous number, should only be used in research of high scientific, education or applied relevance, when other alternatives not involving deception/concealment of information cannot be used to achieve the same goals.

3.30. When resorting to deception or concealment of information, the concealed or manipulated information should be revealed and contextualised in the debriefing (*Debriefing and feedback*; paragraphs 3.18 to 3.21).

Collection and storage of data

3.31. All the data collected in the context of the research should be stored and kept in a secure and accessible form, for a period of at least five years counted from the end of the study/project or, when reported in scientific publications, from the date of the original publication.

3.32. The research data should be placed at the disposal of persons wishing to replicate the study or work on the results, subject to any limitations imposed by the specific legislation and by the general principles of the confidentiality, protection and safety of the participants.

3.33. Once the storage period has ended, the elimination or destruction of the data should be done in conformity with the applicable ethical and legal requirements, with particular consideration of the general principles of the confidentiality, protection and safety of the participants.

Publication and authorship

3.34. The researchers should publish and disclose the research results in an honest, transparent and rigorous manner.

3.35. The results should be published as soon as possible, thus fulfilling the original contribution for which the research was designed, subject to commercial or intellectual issues that might justify the deferral of publication, for example with respect to patent applications.

3.36. The authorship should be defined taking account of the original and significant participation in the research, namely: significant contribution to the research design, data collection and analysis, interpretation of the results, discussion, writing and/or review of the manuscript.

3.37. The definition of authorship should consider as irrelevant any factors that do not refer to direct and significant participation in the research activities, such as: academic or professional status, job or hierarchical position, research group general supervision without specific contributions to the project, assignment of space or equipment for the research, funding or financial compensation, text edition.

3.38. The work and collaboration of intervenors who do not meet the authorship criteria should be recognised whenever justified, and if consented by these persons, in a footnote or in specific sections for the purpose (e.g. acknowledgements).

3.39. Any financial and material support lent to the research and publication should be mentioned and recognised correctly.

3.40. All the authors should reveal the existence of potential conflicts of interest (e.g. being the holder of financial interests or membership in relation to the research results).

3.41. All the authors should be fully accountable for the contents of the publication, unless it is stipulated that their responsibility is limited to a specific part of the study and publication.

3.42. The order of authorship should be agreed by all right at the beginning of the project or preparation of the manuscript, without prejudice to subsequent redefinition, when justified.

3.43. The first author should be considered the one who most contributed to the research activities (generally considered the research design, data collection and analysis, interpretation of the results and discussion) and who undertakes the main responsibility of writing the manuscript.

3.44. With respect to publications that are substantially based on the contents of a thesis or dissertation, it should be assumed that the students are those who most contributed to the respective research activities, and who undertook the responsibility of its writing. Therefore, in conformity with the previous paragraphs and apart from in exceptional circumstances, they should be listed as the first authors.

Misconduct

3.45. All the intervenors with responsibilities in the planning, management, conduct and/or scientific disclosure should recognise that there are practices qualified as misconduct in research.

3.46. To the extent that these practices are recognised, they should also be repudiated, as they promote a deliberately false representation of reality, contradicting the fundamental principles of the scientific process, and compromise the contributions provided by the research as a whole.

3.47. The most serious practices qualified as misconduct in research include: fabrication of data, falsification and plagiarism.

3.48. Fabrication of data consists of creating false data (e.g. answers of participants; observational records) or other research materials (e.g. informed consent).

3.49. Falsification consists of distorting, manipulating, omitting or altering data, results or materials of the research.

3.50. Plagiarism corresponds to the improper use or appropriation of ideas, processes, intellectual property or other type of work without the due credit of or reference to the source or original author.

3.51. The adoption of practices that are manifestly contrary to the general principles conveyed in the present Code (paragraphs 2.1 to 2.5) should also be perceived as misconduct in research.

ANNEX – BIBLIOGRAPHY

The following sources were used in the preparation of this Code.

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GUIDELINE DOCUMENTS

SUBMISSION GUIDE FOR ETHICAL APPROVAL AT ISCTE

Why submit a study for ethical approval?

Ethical approval is perceived as a crucial part of the research process and not merely as a requirement to conduct quality research. Ethical approval promotes the protection of the participants and the research, and the integrity of scientific production. Moreover, it is very often a necessary condition to obtain funding, and many scientific publications will not accept publishing results of studies that have not obtained ethical approval.

What studies are eligible for ethical approval at ISCTE?

Studies that involve data collection with participants are eligible for ethical approval at ISCTE. Studies that do not involve participants, which only use data that are already available in public databases, or that have obtained ethical approval from another entity, are exempt from ethical approval by ISCTE.

Who can submit a study for ethical approval at ISCTE?

All lecturers or researchers of ISCTE-IUL can submit a study for ethical approval at ISCTE. Students can also make submissions, provided that they are guided and supervised by a lecturer or researcher.

How to submit a study for ethical approval at ISCTE?

The submission and respective ethical approval should always take place before the onset of the data collection process. Studies submitted after the gathering of data are not considered eligible for ethical approval. The study plan should be submitted by electronic means – comissao.etica@iscte-iul.pt – using the form provided for this effect (*Submission form for ethical approval*). In addition to the form, informed consent and debriefing templates are also provided, which can be adapted according to the features of the study. Should you decide to use another informed consent and/or debriefing template, please make sure that it complies with the provisions of the Code of Conduct (paragraphs 3.5 to 3.12, and 3.18 to 3.21). The three steps to submit a study for ethical approval at ISCTE are presented below.

3 STEPS TO SUBMIT A STUDY FOR ETHICAL APPROVAL AT ISCTE-IUL

1. Ensure that the study is in conformity with the provisions of the Research Ethics Code of Conduct – ISCTE; when the study processes personal data, it must ensure that the study also complies with the Guidelines for Investigators on Data Protection in Scientific Research Activities
2. Complete the *Submission form for ethical approval* with information about the following aspects: Description of the Study; Participants; Informed Consent and Debriefing; Protection and Safety of the Participants; Statement of Responsibility and Ethical Conduct;
3. Attach the applicable annexes requested in the form (i.e. informed consent; debriefing; the additional form on the processing of personal data, if the study processes personal data; questionnaires/materials of the study), and send the submission to the address: comissao.etica@iscte-iul.pt

The submission form must also be sent in word format

Any doubts about the submission can be clarified through the address indicated above.

What does the submission/ethical approval at ISCTE consist of?

According to the elements of the study, it will be eligible for automatic approval or approval by deliberation (see *Diagram of submission and ethical approval*). However, regardless of the type of approval, the submission process is the same for all studies. In other words, the three steps to submit a study are the same for all submissions.

Does ethical approval at ISCTE exempt or replace other legal/ administrative obligations that could be applicable to the research?

No. Researchers should be attentive to the possible existence of specific requirements, for example, in terms of data collection/storage in certain circumstances (e.g. internal process of authorisation in school or hospital contexts), or under public competitions to obtain funding (e.g. internal process of review and approval of the actual funding agency).

Obtaining ethical approval at ISCTE does not exempt or replace compliance with this type of requirement, nor any other legal/administrative obligations that could be applicable to the research.

TOOLS AND PRACTICAL MODLES

SUBMISSION FORM FOR APPROVAL OF THE ETHICS COMMITTEE

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), relative to an identified or identifiable natural person. A natural person is considered identifiable when able to be identified directly or indirectly, for example by a name, an identification number, location data, electronic identifier (e.g., IP) or other specific elements of the physical, physiological, genetic, mental, economic, cultural, 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. It is considered that a study never processes personal data only on the condition that the investigator does not have access to any format with personal data records during collection and subsequent processing.

If the anonymisation of the data occurs at a stage after the data collection, for example, when the investigator removes personal identification information from an audio transcription of an interview, or when the collected personal data are transferred to another database, the raw data are still personal, and "yes" should be indicated for this question, attaching 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 (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 Entity Responsible for the Processing (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 to 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 a "determination of adequacy". If there is no "determination of adequacy", 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 there are personal data not collected from the participants, the origin of the personal data and whether they derive from sources accessible to the public	☐
If there are automated decisions[4], including the definition of profiles 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	☐

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

[4] Automatic individual decisions occur when decisions are taken about a natural person by technological means and without human involvement. This may be carried out even without definition of profiles. 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.

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.	☐

Name Click here to enter text.

Date Click here to enter text.

Signature

[*Other logos may be entered – e.g., Research Centre*]

INFORMED CONSENT

(For studies where there is **no** processing of personal data of the participants)

This study is part of a research project taking place at **Iscte** – **Instituto Universitário de Lisboa**, (*if funded, indicate the entity and respective references*). The study aims to _____ (*succinctly and clearly describe the aim*).

The study is conducted by _____ (*indicate the name of the investigator and her/his e-mail*), who you may contact to clear up any doubts or share comments.

Your participation in the study, which is highly valued as it will contribute to the advancement of knowledge in this field of science, consists of _____ (*succinctly and clearly describe the type and duration of the tasks to be carried out by the participant*). There are no expected significant risks associated with participation in the study (*if they do exist, indicate what they are and which measures have been taken to mitigate/control their effects*).

Participation in the study is strictly **voluntary**: you may choose freely whether to participate or not to participate. If you have decided to participate, you may stop your participation at any time, without having to provide any justification. In addition to being voluntary, your participation is also **anonymous** and **confidential**. The obtained data are merely intended for statistical processing and none of the answers will be analysed or reported individually. At no point of the study will you be asked to identify yourself.

I declare that I have understood the aims of what was proposed to me, as explained by the investigator, that I was given the opportunity to ask any questions about this study and received a clarifying reply to all such questions, and **accept** participating in the study.

_____ (place), _____/____/_____ (date)

Name:

_____

Signature:

_____

(IF THE ACTUAL PARTICIPANT DOES NOT SIGN DUE TO AGE OR INABILITY (*see Articles 7 - "Minor participants" and 8 - "Adult participants who are unable to provide informed consent" of Law 21/2014 of 16 April*)
(*minors who are able to understand should also sign the document, expressing their assent*)

Name:

_____

Identification Document number: _____ Date or expiry: ____/___/_____

Legal representative:

_____

(*if a relative, indicate the degree of kinship, bearing in mind that the authorisation must be signed by the legal representative, who might not be one of the parents or another relative*)

Signature:

_____

[*Other logos may be entered – e.g., Research Centre*]

EXAMPLE OF INFORMED CONSENT

(example to be adapted according to the circumstances of the study, **for studies where data is collected from the participants**, pursuant to Article 13 of the General Data Protection Regulation (GDPR); if data has not been obtained from the participant, add information about the origin and categories of personal data collected, including, if applicable, whether it came from sources accessible to the public, pursuant to Article 14 of the GDPR)

This study is part of a research project taking place at **Iscte – Instituto Universitário de Lisboa**, (*if funded, indicate the entity and respective references*).

The study aims to _____ (*succinctly and clearly describe the aim*). Your participation in the study, which is highly valued as it will contribute to the advancement of knowledge in this field of science, consists of_____ (*succinctly and clearly describe the type and duration of the tasks to be carried out by the participant*).

Iscte is responsible for the processing of your personal data that are collected and processed exclusively for the purposes of the study, legally based on _____(*indicate* Article 6(a) *and/or* Article 9(2)(a) of the GDPR, *as applicable*).

The study is conducted by _____ (*indicate the name of the investigator and her/his e-mail*), who you may contact to clear up any doubts, share comments or exercise your rights in relation to the processing of your personal data. You may use the contact indicated above to request access, rectification, erasure or limitation of the processing of your personal data.

Your participation in this study is **confidential**. Your personal data will always be processed by authorised personnel bound to the duty of secrecy and confidentiality. Iscte assures the use of appropriate techniques, organisational and security measures to protect personal information. All investigators are required to keep all personal data confidential.

In addition to being confidential, participation in the study is strictly **voluntary**: you may choose freely whether to participate or not. If you have decided to participate, you may stop your participation and withdraw your consent to the processing of your personal data at any time, without having to provide any justification. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal

Your personal data will be kept for _____ (*specify the time, criteria or moment of the study when the data will be anonymised or destroyed*), after which they will be destroyed or anonymised, with their anonymity being assured in the study's results, being disclosed only for purposes of statistics, teaching, communication in scientific meetings, books or articles.

There are no expected significant risks associated with participation in the study (*if they do exist, indicate what they are and which measures have been taken to mitigate/control their effects*).Iscte does not disclose, or share with third parties, information related to its personal data. (*if data is processed by third-parties on behalf of Iscte (outsourcing) or there is intention of sharing data with other research teams or studies, add:* In some cases, the research team may share data with other research teams, or even service providers acting under our supervision and responsibility. In this study, personal data are disclosed to the following entities:

- *identify investigator / research team / or service provider*).

(*if personal data are transferred to a third country or to an international organisation outside the European Economic Area, include that information and note the existence, or not, of a 'adequacy decision' by the Commission; if there is no 'adequacy decision' for that country, information should be included on the risks that could arise to the participants and the measures taken to mitigate them*)

(*if the personal data processing involves automated individual decision-making, including profiling, referred to in Article 22(1) and (4) of the GDPR, include useful information concerning the underlying logic, as well as the importance and foreseen consequences of this processing for the participant*).

Iscte has a Data Protection Officer who may be contacted by e-mail: *dpo@iscte-iul.pt*.
If you consider this necessary, you also have the right to submit a complaint to the Portuguese Data Protection Authority (CNDP).

I declare that I have understood the aims of what was proposed to me, as explained by the investigator, that I was given the opportunity to ask any questions about this study and received a clarifying reply to all such questions. **I accept** participating in the study

and consent to my personal data being used in accordance with the information that was given to me.

Yes ☐ No ☐

_____ (place), _____/____/_____ (date)

Name:

_____

Signature: _____

(IF THE ACTUAL PARTICIPANT DOES NOT SIGN DUE TO AGE OR INABILITY (*see Articles 7 - "Minor participants" and 8 - "Adult participants who are unable to provide informed consent" of Law 21/2014 of 16 April; also, see Article 14 of the GDPR;*)

(*minors who are able to understand should also sign the document, expressing their assent*)

Name:

_____

Identification Document number: _____

Date or expiry: ____/___/_____

Legal representative: _____

(*if a relative, indicate the degree of kinship, bearing in mind that the authorisation must be signed by the legal representative, who might not be one of the parents or another relative*)

Signature: _____

DEBRIEFING/EXPLANATION OF THE RESEARCH

Thank you for having participated in this study. As indicated at the onset of your participation, the study is about [indicate the subject in general terms] and aims to [indicate the general objective(s)]. More specifically, [indicate hypotheses or more specific objectives, when applicable].

In the context of your participation, [reveal elements of deception or concealment of information, when applicable; identify/provide the foreseen measures to deal with any negative consequences for the participants, when applicable].

We remind that the following contact details can be used for any questions that you may have, comments that you wish to share, or to indicate your interest in receiving information about the main outcomes and conclusions of the study: [indicate name and e-mail of the member(s) of the team or coordination].

If you wish to access further information about the study topic, the following sources can also be consulted: [indicate reference publications, websites or other platforms with information about the topic, when applicable].

Once again, thank you for your participation.

SUGGESTED ACTIVITIES

Suggestions for training, teaching and capacity-building activities towards research ethics at ISCTE

In addition to the systematisation of procedures and provision of work tools, the accomplishment of best practices of conduct in research invariably depends on its human participants. This document includes a series of general and specific recommendations for training, teaching and capacity-building activities towards ethics in research at ISCTE, presented in the general context of the mission and duties of the Ethics Committee of ISCTE-IUL (Order number 7095/2011; *Diário da República, 2nd series,* number 90, dated 10/06/2011). These activities seek to promote the awareness-raising and capacity-building of persons with responsibility in research issues (lecturers; employees of research centres and laboratories; researchers; students) and, in general terms, foster a culture of ethics and accountability.

In relation to the general recommendations, the contents presented reflect a process of benchmarking and surveying of good practices. For the specific recommendations, we highlight the relevance of promoting a process of assessment of needs, pre-testing for adjustment of materials and procedures.

A. GENERAL RECOMMENDATIONS

The general recommendations of activities presented in the context of the proposal "Ethics in research – Best practices, best Science (ISCTE-IUL)" concern two aspects: 1. Guiding principles of the constitution and activity of the ethics committee; 2. Training and competences of persons with responsibility in research issues.

1. Guiding principles of the constitution and activity of the ethics committee

The contribution, relevance and centrality of the ethics committee in the context of research carried out in the academic sphere depends, to a large extent, on the construction of a culture and organisational structure that unequivocally positions ethics as a fundamental part of the research process. In this regard, five guiding principles are indicated as being key elements of the constitution and activity of the ethics committee: i) Independence; ii) Capacity-building; iii) Diligence; iv) Transparency; and v) Competence. The institutional decision-making structures are responsible for providing the necessary resources for the attainment of these principles and promoting their monitoring, in a perspective of continuous improvement of the systems and procedures of ethical approval in research.

i. Independence

The principle of independence emphasises the need to prevent conflicts of interest in the activities developed in the area of research, the ethics committee and the organisational structures of the institution. To this end, the members of the ethics committee abstain from participating in deliberations that could have direct implications in other roles that these members play concerning the research (e.g. assessment of study proposals in which they are involved). Likewise, the members of the ethics committee rule their conduct, decisions and recommendations according to strict criteria giving value to ethics in research, irrespective of other needs, interests or expectations that might exist at the institutional level.

ii. Capacity-building

The principle of capacity-building evokes the responsibility of the ethics committee in actively promoting the education, information and support of the participants in the research for the planning and conduct of studies in an ethical form. In other words, this principle implies the committee's responsibility to affirm itself as the driver of the academic community's capacity-building for relevant issues on ethics in research (e.g. through the organisation of periodic sessions of training and discussion open to the academic community, with the actual members of the

committee; disclosure, distribution and referral of periodicals and/or publications of relevance for ethics in research). The principle of capacity-building also accentuates the importance of the committee in providing constructive and educational responses in the opinions it issues on submissions for ethical approval, delineating guidelines for the resolution of any limitations that it may detect.

iii. Diligence

The principle of diligence recognises the importance of assuring prompt answers to doubts raised and requests made to the committee, as well as to the submissions for ethical approval.

iv. Transparency

The principle of transparency highlights the need to frame the ethics committee in an organisational structure that confers the necessary autonomy, but also requires the presentation of accounts and openness to scrutiny, by the academic community, of all the activities and procedures of appraisal/ethical approval.

v. Competence

The principle of competence refers to the general lines of constitution of the ethics committee and working parties appointed for appraisal of submissions for ethical approval (by deliberation), in order to ensure the necessary aptitudes and qualifications for performing the respective duties. Ideally, this principle implies: the inclusion of members with extended experience in areas of research subject to review and ethical approval; the inclusion of at least one member with knowledge in applied ethics; the inclusion of at least one member outside the institution who has training and experience in issues of ethics in research; the observation of criteria of multidisciplinarity and gender parity in its constitution; and the composition of an odd number of members, with a minimum of 3 members.

Also under the principle of competence, the ethics committee may endeavour to establish and formalise collaboration agreements with relevant partners (e.g. National Data Protection Authority; System of Monitoring Surveys in School

Establishments of the Directorate General for Education), with a view to enhancing the streamlining of the approval of projects that imply submission and deliberation by various entities (e.g. delegation of competences; coordination/articulation through a single submission).

2. Training and competences of persons with responsibility in research issues

The training and development of competences of persons with responsibility in research issues (lecturers; employees of research centres and laboratories; researchers; students) constitute a fundamental axis in the promotion of a culture of ethics and accountability. Therefore, the provision of training activities and contents in ethics in research constitutes a priority in any strategy aimed at enhancing the quality of scientific production. These training activities and contents should be designed and provided according to the general and specific needs of the different individuals or groups of people (e.g. workshop format for lecturers, researchers; seminar format for 3rd cycle students; curricular unit or curricular unit module format for 1st and 2nd cycle students). Among the relevant themes in the perspective of training and competences in ethics in research, the general topics can be outlined: i) Ethics in research: what it is and why it's important; ii) Ethical approaches; iii) Reference codes and principles of ethics in research; iv) Models of regulation of research ethics; v) Key concepts of ethics in research; vi) Ethics in research – capacity-building and practical guidelines.

i. Ethics in research: what it is and why it's important

The topic relative to *Ethics in research: what it is and why it's important* aims to demonstrate the practical value of considering and approaching this subject in a systematic form. The contents of this topic can include: Protection, mitigation of damage and promotion of benefits; Trustworthiness; Integrity in the research process; Organisational and professional requirements; Existing and emerging challenges.

ii. Ethical approaches

The topic relative to *Ethical approaches* seeks to promote familiarisation with some of the main models of normative ethical consideration and their application in the western context. In this topic, the contents can include: Consequentialist approaches; Non-consequentialist approaches; Virtue ethics; Other normative approaches.

iii. Reference codes and principles of ethics in research

The topic relative to *Reference codes and principles of ethics in research* aims to promote familiarisation with the historically most relevant models of ethical application in the context of research. The contents of this topic can include: Nuremberg Code; Declaration of Helsinki; Belmont Report; CIOMS.

iv. Models of regulation of research ethics

The topic relative to *Models of regulation of research ethics* seeks to promote familiarisation with various systematic approaches to the regulation in this field (i.e. top-down versus bottom-up approaches) in contexts with different practical, formal and/or legal particularities. The contents of this topic can include the presentation and discussion of existing models in diverse contexts: United States of America, Canada, Australia, New Zealand, United Kingdom, South Africa, Scandinavia (Norway, Denmark, Sweden); the European Context; Local ethics committees.

v. Key concepts of ethics in research

The topic relative to *Key concepts of ethics in research* aims to promote familiarisation with transversal and essential subjects in this field. The contents of this topic can include: Informed consent; Confidentiality and management of information; Relevance of research; Protection of the participants; Integrity and truth in research.

vi. Ethics in research – capacity-building and practical guidelines

The topic relative to *Ethics in research – capacity-building and practical guidelines* aims to promote and apply skills in ethical reasoning, anticipation, decision-making and solving of dilemmas, preparing submissions for ethical approval and responding to requests in the context of the review process. The contents of this topic can include: Identifying issues of relevance in research ethics; Resolving an ethical dilemma in the context of research; Obtaining ethical approval in the context of research; Dealing with unexpected ethical challenges in the context of research; Case analysis.

B. SPECIFIC RECOMMENDATIONS

The implementation of a process of assessment of needs will enable delineating a specific diagnosis and informing the decision-taking with respect to activities and strategic guidelines. The focus of the needs' assessment should be the promotion of a culture and practice of excellence in terms of research ethics at ISCTE-IUL. In this context, the assessment of needs emphasises an approach based on processes, i.e. activities that receive inputs and convert them into outputs, adding value for the organisation. Each process should be operationalised in terms of its specific features, such as the resources that it needs, its sub-processes, the particular product that it produces and its objectives and results. In this regard, the use of the tool embodied in the logical model could consist of an instrument for the planning of the assessment of needs, for the systematisation of the areas of activity to be designed and implemented, and for the pre-testing and adjustment of materials and procedures.

Considering the scope of the proposal "Ethics in research – Best practices, best Science (ISCTE-IUL)", a participatory work methodology is suggested, incident on the needs and expectations of the different stakeholders, in conjunction with the best practices identified in the context of the literature review and benchmarking, and with the testing of the presented materials and procedures (i.e. Code of Conduct; Guideline Documents; Tools and Models). The assessment of needs for preparation of specific recommendations should thus concentrate on three axes.

1. Attitudes and knowledge of the students (2nd and 3rd cycle)

Participatory methodology with focus groups and questionnaires, which should identify a set of conclusions and implications for the promotion of a culture and practices of excellence in research ethics at ISCTE. This includes the training and assessment of the materials and procedures presented in this work proposal and respective adaptation/redesign.

2. Attitudes and knowledge of the lecturers and researcher

Participatory methodology with focus groups and questionnaires, which should identify a set of conclusions and implications for the promotion of a culture and practices of excellence in research ethics at ISCTE. This includes the training and assessment of the materials and procedures presented in this work proposal and respective adaptation/redesign.

3. Pre-testing and adjustment of the materials and procedures

Participatory methodology of implementation, improvement and assurance of the quality of the materials and procedures, with continuous and shared adjustment of the practices of submission and ethical approval, and capacity-building of those involved in research. This includes the training and assessment of the materials and procedures presented in this work proposal and respective adaptation/redesign.

Also includes the preparation and testing of an online platform for the ethical approval submission form (e.g. through Ciência-IUL or MyISCTE).