



UNIVERSIDAD DE JAÉN
Vicerrectorado de Investigación

University of Jaén Code of Good Practice in Research

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1. FOUNDATIONS AND PRINCIPLES

As a product of collective intelligence, science is a social activity that requires ethically based goals and norms. Scientific research is currently the main source of the social legitimation of truth and, at the same time, the first productive force. This double link with truth and utility gives scientific research a force full of opportunities, but it also implies risks and conflicts. Therefore, any science must be provided with practices, purposes, principles and ethical standards that regulate the work of the research community. This ethical code of good practice in scientific research has two main objectives:

1. To protect the quality, veracity and honesty of the scientific research carried out at the University of Jaén.
2. To protect the bioethical rights and obligations of people, animals and the environment during the development of scientific research at the University of Jaén.

Objective and mission:

To establish a code of good practice in research for researchers at the University of Jaén.

Scope:

All research or teaching activities carried out by staff at the University of Jaén.

1.1. ETHICAL AND EPISTEMOLOGICAL PRINCIPLES

Epistemological and ethical principles inform the criteria of veracity and quality that allow good practice in research to be achieved. Research carried out at the University of Jaén must abide by these principles.

Legality

Any research carried out at the University of Jaén must not contravene the laws of the state, the European Union or international laws applicable in Spain.

Honesty

Scientific research carried out at the University of Jaén will be in accordance with the criteria and ethical standards accepted in the scientific community and will avoid incurring any type of bias that intentionally distorts research results. Any deviant use of the research, such as falsification or fabrication of data, its abusive interpretation or plagiarism, must be avoided.

Transparency

Scientific activity is cooperative in nature and therefore requires transparency and publicity. Scientific information generated at the University of Jaén must be public and made available to the scientific community and society, with the sole limitation of restrictions imposed by law. The University of Jaén will promote the use of open-access publications and free programming languages.

Traceability

The public availability of research must also guarantee its traceability. The purpose of traceability is that each set of data or information can be verified by external observers. To this end, the registration of research projects in a public registry from the initial phases (formulation of hypotheses) to the final results is highly recommended.

Rigor

Researchers at the University of Jaén must be guided by the optimum quality standards within their respective disciplines. At all times such standards must include the following methodological criteria: precise formulation and control of hypotheses, parsimony, reflective balance, adequate design of experiments and efficient management of the available means.

Responsibility

Researchers at the University of Jaén must guarantee that their research meets ethical, legal, programmatic and contractual requirements established in the research protocol or research calls, or in agreements established with stakeholders.

Gender and age balance

In research with humans, especially in clinical trials, it is recommended that a balanced representation be attained in terms of gender and age whenever the object of the research allows and requires it.

The promotion of gender and age balance in the leadership of the research structures will also be ensured, whenever possible, through rotation of the management positions within such structures.

Women's leadership of research projects will be promoted in order to strengthen and consolidate their academic career. Similarly, women's direction or co-direction of doctoral theses and R&D projects at any level (international, national or regional) will be supported and promoted.

1.2. BIOETHICAL PRINCIPLES

Bioethical principles are prescriptions and ethical standards that guide research to safeguard the rights of people involved in such research. The University of Jaén undertakes to respect, protect and guarantee these rights in scientific research.

Autonomy and voluntariness

All persons involved in research carried out at the University of Jaén must consent explicitly and without coercion to their willingness to participate in such research.

Justice

Research carried out at the University of Jaén cannot have as its purpose, means or result unfair or unjustified discrimination based on age, gender, sexual orientation, social class, income, or functional or ethnic diversity.

Beneficence

Research carried out at the University of Jaén must have as its goal the acquisition of new knowledge, seeking the autonomy, well-being and health of people and the environment.

No maleficence

No research carried out at the University of Jaén should be aimed at harming the well-being or health of people or be aimed at the deterioration of the environment.

Prudence

In the event of a high level of uncertainty pertaining to the risks and potential benefits of a given technology or research, the burden of proof will fall on the researchers responsible for the research. In applying the principle of prudence, the full range of available alternatives, including no action, must be evaluated.

Sustainability

Research carried out at the University of Jaén must be respectful of ecological balance and be oriented towards promoting efficiency and environmental sustainability, avoiding and minimizing negative impacts on the environment.

2. CONFLICT OF INTEREST IN THE RESEARCH

Research integrity and credibility rests on the integrity of the research staff. Trust and credibility in the researcher may be questioned when society and the scientific community perceive the existence of interests other than those of the research itself. A conflict of interest is a situation in which the judgement of the researcher regarding his or her primary interest (the integrity of the research) may be influenced by a secondary interest, generally of an economic or personal nature, which may alter his or her objectivity and distort good scientific practice. However, the existence of a potential conflict of interest does not in itself mean that the results or findings of an investigation are biased or lead to incorrect conclusions, but only that this is a possibility. The existence of a possible conflict of interest is not reprehensible in itself, as long as it is not hidden, and as long as its existence is reported and appropriate measures are taken.

Good scientific practice recommends that researchers at the University of Jaén who face a potential conflict of interest make a formal declaration of their interests, which is known as a declaration of conflict of interest. This statement must appear throughout the research process, from the project protocol to the resulting scientific publications. Diverse national and international legal provisions regulate the conflict of interest (see Annex).

3. TRANSPARENCY

3.1. Data collection and data management

It is recommended that research protocols, as well as data and research results (including preliminary data, negative, unexpected or discordant results), be kept by the research staff and/or the institution for an adequate period of time (not less than 5 years). The preservation of the data must be done in a secure manner; if they are electronically stored, backups must be made. When the data contain personal information, their collection and preservation must be done in accordance with the Data Protection Law (see Annex).

3.2. Dissemination of results

A primary objective of any research must be the dissemination of its results and findings in a way that they may contribute to scientific knowledge and social benefits. Researchers at the University of Jaén must manage the publication of the results and conclusions of any research in a complete, honest, transparent and precise manner. This also implies communicating the negative or discordant results with the initial hypotheses. The research staff of the University of Jaén must be prudent in the interpretation and dissemination of results, avoiding overvaluations that could confuse or create misunderstandings or false expectations in society.

Once the research has been completed, the complete publication of results should be done as soon as possible, especially when the research received public funding. Exceptions can be considered when part of the results require restriction or protection related to intellectual property or patent.

Research results can be disseminated through scientific meetings (workshops, conferences or congresses) and/or through the publication of articles in specialized and reputed scientific media (indexed journals, books, monographs, etc.). Additionally, diverse options of online publication formats have become an option in recent years (e.g. blogs, repositories). The dissemination of results in several of these formats can be considered as good practice or as redundant publication depending on the field of knowledge or the scientific discipline.

There is growing agreement among the scientific community about the convenience of publishing research results in open-access journals as a way of guaranteeing accessibility to the knowledge generated, provided that such journals are scientifically acknowledged and reputed.

3.3 Authorship

The rules of good scientific practice state that in order to partake of the authorship in the dissemination of research results, researchers must meet the following set of requirements:

- a) Have made a substantial contribution to the conceptualization and design of the research and/or to data collection and/or to data analysis and interpretation.
- b) Have contributed to the writing and/or revision of the manuscript or the research report.
- c) Are able to present in detail the personal contribution to the research and discuss the main aspects of the whole study.

All researchers who have participated sufficiently in the development of the research project must appear as authors; the order of authorship must be agreed within the research team, in accordance with the usual guidelines within each field of knowledge or scientific discipline. Other people whose contribution does not meet the authorship criteria should not appear as authors (in this case they can be recognized in the acknowledgments section of the publication). It is recommended that people who are going to be cited in the acknowledgments section be informed and their permission obtained.

In the dissemination of their research results, authors must state their institutional affiliation, in this case the University of Jaén (according to the 2014 Resolution on normalization of institutional affiliation in publications whose authorship is associated with people from the University of Jaén) and other institutions in the event of multiple affiliation.

The University of Jaén adheres to ORCID (Open Researcher and Contributor ID) as a standard for the international identification of researchers, so it is recommended that the ORCID ID be added to all scientific contributions made by research staff of the university.

4. RESEARCH WITH HUMAN BEINGS

4.1 Consent

In all research carried out at the University of Jaén in which human beings are involved, participants must be informed of the objectives, the methods to be used and the possible risks or inconvenience that may arise from their participation, before starting the research. Participants must also be informed of any other aspect that could be relevant when making the decision to participate.

The information provided must be included as part of a communication process with the participants. Therefore, it must be clear and concise. It must also be proportional to the complexity of the procedure and sufficiently adapted to participants' characteristics such as educational level.

The information must also make a clear statement about the voluntary participation as well as the participants' right to refrain from participating in the research and to withdraw at any time without any consequence.

Consent must be documented, preferably through a written document. In some cases, verbal consent may be given if witnessed by a third person. If the person does not have the capacity to understand and retain the relevant information about the research, any means of consent will not be valid.

4.2 Vulnerable groups

Any research with human beings carried out at the University of Jaén has to especially assess the participation of vulnerable persons. In the context of research, vulnerable persons are those who may not be able to protect their own interests when deciding to participate (for example, those who have difficulty in assessing the risk–benefit ratio of their participation; those whose voluntary participation could be compromised when giving their consent owing to their relationship with the research staff; or those whose physical or psychological condition make them more likely to suffer harm).

When planning the research, the need for the participation of vulnerable persons should be considered. If the research could be carried out with non-vulnerable persons, the participation of the former should be avoided. In the event that their participation is necessary, the consent of a pertinent third party such as guardians, parents or legal representatives must be obtained. Even when this consent has been obtained, it is advisable to obtain the assent of the participants themselves.

4.3 Risks and benefits

The person conducting the research must protect the participants from physical and psychological risks. In the context of the research, risk is understood as the potential physical or psychological harm or discomfort arising from some circumstance of the investigation. The person conducting the research must ensure that the benefits and potential risks and costs to participants are reasonably balanced. The risks and costs must also be minimized. If any physical or psychological damage occurs, action must be taken to alleviate any problems created.

4.4 Confidentiality of information

Confidentiality implies researchers' commitment not to reveal information associated with the participants obtained during the investigation. Information obtained during research should be considered confidential unless previously stated otherwise.

If there are subsequent reasons to disclose the information obtained under conditions of confidentiality, the person's consent must be obtained. In this situation, it is also possible to proceed by anonymizing the information, that is, by decoupling the relationship between data/information and participants.

Researchers must establish conditions for the safekeeping of the information obtained during the investigation and must seek the necessary means to safeguard its confidentiality.

Participants have the right both to access and to refuse to access the information collected during the investigation. Researchers must abide by participants' decision in this regard. If transmitting the information to participants, researchers must do so in a way that is understood by the participants. Research projects with human beings carried out at the University of Jaén must have the approval of the competent authority whenever required by current regulations.

5. ANIMAL RESEARCH

Non-human animals are ethically valuable living beings in themselves; this implies ethical obligations towards them. The instrumental use of non-human animals in experiments carried out at the University of Jaén must be explicitly justified and limited by these three criteria (the three Rs):

- Replacement: Replacing animals with other options in which they are not necessary, such as audio-visual media or virtual reality techniques, or using animals with a less developed perception of stress and pain.

- **Reduction:** Limitation of the number of animals necessary to obtain a valid sample. Statistical studies must be used that allow the researcher to clearly establish the minimum number of subjects to obtain satisfactory scientific results, taking into account the importance of choosing the species that is best adapted to the study.
- **Refinement:** Refinement of actions on animal models, and improvement of their living conditions. Similarly, concepts must be promoted that include environmental enrichment, the use of anaesthesia and analgesia, the classification of severity of procedures or the establishment of early endpoint criteria.

The Ethics Committee of the University of Jaén will guarantee the adequacy of the methodological, ethical and legal aspects of the research carried out in the institution, and guarantee the welfare of the animals used as experimental models in research.

Research projects carried out at the University of Jaén must have the approval of the competent authority. All personnel participating in the related procedures must have accredited training that enables them to perform the functions stated in national and European legislation.

6. RESEARCH WITH BIOLOGICAL AGENTS AND GENETICALLY MODIFIED ORGANISMS

Researchers who carry out research activities with biological agents and genetically modified organisms (GMOs), cell cultures and human endoparasites susceptible of causing any type of infection, allergy or toxicity, must be rigorous in complying with the corresponding regulations. Also, they must always have a favourable report from the Ethics Committee in Research with GMOs and Biological Agents of the University of Jaén.

Researchers who carry out research activities with biological agents and GMOs must be aware of, evaluate and notify the Ethics Committee for Research with GMOs and Biological Agents of the University of Jaén of the risks, if any, of exposure to biological agents and GMOs, as well as take all appropriate measures to remove or minimize the risks arising from the use of biological agents and GMOs in research activities.

7. HEALTH AND SAFETY AND THE ENVIRONMENT

The University of Jaén will ensure the development of research that guarantees the health and safety of people and respect for the environment. In this regard, the research groups, and especially the lead researchers, must be aware of the University's occupational risk prevention and environmental protection policies. Likewise, they must guarantee that their research activities are carried out in accordance with current legislation, as well as making adequate use of the resources, means, facilities and services made available to them by the University of Jaén.

All the research staff of the University of Jaén have the right to have information and effective protection in matters of health and safety at work.

ANNEX

Legal and regulatory frameworks referred to in this document

- Law 14/2007 on Biomedical Research and Law 14/2011 on Science, Technology and Innovation, which establishes the Research Ethics Committees and the Bioethics Committee of Spain as bodies in charge of its surveillance. At the international level, Article 15 of the Universal Declaration on Bioethics and Human Rights of UNESCO, of October 19th, 2005, is relevant. <http://www.boe.es/boe/dias/2007/07/04/pdfs/A28826-28848.pdf>
- Law 14/2011 of June 1st, on Science, Technology and Innovation. <https://www.boe.es/buscar/pdf/2011/BOE-A-2011-9617-consolidado.pdf>
- Article 15 of Universal Declaration on Bioethics and Human Rights of UNESCO, of October 19th, 2005. <http://unesdoc.unesco.org/images/0014/001428/142825s.pdf#page=85>
- Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities. https://www.um.es/c/document_library/get_file?uuid=f3736570-bb84-40b3-8a2e-a9397ef7ef30&groupId=793464
- Royal Decree 178/2004, of January 30th, which approves the General Regulation for the development and execution of Law 9/2003, of April 25th, which establishes the legal regime for the confined use, voluntary release and commercialization of genetically modified organisms.
- Royal Decree 664/1997, of May 12th. National Institute of Safety and Hygiene at Work. Context of the Law on Protection of Occupational Risks.
- Directive 2010/63/EU of the European Parliament and of the Council of September 22nd, 2010, on the protection of animals used for scientific purposes.
- Royal Decree 53/2013, of February 1st, which establishes the basic applicable standards for the protection of animals used in experimentation and other scientific purposes, including teaching.

This document has been written by a working group of the Ethics Commission of the University of Jaén whose members are professors D. Francisco Garrido Peña, D. Santiago Pelegrina López, D. Pedro Pancorbo, D. Francisco Javier Peña Ojeda and D. Antonio José Manzaneda Ávila (coordinator). The document was approved by the Ethics Committee on June 23rd, 2017. It was approved by the Research Committee of the University of Jaén on February 6th, 2019. The Ethics Committee analysed and approved the document with the comments and suggestions made by the Research Commission, and the Governing Council finally approved the document on February 18th, 2018.