

# Bioethical implications of human gene editing: an integrative review

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## Abstract

This study aimed to identify the bioethical implications of gene editing in human cells using the CRISPR-Cas9 technique. An integrative literature review was conducted, encompassing scientific articles published in the last five years and available on the Coordination for the Improvement of Higher Education Personnel journal portal. In total, 12 articles were analyzed, and the results highlighted concerns regarding the impossibility of obtaining consent from unborn individuals, the unknown risks of hereditary genetic modifications, and the need to ensure universal access to the benefits of gene editing. These findings were discussed in light of bioethical principles, drawing on key documents that guide research and clinical procedures in humans. The study concluded that the main bioethical implications identified concern informed consent, human dignity, the risks and benefits of gene editing, and equitable access to scientific advances.

**Keywords:** Gene Editing. CRISPR-Cas Systems. Bioethics. Human genome.

## Resumo

### Implicações bioéticas relacionadas à edição genética humana: revisão integrativa

Este estudo buscou identificar as implicações bioéticas relacionadas à edição genética em células humanas utilizando a técnica CRISPR-Cas9. A metodologia consistiu em uma revisão integrativa da literatura, abrangendo artigos científicos publicados nos últimos cinco anos, disponíveis no portal de periódicos da Coordenação de Aperfeiçoamento de Pessoal de Nível Superior. Foram analisados 12 artigos, e os resultados destacaram preocupações com a impossibilidade de consentimento por indivíduos ainda não nascidos, os riscos desconhecidos de modificações genéticas hereditárias e a necessidade de garantir que os benefícios da edição genética sejam universalmente acessíveis. Tais resultados foram discutidos à luz dos princípios bioéticos, tendo como fundamentação alguns documentos que embasam as pesquisas e procedimentos clínicos em seres humanos. Concluiu-se que as principais implicações e os aspectos bioéticos presentes nos estudos dizem respeito ao consentimento informado, à dignidade humana, aos riscos e benefícios da edição genética e ao acesso equitativo dos avanços científicos.

**Palavras-chave:** Edição de genes. Sistemas CRISPR-Cas. Bioética. Genoma humano.

## Resumen

### Implicaciones bioéticas relacionadas con la edición de genes humanos: revisión integradora

Este estudio pretendió identificar las implicaciones bioéticas relacionadas con la técnica CRISPR-Cas9. La metodología utilizó una revisión integradora de la literatura, abarcando artículos científicos publicados en los últimos cinco años disponibles en el portal de revistas Coordinación para el Perfeccionamiento del Personal de Educación Superior. Se analizaron doce artículos, y los resultados destacaron preocupaciones sobre la imposibilidad de obtener consentimiento de individuos aún no nacidos, los riesgos desconocidos de modificaciones genéticas hereditarias y la necesidad de garantizar que los beneficios de la edición genética sean universalmente accesibles. Estos resultados se discutieron a la luz de los principios bioéticos, con base en algunos documentos que fundamentan las investigaciones y procedimientos clínicos en seres humanos. Las principales implicaciones y aspectos bioéticos presentes en los estudios se refieren al consentimiento informado, a la dignidad humana, a los riesgos y beneficios de la edición genética, y al acceso equitativo a los avances científicos.

**Palabras clave:** Edición Génica. Sistemas CRISPR-Cas. Bioética. Genoma humano.

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The Human Genome Project—started in 1990 and completed in 2003—aimed to map and understand the genes that make up the human genetic code. In 2001, an initial draft of the genome was published, revealing the sequence of approximately 90% of the human genome, a fact that represented a significant scientific advance for biotechnology<sup>1</sup>.

This same historical context saw the publication of the *Universal Declaration on the Human Genome and Human Rights*, adopted by the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1997. This is considered an important document, as it refers to the establishment of ethical guidelines for genetic research. The scope of this declaration emphasizes fundamental principles, such as respect for human dignity, prohibition of discrimination based on genetic characteristics, and protection of the privacy and confidentiality of genetic information. In addition, the declaration underscores the States' ethical responsibility for ensuring that the use of genetics is compatible with human rights and fundamental freedoms. The document contains principles—still current today—that are essential to guide global policies and practices related to human genetics, ensuring a balance between scientific advancement and the protection of individual rights<sup>2</sup>.

Scientific development led to discovery of the possibility of human genome editing, involving techniques to modify deoxyribonucleic acid (DNA) in human cells for the purposes of correcting mutations, treating diseases or improving specific characteristics. Gene editing tools can enable precise changes in the human genome, creating opportunities for significant advances in medicine and biotechnology<sup>3</sup>.

In this context, the technique known as *Clustered Regularly Interspaced Short Palindromic Repeat*; *Cas9* nuclease (CRISPR-Cas9)—which represents an innovation in gene editing—has acquired significant relevance over the last decade. The capacity to make precise DNA cuts using the CRISPR-Cas9 technique has been demonstrated by researchers; since then, CRISPR-Cas9 has been adopted in biomedical research, enabling not only the correction of genetic mutations in human cells, but also the modeling of complex characteristics in animals<sup>4</sup>.

The CRISPR-Cas9 gene editing technique can be applied to both somatic cells and germline cells. Editing somatic cells aims to correct specific DNA mutations in tissues or organs, potentially providing treatment for several diseases. In turn, editing germline cells—such as gametes or embryos—aims to modify DNA hereditarily, thereby enabling the transmission of changes to future generations<sup>5</sup>.

Due to this capacity to permanently modify the genome and transmit these changes to future generations, altering genes in germline cells raises complex bioethical dilemmas related to issues such as: safety, social justice, and potential misuse of the technology for non-therapeutic purposes. The debate on the ethics of germline cell gene editing is a highly relevant subject for researchers, legislators, bioethicists and society in general, requiring a cautious and bioethically based approach to promote responsible and morally acceptable scientific advances.

As for research ethics, a case related to germline cell gene editing has received major prominence and generated significant repercussion in recent years. In 2018, a Chinese scientist unveiled the creation of the world's first CRISPR-Cas9 gene-edited babies. With the argument of making them immune to the human immunodeficiency virus (HIV), the use of CRISPR-Cas9 modified a gene responsible for encoding a protein that is essential for the entry of HIV into human cells. Such procedure caused a huge global controversy, leading to wide debate on ethical, legal and scientific issues of gene editing in humans. The main concerns notably include the lack of proper informed consent, the unknown risks of modifying the human genome, and the possible consequences for future generations. These factors led the scientific community to request the temporary suspension of clinical research involving gene editing in human germline cells, showing the need for strict regulation and effective ethical supervision in this field<sup>6</sup>.

Considering the paradigms permeating discussions related to the advances and challenges of the development and preventive and therapeutic clinical applications of human gene editing techniques, this study seeks to identify, in the scientific literature, the bioethical implications and aspects related to gene editing in human cells.

## Method

This is an integrative literature review to compile published studies on similar topics, thus enabling the results to impact scientific evidence-based practice<sup>7,8</sup>.

For this study, the review adopted the following steps: formulation of the research question; search for relevant and valid studies for research; selection of studies; survey of data extracted from included studies; synthesis and narrative of results; and discussion of main findings.

The PICO strategy—specific to non-clinical research—was adopted to define and identify the object of study. This method facilitates the development of a clear and relevant research question, which is essential for the search for scientific evidence that ensures research quality. The PICO strategy considers three elements: population or problem, phenomenon of interest, and context<sup>9</sup>.

As applied to this research, PICO strategy's first element, the problem (P), consists in bioethical implications; the second element, the phenomenon of interest (I), is human gene editing; and the third element, the context (CO), is the CRISPR-Cas9 technique.

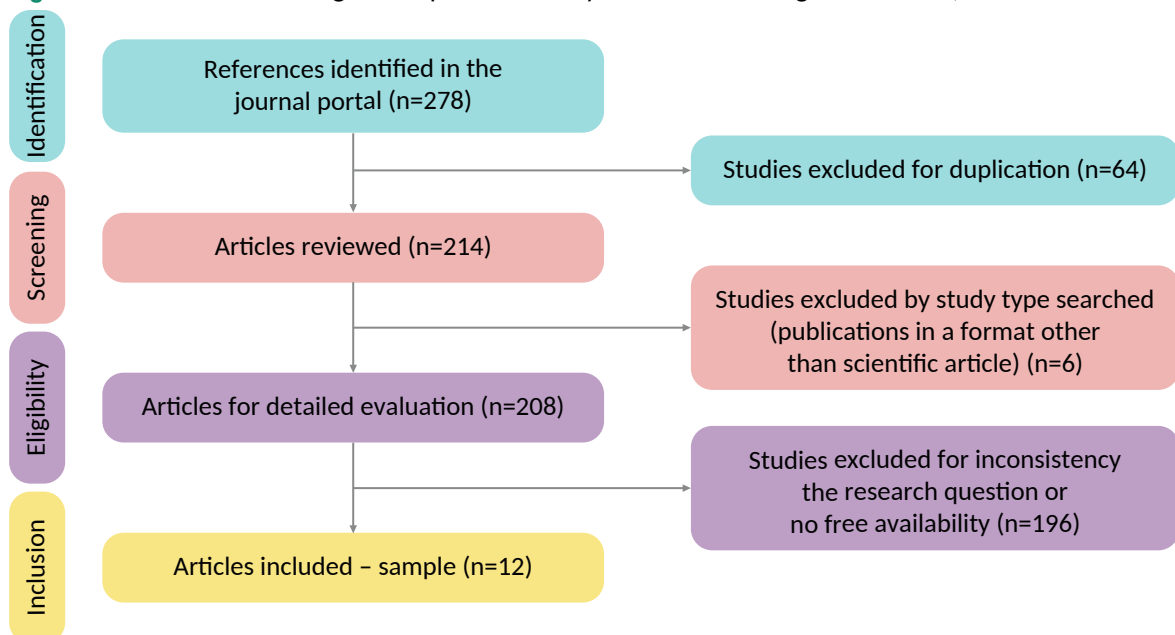
The following research question was established: *what are the bioethical implications of using the CRISPR-Cas9 technique in human gene editing?* According to the Health Sciences Descriptors (DeCS) database, we searched and selected the following controlled descriptors: “bioethics,” “CRISPR-Cas systems,” and “gene editing.” Subsequently, the descriptors were combined using the Boolean operator “and” to perform the search.

The search was conducted exclusively on the Coordination for the Improvement of Higher Education Personnel (CAPES) journal portal. For the screening stage, we determined the following inclusion criteria: publications in the format of scientific articles, original, published in full, without language restriction, and with free-access availability. We excluded studies that did not address the theme, that did not meet the inclusion criteria, and duplicate articles.

The article search and identification stage conducted between May and June 2024, and considered a five-year time period.

The initial study selection was based on title reading, and the final sample was determined after the reading of abstracts of previously selected articles. Figure 1 presents a flowchart with the steps for selecting the articles elected for final analysis.

**Figure 1.** Flowchart describing the steps of the study selection for integrative review, 2024



## Results and discussion

For the final sample, we selected 12 articles that met the established eligibility criteria. Chart 1 presents the main characteristics of these

articles, including: author(s), year of publication, country of origin, and main findings related to the objective of this study, combining aspects related to bioethical implications, recommendations, and perspectives.

**Chart 1.** Characterization of articles included in the review, according to author(s), year of publication, country of origin, title and main findings (Jequié/BA, Brazil, 2024)

Author(s); year	Country	Title	Main findings
Actis AM; 2021 <sup>10</sup>	Argentina	<i>Ethical issues related to gen editing using CRISPR-Cas9 technology</i>	<ul style="list-style-type: none"> <li>- It shows the risk of the relation between gene editing and the old concept of eugenics.</li> <li>- It indicates the need to ensure the protection of patient autonomy and rights.</li> <li>- It notes the consideration of the universities' role in ethics training for future professionals, emphasizing a practical approach.</li> </ul>
Ahumada-Ayala M and collaborators; 2023 <sup>11</sup>	Mexico	<i>Editing the human genome with CRISPR/Cas: a review of its molecular basis, current clinical applications, and bioethical implications</i>	<ul style="list-style-type: none"> <li>- It suggests the need for international regulation of the use of gene editing by <i>ad hoc</i> expert committees.</li> <li>- It recommends limiting the use of gene editing until issues related to safety and bioethics are satisfactorily resolved.</li> </ul>
Gómez-Tatay L, Aznar J; 2019 <sup>12</sup>	Spain	<i>CRISPR-CAS9. The greatest advancement in genetic edition techniques requires an ethical reflection</i>	<ul style="list-style-type: none"> <li>- It expresses concern about safety for future generations due to the risks, as genetic changes will be permanent and transmitted from generation to generation.</li> <li>- It notes the need to ensure fair and safe development while respecting human dignity.</li> </ul>
Gonzalez-Avila LU and collaborators; 2021 <sup>13</sup>	Mexico	<i>The challenge of CRISPR-Cas toward bioethics</i>	<ul style="list-style-type: none"> <li>- It notes the need to monitor the use of gene editing techniques without changing fundamental rights, acting with moral and ethical principles.</li> <li>- It indicates the protection of patient human dignity, integrity, and genetic information to avoid inappropriate uses.</li> <li>- It warns about the inherent risk of adverse effects of treatments based on gene editing.</li> <li>- It concludes that these techniques must be carefully evaluated and observed, not for prohibiting them but for using them with care, as, through them, some diseases could be eliminated.</li> </ul>
Hirsch F, Iphofen R, Koporc Z; 2019 <sup>14</sup>	Croatia	<i>Ethics assessment in research proposals adopting CRISPR technology</i>	<ul style="list-style-type: none"> <li>- It indicates the unpredictability of risks until the technology is well developed and widely used.</li> <li>- It emphasizes that ethical review is not intended to preclude the implementation of new technologies, but to ensure their effective monitoring and to preserve scientific progress within accepted moral limits.</li> <li>- It argues that the crucial element for responsible and ethical use of genome editing tools lies in researchers themselves. The researchers' ethical awareness is fundamental.</li> </ul>

continues...

Chart 1. Continuation

Author(s); year	Country	Title	Main findings
Li J, Zhang X; 2019 <sup>15</sup>	China	<i>Should parents design their children's genome: some general arguments and a Confucian solution</i>	<ul style="list-style-type: none"> <li>- It notes arguments against and in favor of the genetic conception of human embryos and considers that all these arguments have some flaws.</li> <li>- It resorts to Confucianism and concludes that germline cell gene editing is ethically permissible for its benefit to the prosperity and integrity of a family.</li> </ul>
Marfany G; 2019 <sup>16</sup>	Spain	<i>Interrogantes y retos actuales de la edición genética</i>	<ul style="list-style-type: none"> <li>- It indicates the possibility of lack of equity and universal access to gene therapy by gene editing.</li> <li>- It considers that society needs to reflect not only on whether humans can or should be genetically edited, but also on whether altering genetic information to shape future generations is really desirable.</li> </ul>
Posse FAG and collaborators; 2024 <sup>17</sup>	Colombia	<i>Genetic editing with CRISPR Cas9: recent biomedical and biotechnological applications</i>	<ul style="list-style-type: none"> <li>- It indicates that approval of a gene editing-based treatment for clinical use is valid if the expected benefits outweigh the therapeutic risks.</li> <li>- It points out that safe and responsible development of CRISPR-Cas9 technology depends on our capacity, as a scientific community and as society, to establish comprehensive policies to regulate gene editing technology.</li> </ul>
Ranisch R, Trettenbach K, Arnason G; 2023 <sup>18</sup>	Germany	<i>Initial heritable genome editing: mapping a responsible pathway from basic research to the clinic</i>	<ul style="list-style-type: none"> <li>- It warns about the difficulty as to determining all risks involved in gene editing, considering that some risks or effects may arise only years after applying the technology, at which time it may be difficult or impossible to undo them.</li> <li>- It notes that participant informed consent for procedures is an essential requirement. This raises the issue of dealing with subsequent non-consent of their descendants.</li> </ul>
Schleiden S and collaborators; 2020 <sup>19</sup>	Germany	<i>Human germline editing in the era of CRISPR-Cas: risk and uncertainty, inter-generational responsibility, therapeutic legitimacy</i>	<ul style="list-style-type: none"> <li>- It questions whether the transfer of genetic alterations to future generations has ethical and legal justification.</li> <li>- It notes the need for rigorous preclinical scientific testing and evaluation prior to any clinical application of germline cell gene editing in humans.</li> <li>- It advises that all germline cell gene editing treatments should be registered in a specific database.</li> <li>- It recommends that rigorous monitoring programs should be established in order to assess and control the long-term effects of interventions in germline cells.</li> <li>- It points out the need to clarify which risks can be legitimately considered acceptable.</li> </ul>
Sganzerla A, Pessini L; 2020 <sup>20</sup>	Brazil	<i>Edição de humanos por meio da técnica do CRISPR-cas9: entusiasmo científico e inquietações éticas</i>	<ul style="list-style-type: none"> <li>- It notes that DNA editing in the early stages of human life raises several ethical concerns about the capacity to create subhumans or superhumans, sophisticated forms of new eugenics, in addition to possible genetic diseases and deviations that are still unknown and may compromise human life in the future.</li> <li>- It warns that gene editing human embryos using current technologies may have unpredictable and undesirable consequences on future generations.</li> </ul>

continues...

Chart 1. Continuation

Author(s); year	Country	Title	Main findings
Soni S; 2021 <sup>21</sup>	South Africa	<i>The brave new world: should we tread down the path to human germline editing?</i>	<ul style="list-style-type: none"> <li>- It expresses concerns about the social exclusion that gene editing may cause.</li> <li>- It argues that the moral and social issues raised by human gene editing require a level of ethical reflection -- still unaddressed by current initiatives -- and need to be included on the agenda of a broad social debate.</li> <li>- It concludes that, if gene editing results in healthier embryos, potentially healthy births, and reduced mortality rates, the State should adopt measures to promote it.</li> </ul>

Regarding the location of the countries of origin of the selected articles, it was noted that the sample was composed of publications from almost all continents, with a predominance of articles from South America (Argentina, Brazil and Colombia) and Europe (Germany, Spain and Croatia). In addition, Africa (South Africa), Asia (China) and North America (Mexico) also had articles selected. This diversity demonstrates the relevance and timeliness of the theme, as the global scientific community expresses concerns and the need to expand debates on the ethics of gene editing through the CRISPR-Cas9 technique.

Among the bioethical implications addressed in the articles, it was found that some issues were recurrent in most publications, and it is relevant to list and discuss these issues. The bioethical aspects most mentioned in the articles were: the impossibility of informed consent by individuals who may suffer effects of gene editing in germline cells; the limitations as to full knowledge of possible risks and benefits of gene editing; concerns regarding respect for human dignity and universal and equitable access to benefits of gene editing; and, finally, the need to guarantee the protection of the autonomy of individuals submitted to gene editing.

Informed consent is a key element in conducting clinical research and procedures in humans, ensuring that participants are fully aware of the objectives, methods, potential risks and benefits before agreeing to participate. This principle is largely supported by documents such as the World Medical Association's

*Declaration of Helsinki*<sup>22</sup>, which emphasizes the need to respect the autonomy of individuals and the protection of research participants. The *Declaration of Helsinki* recommends that consent should be voluntary, informed and documented, ensuring that participants are properly informed in understandable language. In addition, guiding documents, such as the *Universal Declaration on Bioethics and Human Rights*<sup>23</sup>, reinforce the importance of informed consent, noting human dignity, fundamental freedoms and rights as indispensable ethical pillars for scientific practice. Strict adherence to these guidelines is essential to promote ethics in biomedical research and ensure protection and respect for individuals<sup>24</sup>.

The concern expressed in some articles analyzed in this review<sup>12,13,18,19</sup> refers to the impracticality of informed consent by human beings who will be born in the future and who will have their genetic codes modified due to a choice of their parents. Due to the hereditary nature of genetic modifications, the implications related to informed consent in germline cell gene editing are particularly complex. By modifying the genome in embryos or gametes, the effects of genetic changes will be transmitted to future generations, affecting individuals who will not have the opportunity of consenting to or refusing the intervention. This scenario raises serious ethical concerns, including the autonomy and right to non-maleficence of future children, who are unable to make informed decisions about alteration in their genetic code.

The assessment of the risks and benefits of germline cell gene editing procedures

raises debates and was based on some of the selected articles<sup>12,14,17-20</sup>.

The possible benefits of human genome editing include improved speed and accuracy in diagnostics, development of more specific therapies, and prevention of genetic diseases. On the other hand, the main risks are associated with alterations in the germline and hereditary lineage, which modify the DNA of human embryos, altering characteristics of the descendants. In this context, there is the possibility of unforeseen effects on the genome, such as undesired mutations capable of giving rise to new genetic diseases<sup>25,26</sup>.

The *Declaration of Helsinki* proposes that the potential benefits of research should outweigh the foreseeable risks<sup>22</sup>. The issue with germline cell gene editing is that the possible long-term risks caused by the modifications resulting from this procedure are still unknown.

Some authors<sup>12,13,16,21</sup> have expressed concerns about preserving human dignity and ensuring that the benefits of gene editing are accessible to all in a fair and equitable manner. Human dignity demands respect for the integrity and fundamental rights of all participants in scientific studies, protecting their physical, mental and moral health<sup>27</sup>. It is essential that the benefits of research on human beings are universally and equitably accessible, aiming to reduce inequalities and promote social justice. Ensuring that scientific advances are available to all people—regardless of socioeconomic status or geographic location—is fundamental for fair distribution of research benefits, contributing toward improving the well-being and quality of life of society as a whole<sup>23</sup>.

Another issue presented in some articles<sup>10,18</sup> concerns the care to ensure the autonomy of participants involved in gene editing. The principle of autonomy assures individuals the right to opt out of participation in research at any time, without suffering coercion or penalties<sup>22</sup>. Once again, germline cell gene editing reaches a bioethical limitation, as subjects who will suffer the consequences of such procedures—whether beneficial or not—have not even been born.

The repercussion of research involving gene editing in the last decade led the World Health

Organization (WHO) to publish two reports<sup>28,29</sup> with recommendations on the issue. These documents provide guidance on the governance and supervision of human genome editing in nine different areas, such as: human gene editing registries; international research and medical travel; illegal, unregistered, unethical, or unsafe research; intellectual property; and education, engagement, and capacity building. The recommendations emphasize improvements needed to develop capacity in all countries, ensuring that human genome editing is used safely, effectively and ethically.

In fact, all bioethical implications raised by the articles analyzed constitute important elements for discussion, which require in-depth reflection and careful monitoring by States and international regulatory agencies. It was noted, in the articles that the authors searched, that almost all pointed out the possible ethical issues related to gene editing with the CRISPR-Cas9 technique, but did not risk (or, when they did, it was in a subtle and cautious manner) to minimize the risks to such extent that they would recommend the unrestricted use of the technique in human germline cells.

Thus, it is reinforced that studies need to be developed so the effective benefits of gene editing with the CRISPR-Cas9 technique can be known, so that science advances in a safe and committed way, clearly seeing the possible risks involved, respecting bioethical principles and acting to promote a more just, equitable and healthy society.

## Final considerations

The advancement of gene editing, especially with the CRISPR-Cas9 technique, provides promising opportunities for medicine and biotechnology. However, the integrative review found significant bioethical implications that require rigorous consideration. The impossibility of informed consent by unborn individuals, the need to protect autonomy and human dignity, and the importance of ensuring universal and equitable access to the benefits of gene editing were central issues pointed out in the studies analyzed and require careful ethical consideration. Guiding

documents—such as the *Declaration of Helsinki*, the *Universal Declaration on the Human Genome and Human Rights*, and the *Universal Declaration on Bioethics and Human Rights*—remain key to ensuring that scientific progress does not


compromise human rights. The implementation of international recommendations is essential to ensure safe, ethical and fair applications of gene editing, promoting scientific advances that respect and protect all individuals involved.

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#### Participation of the authors

Anderson Jambeiro de Souza and Jacqueline Maia Santos were responsible for the study design, theoretical framework and methodology preparation, data production and collection, discussion and conclusion; manuscript drafting, critical review, and adaptation to the journal's standards. Charles Souza Santos, Maria Madalena Souza dos Anjos Neta and Sérgio Donha Yarid worked in the study supervision and manuscript final critical review.

**Data availability:** All data used or generated in this study are described and presented in full in the body of the article.

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