Revista Bioética
Print version ISSN 1983-8042 | On-line version ISSN 1983-8034

Rev. Bioét. vol.34 Brasília 2026

Informed consent in research with older adults: practical applications and challenges

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Abstract

The application of informed consent for the participation of older adults in research faces challenges related to understanding, autonomy, and decision-making capacity. The aim of this study is to identify ethical guidelines, common challenges, and recommended practices in the implementation and obtaining of informed consent for research involving this population. A literature review was conducted on studies published between 2019 and 2024 in international academic databases. Inclusion and exclusion criteria were applied, resulting in the selection of seven studies. The main challenges identified were the exclusion of older adults with mild cognitive impairment, the lack of instruments to assess their capacity to consent, and the inadequate presentation of information. Ethical guidelines emphasize equity, respect for autonomy, the use of legal representatives, and the need to adapt consent materials. Considering the findings, it is essential to promote regulations and sensitive practices to ensure accessible, ethical, and respectful informed consent.

Keywords: Informed consent. Research. Aged.

Resumo

Consentimento informado na pesquisa com pessoas idosas: aplicações práticas e desafios

A aplicação do consentimento informado para participação de pessoas idosas em pesquisas enfrenta desafios relacionados à compreensão, autonomia e capacidade de decisão. O objetivo deste estudo é identificar as diretrizes éticas, os desafios frequentes e as práticas recomendadas na aplicação e obtenção do consentimento informado para pesquisas com essa população. Foi realizada revisão de literatura publicada entre 2019 e 2024, em bases acadêmicas internacionais. Foram aplicados critérios de inclusão e exclusão que culminaram na seleção de sete estudos. Os principais desafios identificados foram a exclusão de pessoas idosas com comprometimento cognitivo leve, a ausência de instrumentos para avaliar sua capacidade de consentir e a apresentação inadequada das informações. As diretrizes éticas enfatizam equidade, respeito à autonomia, uso de representantes legais e necessidade de adaptar os materiais de consentimento. Diante dos resultados, faz-se essencial promover regulamentações e práticas sensíveis para um consentimento informado acessível, ético e respeitoso.

Palavras-chave: Consentimento livre e esclarecido. Pesquisa. Idoso.

Resumen

Consentimiento informado en la investigación con personas mayores: aplicaciones prácticas y desafíos

La aplicación del consentimiento informado para la participación de personas mayores en investigaciones enfrenta desafíos relacionados con la comprensión, la autonomía y la capacidad de decisión. El objetivo de este estudio es identificar las directrices éticas, los desafíos frecuentes y las prácticas recomendadas en la aplicación y obtención del consentimiento informado en investigaciones con esta población. Se realizó una revisión de la literatura publicada entre 2019 y 2024 en bases académicas internacionales. Se aplicaron criterios de inclusión y exclusión que resultaron en la selección de siete estudios. Los principales desafíos identificados fueron la exclusión de personas mayores con deterioro cognitivo leve, la ausencia de instrumentos para evaluar su capacidad de consentir y la presentación inadecuada de la información. Las directrices éticas enfatizan la equidad, el respeto a la autonomía, el uso de representantes legales y la necesidad de adaptar los materiales de consentimiento. A la luz de los resultados, es esencial promover regulaciones y prácticas sensibles para un consentimiento informado accesible, ético y respetuoso.

Palabras clave: Consentimiento informado. Investigación. Anciano.

The author declares no conflict of interest.

Research

Informed consent (IC) has been a fundamental principle in biomedical research ethics since its first formulations in the *Nuremberg Code* [1], enacted after trials of Nazi doctors who carried out medical experimentation during World War II. Thus, IC has been globally consolidated as an essential requirement for protection of the rights and well-being of participants in scientific studies, ensuring voluntary participation and full understanding of risks and benefits involved [2].

The *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, first published in 2002 in Geneva and updated in 2016 by the Council for International Organizations of Medical Sciences (CIOMS) [2] in collaboration with the World Health Organization (WHO), establish the fundamental ethical guidelines for obtaining informed consent in research with individuals capable of making decisions autonomously. According to the document, researchers are responsible for informing potential participants of relevant details of the study and ensure they understand the information in its entirety before making any decisions about the research.

This process must be conducted without coercion, undue influence, or manipulation, in order to respect participant freedom of choice and autonomy. In this context, IC constitutes a continuous process, which begins with the first contact with a potential participant and extends until the formal consent document is signed by the declarant.

The guidelines also include specific instructions for studies with adults who cannot provide informed consent autonomously, determining that researchers and ethics committees must ensure permission is obtained through the legal representative of the potential participant. Furthermore, the recommendation is that subject consent is obtained as possible, providing them with adequate information according to their understanding capacity. The consent of participants with impaired decision-making capacity should be understood as a continuous process that is sensitive to changes in their cognition, and not only as the lack of explicit refusal. The reason is that the document addresses not only the importance of minimizing risks for this group, but also ensuring that potential individual benefits outweigh these risks.

Specifically in the field of geriatric research, older adults are generally classified into two groups, independent and autonomous individuals and individuals with increasing dependency and declining cognition, with the latter being considered vulnerable. This raises questions about the legal competence of these individuals to make appropriate and informed decisions about their health/illness processes, as well as about their participation in research [3]. The relevance of institutional review committees in fostering research involving geriatric patients has also been noted, regarding a favorable risk-benefit ratio, without underestimating the subjects' competence to make independent decisions about their participation in studies [4].

Each country implements its own regulations based on international guidelines, establishing comprehensive ethical and legal principles for research with human beings, with the aim of ensuring the protection of participant rights and well-being. However, not all countries have legislation that is complete enough to establish recommendations for the IC process in research with older adults [5]. Chile's regulation [6] specifically provides for the participation in research of individuals with neurodegenerative or psychiatric diseases and describes the advance application of consent for possible future participation, when the declarant no longer has autonomy to consent. This provision aims to safeguard the rights of vulnerable individuals and, thus, respect their autonomy as per the established ethical and legal framework.

This narrative literature review aims to identify current ethical guidelines and challenges in the informed consent process for research with older adults, as well as to describe recommended best practices, according to recent studies. Such analysis is fundamental to adapt and reinforce policies and practices that protect the autonomy and well-being of older adults in the context of scientific research, in order to contribute to the fulfillment of universal ethical principles and to the promotion of ethical

and responsible research. Thus, it contributes to the development of more inclusive regulatory frameworks that are sensitive to the specific needs of this vulnerable demographic group, facilitating the advancement of scientific research in an ethical manner and with respect for the fundamental rights of older adults.

Method

This study was based on the review of available literature, using the narrative literature review methodology [7], which provides the description of theoretical advances on an issue through subjective and critical analysis. The proposal here is to identify studies and research related to the ethical guidelines that regulate the informed consent process involving older adults. To this end, the following keywords were defined for search in English: "*consent*," "*informed consent*," "*ethic*," "*research*," "*age*," "*aging*," "*older people*". The searches were conducted in December 2024, in both multidisciplinary and health-specific databases, including PubMed, Web of Science, and Google Scholar. The search terms consisted of keywords combined with the Boolean operators "*and*" and "*or*", as described below: PubMed: "((informed consent[Title]) *or* (consent[Title])) *and* (((age*[Title]) *or* (older*[Title])) *or* (geriatric[Title]))"; Web of Science: "(((TI=(informed consent)) *or* TI=(consent)) *and* TI=(older*))".

We established as inclusion criteria: studies with titles and abstracts in English, Spanish, or Portuguese, regardless of the country of publication, published between 2019 and 2024, focusing on IC applied to research with individuals aged 60 years or older. Researches in which IC applied to medical clinical practice and other health care professions were excluded.

Thus, the article screening and selection process adopted the analysis of abstracts and the verification of compliance with the eligibility criteria described above. The selected articles were then analyzed in full text. The extraction of relevant data and the synthesis of evidence used an Excel matrix, prepared by the researcher, providing the compilation of integral aspects of the publications, such as study year and country, the population or sample under study, the type of analysis, and the main learnings and conclusions of each research. The results were synthesized into the following thematic categories: IC process challenges, ethical guidelines, and recommended practices.

Results

With the search equation, we identified in the databases a total of 54 studies: 36 from PubMed and 18 from Web of Science. After the initial screening process, we selected 26 articles, excluding duplicates and articles that did not meet the established eligibility criteria. These studies were analyzed in their full text, resulting in the selection of seven studies for further analysis. This research stage was conducted between December 2024 and May 2025. Figure 1 presents the article selection and inclusion process.

In general, the studies were published between 2020 and 2023, with English as the predominant language and the following countries of origin: United States, Canada, France, Jordan, Italy, and Pakistan. Of the seven studies, only two were literature reviews, as the others used qualitative and quantitative methods. Table 1 presents the general characteristics of each study.

Figure 1. Article selection process

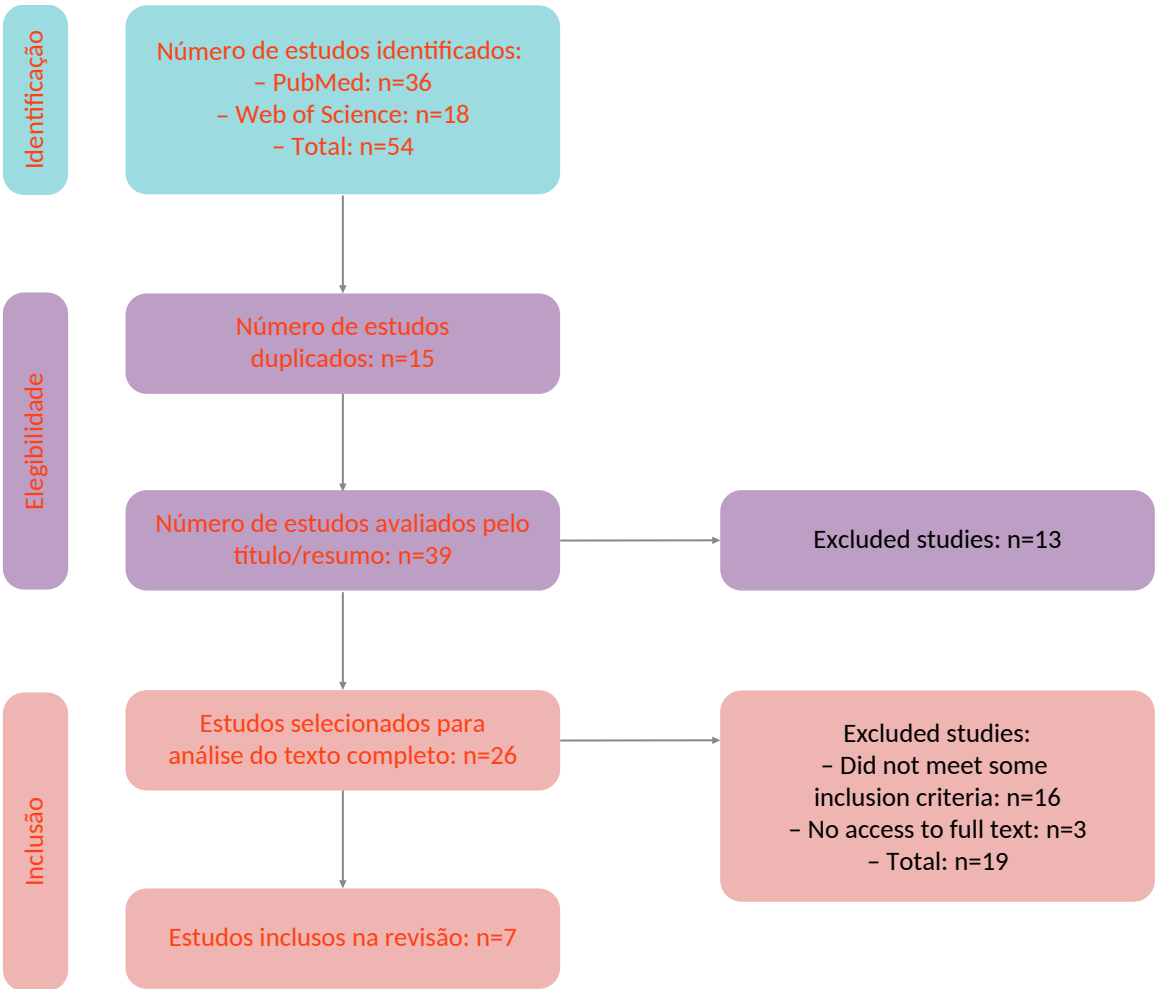

Table 1. General characteristics of the selected articles

No.	Author; year	Title	Country	Study type/methodology
1	Boie, Jaiswal, Wittich; 2023[8]	Adaptations to the administration of informed consent when conducting research with older adults that are deafblind	Canada	Systematic field notes, with adaptations recorded and subsequently analyzed through qualitative description.
2	Del Signore and collaborators; 2023[9]	Capacity to consent to research in older adults with normal cognitive functioning, mild and major neurocognitive disorder: an Italian study	Italy	Quantitative descriptive study; 54 participants with major neurocognitive disorder (major NCD), 22 with mild neurocognitive disorder (mild NCD), and 37 individuals with normal cognitive functioning (NCF).
3	Southerland and collaborators; 2022[10]	Inclusion of older adults and reporting of consent processes in randomized controlled trials in the emergency department: A scoping review	United States	Scoping review; 269 studies underwent title/abstract and full-text assessment.

continues...

Table 1. Continuation

No.	Author; year	Title	Country	Study type/methodology
4	Shepherd; 2021 [11]	How nurses can support the inclusion in research of older people who lack capacity to consent	United States	Literature review.
5	Jacob and collaborators; 2020 [12]	Recruiting older people from the Pakistani community in Community Ageing Research 75+	Pakistan	Observational-experiential study; longitudinal cohort study that collects a wide range of data on health outcomes, social aspects, and economic aspects.
6	Altawalbeh, Alkhateeb, Attarabeen; 2020 [13]	Ethical issues in consenting older adults: academic researchers and community perspectives	Jordan	Quantitative descriptive study; a total of 250 academic researchers and 233 older adults participated in the study.
7	Ecarnot and collaborators; 2020 [14]	Factors associated with refusal or acceptance of older patients (≥ 65 years) to provide consent to participate in clinical research in cardiology: a qualitative study	France	Qualitative approach; individual semi-structured interviews and clinical trial; 16 participants.

Challenges of the informed consent process

In medical research contexts, older adults with impaired decision-making capacity are often excluded from studies due to ethical concerns and practical challenges. A lack of knowledge is observed among the professionals involved regarding the legal framework that supports the inclusion of this population in scientific studies [11]. Furthermore, assessing capacity to consent requires choosing appropriate instruments, which should vary according to the degree of cognitive impairment in order to select the appropriate tools for each case [9].

Therefore, it is evident that obtaining IC from older adults involves several ethical and practical challenges. In a study conducted in Jordan [13], both researchers and older adults reported that the requirement of a signature on written forms and the impact of age-related physical limitations were the main obstacles when giving consent.

Also noted is the importance of an IC process that not only adequately informs participants about the study details but also considers specific individual and contextual concerns. It should be taken into account that patient decisions to participate in clinical trials depend on their understanding of the study and are deeply influenced by the potential participant's perception of their ability to cope with their health condition and by their available personal resources. The articles analyzed for this discussion suggest that factors such as trust in the medical team, perceptions about the personal benefits the study may provide, and logistical barriers have a crucial relevance in the patient's final decision-making [14].

Another significant finding is the low frequency with which the older adults' capacity to give informed consent is formally assessed, given that these patients face acute or chronic conditions that can compromise their cognitive abilities. Approximately one-quarter of the studies included in the review deliberately excluded patients due to their impaired decision-making capacity, and only a small percentage used formal instruments to assess this capacity. This raises concerns about the uniform application of ethical and legal standards in clinical research practice, especially in contexts in which participants may face critical decision-making in medical emergency situations [10].

There are several deficiencies that impact IC processes. Older adults with deafblindness, for example, face multiple access barriers to participate in research, especially when consent forms are in written language, which makes them

inaccessible to this group, as this characteristic can limit their ability to fully understand the study details and make informed decisions. Research ethics committees often have little or no experience in adapting IC processes for people with deafblindness, which can hinder the implementation of appropriate and accessible practices [8].

Finally, researchers may also face significant barriers stemming from cultural and linguistic differences, which hinders the recruitment of participants for scientific studies [11].

Ethical guidelines

Ethical guidelines should promote equity in access to research, including the obligation to adapt informed consent methods to ensure that older adults participate on equal terms with other participants [8]. Even when decision-making capacity is compromised, it is essential to respect the dignity and rights of older adults, enabling their participation as possible, protecting them from unnecessary risks, and ensuring that any involvement in research provides them with potential benefits, direct or indirect, in addition to guaranteeing their privacy [11,13].

It is also fundamental to respect the autonomy of older adults in deciding to participate in clinical research, ensuring that they fully understand the nature of the study and the potential benefits and risks, so they can make informed decisions that reflect their personal values and preferences—taking into consideration their cognitive and mental capacity. This implies the adoption of IC methods adapted to their particularities and that enable their fair participation in research [4,14], following ethical guidelines that promote inclusion and respect for the culture and individual preferences of the participants [12].

In this context, family members and friends are extremely important in decision-making, as they help ensure that the interests and preferences of older adults are ethically considered [11].

Best practices

Based on the studies analyzed and the results involving the ethical challenges and guidelines of IC with older adults, the recommendation is the adaptation of consent processes and assessment instruments according to the participants' specific level of cognitive functioning, in order to ensure they understand the risks and benefits of the research. To this end, the use of validated and sensitive instruments to assess decision-making capacity—such as the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR)—and to perform neuropsychological tests—such as the Mini-Mental State Examination (MMSE)—ensures ethical and accurate assessment. Therefore, it is necessary to train health researchers and health care professionals in the proper use of these tools [9].

Dedicating more time to the consent process and treating older adults as autonomous individuals, respecting their cultural beliefs, are other recommended practices, which are considered effective strategies by both academic researchers and patients [13].

One of the studies analyzed also notes the urgent need to improve the notification and documentation of IC processes in clinical studies. The lack of records on the use of legal representatives for patients with impaired decision-making capacity shows a gap in the protection of the rights of more vulnerable participants. This is particularly relevant for older adults, who may be more exposed to suboptimal decisions due to complex medical conditions and cognitive decline associated with aging [10].

In this regard, it is worth noting the fundamental role played by nurses in the care for older adults with cognitive impairment. Alongside family and friends [11], these professionals contribute to ensuring that individuals have the opportunity to participate in and benefit from research.

Furthermore, researchers and ethics committees should receive adequate training on how to adapt and facilitate the IC process for people with deafblindness, thus promoting greater inclusion and respect for diversity in research. Notably, the recommendations for this specific group include the following: use of informed consent forms, electronic or printed, in simplified formats—without complex visual elements such as logos or checkboxes—to facilitate access via electronic

devices or scanners; adaptation of processes to enable interpretation in sign language or other communication methods that are accessible for those who rely on interpreters; and allowance for verbal or signed answers to demographic questionnaires and other stages of the research process, eliminating barriers that could arise from requiring signature on paper [8,13].

Finally, the cultural adaptation of the IC process is also essential. In this regard, it is necessary to use community communication and the local dialect in order to clearly inform the objectives and details of the study, being fundamental to have bilingual researchers and adapt the questionnaires and forms to the dialect of the ethnic group in question [12].

Discussion

Current ethical guidelines emphasize the importance of adapting informed consent processes to ensure equity in the participation of older adults in research. The American Medical Association (AMA) [15] and the National Institutes of Health (NIH) [16], both from the United States, specifically recommend the implementation of adapted consent methods and the inclusion of legal representatives, when necessary. These guidelines emphasize respect for participant autonomy and dignity, aligning with the fundamental ethical principles for biomedical research.

The assessment of patient decision-making capacity is a complex process that depends on multiple variables and can be challenging. Among the various instruments available for such assessment, the MacCAT-CR was the most cited in the studies analyzed, a widely used and validated questionnaire. However, its application requires considerable time, which makes it a complex tool for the research context. A recent instrument is the San Diego Brief Assessment of Capacity to Consent (UBACC), from the University of California, which has shown promise for daily clinical practice due to its simplicity, relevance, and applicability in elderly patients [17].

Thus, we note the need to consider the clinical setting and specific characteristics of patients in the development and execution of IC processes, which is one of the recommended practices in this research context. Furthermore, promoting inclusion and respect for the culture and individual preferences of participants is essential: thus, adapting consent methods and adequately training researchers to ensure equitable and ethical participation in clinical and scientific research is indispensable.

Final considerations

Adapting and reinforcing IC-related policies and practices is crucial so as to ensure that research with older adults is ethical, inclusive, and respects the fundamental rights of participants. This analysis emphasizes the importance of continuing to advance towards more sensitive and equitable regulatory frameworks that promote responsible and ethical scientific research at all levels.

Ethical guidelines recommend adapting IC methods to ensure that older adults fully understand the risks and benefits of research, while their rights to autonomy and dignity are respected. It is essential to involve legal representatives whenever necessary and to ensure that the consent process is continuous and accessible, especially for individuals with cognitive, mental, and/or sensory disabilities. Within this process, continuous training of researchers and inclusion of family members in decision-making are fundamental, in order to ensure inclusive and respectful participation.

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

Editor in charge: Dilza Teresinha Ambrós Ribeiro

Received: 7.24.2025
Revised: 2.27.2026
Approved: 3.3.2026