

ETHICAL CRITERIA FOR THE EVALUATION OF RESEARCH PROJECTS AND PAPERS



Scope

This document outlines the ethical criteria for evaluating research projects and studies, ensuring they are socially relevant, methodologically sound, and respectful of human rights. It emphasizes justice in participant selection, data protection, and the need for independent ethical review. The principles of autonomy, dignity, trust, and non-maleficence guide its recommendations.

This is a full translation based on the document from the Ethics Committee for Research and Teaching at the University of A Coruña (CEID-UDC), approved by the Research Committee on March 18, 2025, available at:

<https://www.udc.es/en/ceid/procedemento-avaliacion/>

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1. Social and Scientific Relevance

Research is not an end in itself, but a means to generate knowledge that leads to the improvement of other goods. Therefore, it must provide a benefit to health, well-being, or knowledge, which are valuable in themselves. Research that merely replicates already proven and known results, that analyzes insignificant problems, or that presents methodological deficiencies cannot guarantee such a benefit.

At least three ethical reasons justify the requirement for value or social relevance, which in turn is the justification for research. First, justice, which demands the responsible use of limited economic, personal, and material resources. This supports the principle of non-maleficence, since exposing human beings to risks would only be justified by the achievement of a greater benefit (see Criterion 3: Favorable Risk-Benefit Balance). Second, avoiding exploitation, ensuring that people are not used merely as means to obtain knowledge, respecting their dignity and rights. Finally, trust, both among participants, researchers, and other involved agents, and from society in the research activity itself.

It is essential to justify the necessity and social interest of the research, highlighting its contribution to the advancement of knowledge and the improvement of living conditions for people, societies, and the planet.

2. Methodological Validity

The European Code of Conduct for Research Integrity (2023) and the Ethical Code for Research at the University of A Coruña (2019) identify, among the fundamental principles for scientific integrity, the reliability in ensuring the quality of research, which is reflected in the design, methodology, analysis, and use of resources. This is because a study with methodological errors is not only scientifically useless but also ethically unacceptable.

To ensure this validity, the research must be well-designed and provide sufficient guarantees of the reliability of the results. The methodology must be valid and feasible: definition of one or more scientific objectives; research design based on recognized principles, methods, and practices; and the ability to demonstrate the initial hypothesis, as well as to achieve the stated objectives. To this end, the competence of the research team and the suitability of the facilities, procedures, and materials must also be ensured.

Unlike the previous requirement, which assesses the ethical correctness of the goal or outcome of the research, the evaluation of methodological validity involves a judgment about the suitability of the means to achieve the proposed goal; that is, whether the scientific design and the personal and material resources are appropriate to achieve the stated objectives.

The purpose of the evaluation is not to indicate what would be the best possible methodological choice or to make comparative judgments, but solely to assess whether the methodology proposed in the study/project is adequate to carry out the research rigorously and effectively.

The ethical justification for this requirement is similar to the previous one: justice and dignity, in terms of avoiding exploitation, and trust. The careful and equitable use of limited resources requires avoiding their waste; if knowledge is not generated or proportional benefits are not obtained, it is not justified to expose participants to risks or cause harm, however minor.

3. Favorable Risk-Benefit Balance

Research involves risks, but it is considered ethically acceptable to assume them. Risk refers to the possibility of suffering harm, loss, injury, or other negative effects or discomforts, which may manifest in different areas. On the physical level, it includes any harm to health; on the psychological level, it may result in behavioral changes, anxiety, guilt, feelings of worthlessness, fear, or anger, among others. It may also have moral and social repercussions, such as stigmatization, disruption of interpersonal relationships, shame, or loss of respect.

Weighing these factors requires comparing the risks and benefits for the participants and contrasting the risks to them with the benefits to society. In this way, research is only justified when the potential risks and harms to participants are identified and minimized, the potential benefits are identified and maximized, and these benefits outweigh the risks—both for the participants and for society. Conversely, when the risks of the research outweigh the potential benefits for individuals and for useful knowledge for society, it is not ethically justified.

The balance between risks and benefits must be periodically re-evaluated throughout the study, providing monitoring mechanisms to identify possible adverse effects during its execution and mitigation plans to reduce negative impacts.

Despite the comparative judgment, the ethical justification for this requirement is not exclusively utilitarian. On one hand, there is the duty of **non-exploitation or non-instrumentalization**, which rests on the value of the dignity of the participants; on the other, a **deontological foundation** based on two classical principles of bioethics: the duty **not to cause harm** to people (**principle of non-maleficence**), which justifies minimizing risks; and the duty **to act for the benefit of others** (**principle of beneficence**), which relates to the need to maximize the benefits both for the participants and for society, which could even be reinforced by the aforementioned principle of justice. Finally, trust that there will be no unnecessary exposure to risks after the required weighing of those risks against the benefits.

4. Justice and Equity in Participant Selection

When selecting participants, both the overuse and the marginalization of certain groups must be avoided.

The main eligibility criterion for participants should be their suitability for achieving the research objectives—not the ease of recruitment, whether due to proximity, ease of observation or access,

or vulnerability. Therefore, to ensure the ethical soundness of the research, the research team must carefully examine the existence of vulnerability situations arising from factors such as age, sex-gender, cognitive capacity, social exclusion, or lack of socioeconomic resources.

Equitable selection requires that all groups of people have the opportunity to participate in the research, unless there are scientific or risk-related reasons that justify restricting their eligibility—for example, due to significantly higher exposure to such risks. Selection is equitable when the benefits of the research are accessible to the groups involved and not only to privileged sectors. This should be understood both in a **positive sense**—including people to whom the results may apply or who may benefit from them—and in a **negative sense**—not excluding people who could potentially benefit, even if there are certain access difficulties for their participation.

This explains the recruitment and inclusion of groups that were previously excluded, understudied, or made invisible, such as children or women.

Finally, it is important to emphasize its interaction with other ethical requirements, such as social value, scientific relevance, and methodological validity, and in particular, the favorable risk-benefit balance. Therefore, in addition to identifying and selecting participants based on their scientific relevance to the research and its objectives, equitable selection requires that the research design minimizes risks and ensures the maximization of benefits, so that eligibility is based not only on scientific suitability but also on not increasing the risk of participants being harmed or worsened by their participation, despite their scientific suitability.

The ethical justification for this requirement is linked to **equality** and the **prohibition of discrimination**, as well as to **justice as recognition**, which ensures the proportional representation of any participant. It is also related to **distributive justice**, since participants must not be merely recipients of the burdens or harms derived from the research, but also they must also receive the potential benefits, and this is linked to the **principle of non-maleficence**, insofar as eligibility criteria must consider how to minimize risks and harm to participants. Once again, **trust** in the fairness of the selection criteria and the **impartiality** of those who design and apply them is at the core of these principles.

5. Respect for Participants

Respect for fellow researchers, participants, society, material resources, ecosystems, cultural heritage, and the environment is a core principle present in the **European Code of Conduct for Research Integrity (2023)** and the **Ethical Code for Research at the University of A Coruña (2019)**.

This requirement encompasses several aspects. First, respect is based on the **initial consent** of individuals to participate in the research and the guarantee of their **right to withdraw** at any time. Second, it involves the duty to **monitor and ensure the health and well-being** of participants, as well as to intervene to prevent adverse effects, discomfort, or to treat any harm that may arise during the research; that is, to ensure the **quality and safety** of the research and the **absence of instrumentalization**. Third, it includes the **protection of privacy** and the **guarantee of confidentiality** of information and data. Finally, respect also requires **providing participants with new information**

obtained during the research—particularly if it has implications for their health or well-being—**allowing access to results, and sharing the benefits.**

Trust plays a central role in the ethical justification of this requirement. Initially, trust in the **quality and safety** of the research. Secondly, trust in the **protection of the health and well-being** of those who ultimately agree to participate, as well as in the **absence of harm and instrumentalization**—aspects directly linked to the **dignity** of participants and the **four principles of bioethics**, especially **non-maleficence** and **beneficence**. Lastly, trust is a core value in **safeguarding privacy** and **ensuring confidentiality**, due to the ethical relevance of the information obtained and handled in research.

5.1. Informed Consent

This requirement expresses the need to guarantee **respect for the autonomy** of participants, allowing them to decide whether and how they wish to contribute to the research. Sufficient and appropriate information must be provided so that the person understands what it means to participate in the research and can, based on that information, make a **free and voluntary decision**, including the possibility of **withdrawing consent without consequences**.

A valid informed consent essentially consists of three requirements:

1. **Capacity**, meaning the participant's ability to understand the information about the research, appreciate its meaning, scope, and consequences, deliberate rationally about it, and make a decision about participation in accordance with their own values and interests. In general terms, it is presumed that individuals over the age of 18 have full capacity to give informed consent autonomously. Conversely, the participation of minors or individuals with diminished capacity to consent is subject to a different framework, which usually requires the involvement of third parties to support or complement the decision-making process. Legislation recognizes different levels of progressive autonomy depending on age, aiming to address the biopsychosocial development process. Children must always be heard. From the age of 12, it is mandatory to do so, and their refusal takes precedence over the opinion of those holding parental authority; from the age of 14, they can consent to the processing of their personal data; and from the age of 16, they can consent on their own to any health-related intervention, with some exceptions, and may request legal emancipation.
2. **Information**, which operates on two levels: the provision of information by the researcher, consisting of the communication of necessary and relevant data—description and characteristics of the research, purpose or objectives, probable risks and benefits, etc.—in appropriate conditions and tailored to the participant's needs to make a decision; and the participant's understanding of that information so they can make a genuinely autonomous decision.

ABOUT ETHICAL CRITERIA

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3. **Voluntariness**, in the sense of intentionality and freedom of will to decide about participation, without unjustified control and free from coercion, manipulation, or undue influence. It is important to consider possible factors of power or dependency, conflicts of interest, or situations of vulnerability, in order to avoid or neutralize them and ensure they do not unduly influence consent.

Consent to participate in research is not merely a mechanism to protect participants from researcher abuse—as in the early regulations of research ethics involving human beings—but rather the final expression of a deliberative process between the researcher and the participant, in which the latter exercises their capacity to exercise self-determination in the form of an informed and voluntary decision aligned with their values and preferences; that is, it is based on a **relational**, not individualistic, conception of autonomy—one rooted in a relationship of **trust**.

The usual and primary ethical justification for this requirement is the **autonomy** of individuals, but that alone is not sufficient. Therefore, the foundation for respecting autonomy should be complemented by the value of **trust**, the obligation of **non-instrumentalization or non-exploitation** (linked to the **principle of non-maleficence** and the value of **dignity**), and the **principle of justice**.

5.2. Respect for Privacy, Confidentiality Commitment, and Data Protection

Respect for privacy is a fundamental principle in research involving human beings, both in terms of physical privacy and information related to a person's intimate or private sphere, which often includes **sensitive data** deserving special protection. This means ensuring the **confidentiality** of information and minimizing any unnecessary intrusion into their private life.

To meet this criterion, the following must be considered:

- The **purpose limitation principle**: research must be limited to the specific, explicit, and legitimate purposes defined in the study or project, avoiding any subsequent uses incompatible with those purposes.
- The **data minimization principle**: only collect information strictly necessary to achieve the research objectives. Irrelevant or excessive data collection must be avoided, and the data processed must be accurate and up to date.
- Minimize any interference in participants' personal sphere, especially when the methodology involves direct interactions such as interviews, observations, or the collection of sensitive data.

The **commitment to confidentiality** requires that researchers adopt measures to ensure the **security of the data** handled, in accordance with current regulations—particularly the **General Data Protection Regulation (GDPR)** and the **Spanish Organic Law on Personal Data Protection and Guarantee of Digital Rights**. This includes **anonymization** or

pseudonymization of data, with clear specification of who will have access to the information, how it will be stored, how long it will be retained, and the procedure for its deletion.

When the research poses a **high risk to the rights and freedoms** of participants, it is mandatory to carry out a **data protection impact assessment**, in accordance with Article 35 of the GDPR. This procedure helps identify and mitigate potential privacy violations, especially when processing sensitive data or using advanced technologies for analysis.

The ethical justification for this requirement is based on **respect for the dignity** of participants, ensuring that they are not subjected to undue intrusions into their private lives. Secondly, it is grounded in **respect for their autonomy**, understood here as **informational autonomy**, meaning that the participant must be able to control and decide the fate of the information related to them. Finally, it is closely linked to the **principle of trust**: both in the research team's commitment to protect the information and in the assurance that the data will be handled with full responsibility, minimizing risks and ensuring the protection of fundamental rights.

6. Independent Evaluation

An independent and competent body must assess the soundness of the research design, ensure fair participant selection and respect for participants, confirm the existence of an appropriate risk-benefit balance, and verify compliance with other methodological and ethical requirements and the necessary procedures. This body—typically a **research ethics committee**—ensures that all the above conditions are met. Additionally, it helps identify and prevent **conflicts of interest** among researchers, which could distort the design and execution of the research, and it safeguards **social responsibility** regarding research quality, ensuring that participants are treated ethically.

All the values and principles mentioned are combined in the ethical justification of this requirement:

- **Social and professional trust** in the committee's rigor and independence in fulfilling its duties, and therefore in the **quality and integrity** of the research evaluation;
- **Protection of the dignity, safety, and rights** of participants, both through fair selection for participation and throughout the research process;
- And the **guarantee of researchers' rights and scientific integrity**, ensuring that the research does not cause harm and produces benefits.

USEFUL REFERENCES

- Committee on Research and Teaching Ethics of the University of A Coruña (CEID-UDC): <https://www.udc.es/en/ceid/>
- Ethical criteria for the evaluation of research projects and papers by the Committee on Research and Teaching Ethics of the University of A Coruña (CEID-UDC), approved by the Research Commission on March 18, 2025: <https://www.udc.es/en/ceid/procedemento-avaliacion/>
- Templates and Guidelines: <https://www.udc.es/en/ceid/modelos-guias/>
- Links: <https://www.udc.es/en/ceid/ligazons/>