Chapter 02 / Capítulo 02

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Ethics in Research / Ética en la Investigación

The research process is a systematic, methodical sequence of steps designed to increase our knowledge and understanding of a specific topic or problem. From the conception of an idea to the communication of results, this process involves several key stages: identifying and formulating the research question, reviewing existing literature, selecting an appropriate methodological approach, collecting and analyzing data, and finally interpreting and disseminating the findings. Each step in the research process is crucial and contributes to the integrity and validity of the study, enabling researchers to make significant contributions to the existing body of knowledge in their field of study. This process is not only fundamental to academic and scientific advancement but also plays a crucial role in informed decision-making in various sectors such as health, education, economics, and public policy.

2.1. Stages of the process

The research process unfolds through several key stages, each with its own objectives and methods. The first stage is identifying the problem or formulating the research question. This phase is fundamental, as it establishes the direction and focus of the study. It requires a clear understanding of the subject area, identifying gaps in existing knowledge, and formulating a specific, relevant, and researchable question. This step often involves a thorough review of existing literature to understand the current state of knowledge on the topic.

The second stage of the research process is the planning and design of the study. Here, the researcher decides on the methodology to be used, including the study design, the selection of data-collection techniques, and the methods for data analysis. This phase also includes planning how the ethical aspects of the research will be addressed, as well as obtaining the necessary approvals and informed consent from participants, if necessary. The research design should be aligned with the study objectives and be appropriate for answering the research question.

The third stage is data collection, which is the process of obtaining the information needed to answer the research question. Depending on the study's focus, this may include conducting experiments, administering surveys, conducting interviews, observing, or collecting data from secondary sources. This phase requires the rigorous and systematic application of the selected methods to ensure that the collected data are reliable, valid, and sufficient for further analysis.

Finally, the last stage is the analysis and interpretation of the data, followed by the presentation of the results. In this phase, the researcher analyzes the collected data to extract meaning and answer the research question. Analysis methods vary depending on the nature of the data and may include statistical analysis, thematic or interpretive analysis, among others. Once the data have been analyzed, the results are presented in a clear and coherent manner, typically in a research report or academic article. This stage also includes reflection on the study's limitations and the implications of the findings for practice and future research. Taken together, these stages constitute the research process, a rigorous and methodical path toward the generation of new knowledge. These stages

They coincide with three basic processes: planning, execution, and completion, as shown in the following figure.

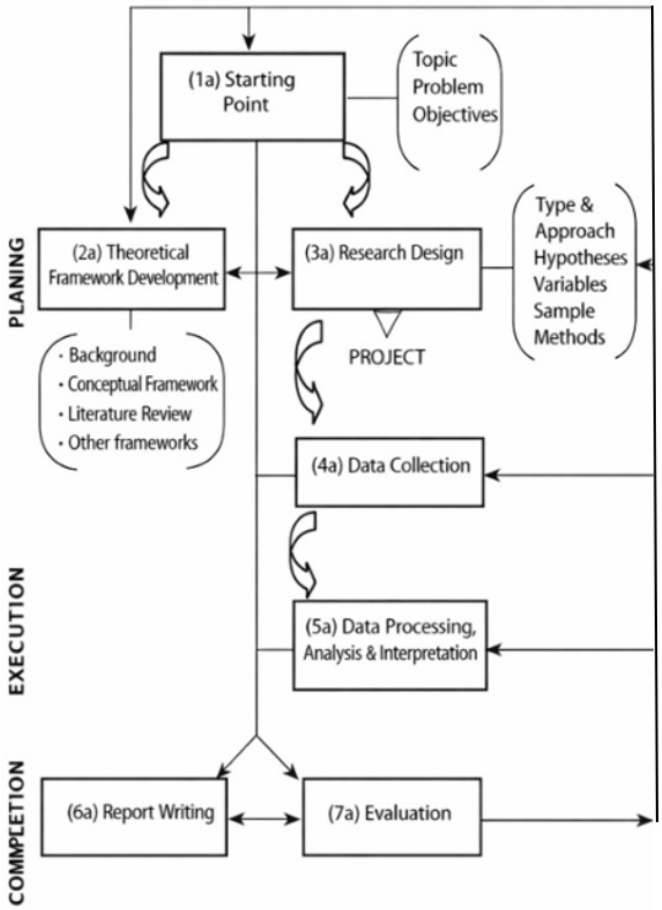

Figure 2.1. Stages of the research process

2.2. Purpose of clinical research in humans and animals

Medical research seeks to understand the characteristics, processes, developments, and relationships in human beings, including pathologies and the effectiveness of treatments to restore health. Its main focus is to validate clinical practices based on scientific evidence, rather than just tradition or empiricism. Although these objectives are noble, they do not guarantee morality in all research practices. Many procedures carry risks and costs, and as in any human activity, objectives can be corrupted by questionable means or selfish ends. There may also be misuse of results for inhumane purposes, as has occurred in the past. Therefore, it is crucial to adhere to ethical principles that do not limit progress but serve as guidelines to align science and humanity, preventing them from conflicting.

2.3. Summary of legal and ethical regulations

The foundation of ethics in medical research is based on the Declaration of Helsinki, which states that scientific or social interests should never override those of the individual. It highlights the need to balance the objectives of a study with the risks to participants, the approval of a clinical trial protocol by a competent Ethics Committee, and informed, voluntary, and prior consent of the patient. This led to the creation of Clinical Research Ethics Committees.

In Spain, legislation on biomedical research is extensive, encompassing European guidelines, national laws, and regional regulations. The most relevant legal documents are LAW 41/2002, which regulates patient autonomy and rights regarding clinical information and documentation; Royal Decree 223/2004, which regulates clinical trials with medicinal products; Circular 7/2004 on clinical research with medical devices; Order SCO/256/2007, which establishes principles and guidelines for good clinical practice and the requirements for manufacturing or importing investigational medicinal products for human use; and LAW 14/2007 Biomedical Research.

2.4. Ethics in clinical research

Clinical research is based on essential principles, which are detailed below in line with the Declaration of Helsinki.

2.4.1. Scientific and social interest of the objectives

In biomedical research, the convergence of scientific and societal interests is fundamental to the development and application of discoveries that benefit society. On the one hand, scientific interest focuses on advancing knowledge and understanding of biological and pathological processes. This involves researching the molecular and genetic bases of diseases, developing new technologies and diagnostic methods, and exploring innovative therapeutic avenues. The goal is to expand the boundaries of knowledge in fields such as genetics, pharmacology, physiology, and other related areas, which is essential for the continued progress of medical science.

On the other hand, the social interest in biomedical research focuses on how these scientific advances can be applied to improve the health and well-being of the population. This includes developing more effective and safer treatments, creating vaccines to prevent disease, and implementing evidence-based public health strategies. In addition, it addresses ethical and equity issues in access to medical advances, ensuring that the benefits of biomedical research are accessible and relevant to diverse populations.

The synergy between scientific and social interests is what drives biomedical research forward. While scientific interest guarantees rigor and innovation in research, social interest ensures that its results have a positive, tangible impact on society. Thus, biomedical research not only advances knowledge but also works to solve real health problems and improve the quality of life for people around the world. Integrating these two aspects is essential for biomedical research to be ethical, effective, and truly transformative.

2.4.2. Scientific validity

Medical research involving human subjects should be conducted exclusively by professionals with appropriate scientific qualifications. Such projects should be based on a thorough knowledge of the relevant scientific literature, other relevant sources of information, and well-conducted laboratory or animal experiments.

2.4.3. Risk-benefit ratio

In medical research, the physician's primary responsibility is to safeguard the life, health, privacy, and dignity of the human being. Research should be conducted only if the intended objectives justify the risks and costs to the individual involved. This consideration is crucial, especially in the case of healthy volunteers. All necessary measures should be taken to minimize the impact of the research on their physical and mental well-being and personality. Physicians should avoid participating in research involving human subjects unless they are convinced

that the associated risks have been adequately assessed and can be effectively managed. If, during the experiment, it becomes apparent that the risks outweigh the potential benefits, or if conclusive evidence of positive or beneficial results is obtained, they should immediately discontinue the experiment.

2.4.4. Informed consent

In any research involving human subjects, each potential participant must receive detailed information about the purposes, methods, sources of funding, potential conflicts of interest, the researcher's institutional affiliations, expected benefits, foreseeable risks, and discomforts that may arise from the experiment. Individuals must be informed of their right to participate in or decline to participate in the research and to withdraw their consent at any time. It is important to ensure that the individual has fully understood this information before obtaining their informed and voluntary consent, preferably in writing. If it is not possible to obtain consent in writing, the process for obtaining it must be formally documented and certified. Certain research populations are particularly vulnerable and require additional protection. It is necessary to recognize and address the special needs of those who are economically and medically disadvantaged. Likewise, special attention should be given to those who cannot give or withhold consent for themselves, those who may be under pressure to consent, those who will not benefit directly from the research, and those whose participation in the research is combined with their medical care.

2.4.5. Respect forde research participants

It is essential to protect the privacy of research participants, including their body image, habits, and personal beliefs. It is also vital to ensure the confidentiality of their identities and the secure, long-term storage of the data collected. During the course of the study, participants must be informed of any new relevant information that emerges, even if this could lead to the revocation of their consent. A constant commitment to participants' optimal well-being must be maintained. At the conclusion of the research, it is important to acknowledge the participants' contributions by sharing the final results of the study with them.

2.4.6. Fair selectionde of participants

The selection of participants for a research study should be based on the most appropriate population groups for the study objectives, avoiding disproportionate selection of individuals from more accessible or socially vulnerable groups. The risks associated with the study for the selected subjects should be balanced by the benefits or value of the information that will be obtained, and that will be relevant to the population they represent.

2.5. Ethics of scientific publishing

The ethical responsibility of researchers in scientific publishing is twofold: on the one hand, they must contribute to the growth of knowledge that is integrated into professional skills and effective clinical practice; on the other hand, they must reflect the integrity and scientific quality of their work as authors. Researchers have a scientific and social obligation to report the actual results of their research honestly, avoiding the fabrication, concealment, manipulation, or distortion of data.

The growing importance of the number of articles published in the evaluation of professional merit, rather than achievements in other fields such as healthcare practice or teaching development, has generated problematic situations that require deep ethical reflection. In some cases, the attitude of publishing for the sake of publishing ("paper mania") has become

more important than the content and quality of what is published, reflecting the popular maxim of "publish or perish" in academic circles.

The increase in scientific publishing is also linked to hyper-individualism, professional ego, and the personal desire to gain recognition for contributions to scientific advancement. Sometimes, the recognition given to the researcher can exceed the research's actual value and practical usefulness.

2.5.1 Authorship

The proper attribution of authorship in scientific publications requires the definition of clear and uniform criteria to determine who qualifies as an author of a scientific work. Morally, an author is considered a researcher who can publicly explain their contribution at all stages of the original research. According to the International Committee of Medical Journal Editors (ICMJE), also known as the Vancouver Group, authorship of a publication implies significant contribution in three key areas: active participation in the conception and design of the study or in the analysis and interpretation of the data; drafting or critical revision of the intellectual content; and approval of the final version to be published.

The phenomenon of ghost authorship can manifest itself in various ways, considered forms of "artificial inflation" of publications: fragmented publication, which consists of dividing a study into several small articles; repeated publication, where previous observations are reiterated with or without new data (known as the "sausage technique"); and the "commercial exchange" of authorship, where researchers who did not participate in the original experiment or in the writing of the article appear as co-authors in exchange for including the other researchers as co-authors in their own future publications.

2.5.2. Plagiarism

One of the most common methods of intellectual fraud in scientific research is the total or partial reproduction of ideas or content from other publications without proper attribution. The widespread availability of publications in electronic formats facilitates fraud and deception, especially through the use of "copy and paste" software, which becomes a tempting tool for potential offenders. Plagiarism involves taking someone else's work and presenting it as one's own without acknowledging the original authors, pretending that the ideas or words of others are one's own. Plagiarism is a violation of professional integrity that diminishes the credit due to the true author and constitutes a serious abuse of the trust placed in the scientific community.

2.5.3. Conflict of interest

A conflict of interest arises when an author, reviewer, or editor of a publication has financial or personal relationships that could inappropriately influence their decisions, regardless of whether they believe such relationships could influence their scientific judgment. To minimize these conflicts of interest, it is recommended to differentiate the physician's roles as clinician and researcher clearly, and to ensure that the physician responsible for the patient's clinical care obtains informed consent to participate in the study. In addition, it is important to clearly inform participants of any financial benefits of the research, ensure that participants are financially covered for any harm suffered during the study, and ensure that publication of the research results is not conditional on whether the results are favorable or unfavorable.

2.5.4. Edition

Medical publications have an ethical responsibility to openly disclose their peer review

process for articles submitted for publication, while ensuring the confidentiality of manuscripts. They must also be clear in their policy on intellectual property rights and ensure accurate dissemination of news related to biomedical research in the media. On the other hand, researchers must maintain a constant commitment to applying high ethical standards. This is crucial to preserving society's trust in research, preventing study participants from being seen merely to increase scientific knowledge, and ensuring that research results translate into tangible benefits for future patients.