

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

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-IUL, 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 multidisciplinary 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-IUL. 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-IUL. 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).