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Ethical considerations in utilizing eConsent in biomedical research

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Abstract

Informed consent is crucial to uphold the autonomy of participants in healthcare research. Despite being widely used, electronic consent remains inadequately regulated in many countries, posing numerous ethical risks. This article aims to critically examine the ethical implications associated with using electronic consent and propose solutions to such issues. Ethical concerns include providing insufficient information for informed decision-making, limitations in assessing individual capacity to consent, communication barriers with participants, selection bias, difficulties in verifying participant identity, and breach of privacy and confidentiality. To address these concerns, a proactive approach must be adopted, anticipating and implementing measures to safeguard participant rights. Countries lacking specific regulations should prioritize the establishment of guidelines to ensure the ethical use of electronic consent in healthcare research.

Keywords: Informed consent. Research, ethics. Consent forms. Scientific misconduct.

Resumo

Considerações éticas sobre o uso do consentimento eletrônico em pesquisa biomédica

O consentimento informado desempenha um papel crucial na defesa da autonomia dos participantes de pesquisa em saúde. Apesar de sua ampla adoção, o consentimento eletrônico permanece inadequadamente regulamentado em muitos países, gerando riscos éticos. Este artigo tem como objetivo examinar criticamente as implicações éticas associadas à utilização do consentimento eletrônico em pesquisas e propor possíveis soluções. As preocupações éticas incluem fornecimento inadequado de informações para permitir uma tomada de decisão informada, limitações na avaliação da capacidade de consentir, barreiras de comunicação com os participantes, viés de seleção, dificuldades em verificar a identidade dos participantes e comprometimento da confidencialidade e privacidade. É imperativo adotar uma abordagem proativa, antecipando e implementando medidas para salvaguardar os direitos dos participantes. Países que carecem de regulamentações específicas devem priorizar o estabelecimento de diretrizes para garantir o uso ético do consentimento eletrônico em pesquisas em saúde.

Palavras-chave: Consentimento informado. Ética em pesquisa. Termo de consentimento. Má conduta científica.

Resumen

Consideraciones éticas en el uso del consentimiento electrónico en la investigación biomédica

El consentimiento informado es fundamental en la defensa de la autonomía de los participantes en la investigación en salud. A pesar de su amplia adopción, el consentimiento electrónico está insuficientemente regulado en muchos países, lo cual plantea numerosos riesgos éticos para los participantes. Este artículo tiene como objetivo examinar críticamente las implicaciones éticas asociadas con el uso del consentimiento electrónico en investigación y proponer posibles soluciones a tales problemas. Las preocupaciones éticas incluyen la provisión de insuficiente información para tomar decisiones informadas, limitaciones en la evaluación de la capacidad individual para consentir, barreras de comunicación con los participantes, sesgo de selección, dificultades para verificar la identidad de los participantes y violaciones de privacidad y confidencialidad. Para abordar estas preocupaciones, es imperativo adoptar un enfoque proactivo que anticipa e implementa medidas para salvaguardar los derechos de los participantes. Los países que carecen de regulaciones específicas deben garantizar el uso ético del consentimiento electrónico.

Palabras clave: Consentimiento informado. Ética en investigación. Formularios de consentimiento. Mala conducta científica.

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Informed consent is crucial to maintain the ethical principles of research by safeguarding and upholding individuals' rights as research participants [1]. Informed consent protects free and voluntary participation, as the individual makes informed decisions based on their values, rights, interests, or preferences [2]. As such, informed consent is not a mere signature, but a comprehensive process that complies with basic requirements, such as providing clear and accurate information about the study, its purpose, risks and benefits, and, if applicable, possible treatment alternatives. Informed consent is a fundamental research step to inform potential participants about the confidentiality and privacy of their data, avoid coercion, and protect their right to continue receiving healthcare, regardless of their decision [3]. However, complying with all these requirements has become a challenge in recent decades due to the increased use of electronic informed consent (eConsent), particularly during and after the COVID-19 pandemic [4].

Some countries have regional regulations for eConsent, such as the General Data Protection Regulation (GDPR) in the European Union, which establishes specific requirements for personal data collection, processing, and storage, including remotely collected medical information [5]. Nonetheless, this is not the case in most countries, particularly those with low- and middle-income economies. Given the global use of eConsent in health research, discussing the ethical issues arising from this new form of consent is important to ensure participants are protected from unethical practices. We hereafter present a critical examination of the ethical implications of utilizing eConsent in healthcare research and propose strategies to prevent or mitigate such issues.

Ethical challenges in utilizing eConsent

Some advantages of eConsent have been described, such as the increased recruitment of participants, better comprehension of information via virtual interactions, and simplified data storage. However, data show that this method does not show equal or superior advantage compared to traditional informed consent, since its implementation can be hampered by the digital skills required to use it [6-10].

The current lack of eConsent regulation in many countries also leads to frequent disapprovals by ethics committees, resulting in extra labor by researchers and unnecessary use of public resources. In the United States, for example, 37% of Institutional Review Boards typically do not approve eConsent use [11]. In some cases, implementing eConsent has been reduced to providing incomplete information that fails to meet the basic requirements of an IC. Some online surveys often lack enough information to enable informed decisions [12-15], and, in some studies, consent is considered automatically given if the participant accesses and fills out the online questionnaire [14,16].

The use of eConsent should not imply that the amount of information provided should be reduced [17]. On the contrary, it should be clearer and perhaps even more detailed as this modality is likely to make it more challenging for participants to seek clarifications with the researchers to address their concerns [18]. Therefore, when implementing eConsent, specific processes must be in place to enable a continuous communication channel between researchers and participants, particularly in studies that require follow-up [19].

A limited and often non-existent direct channel of interaction between the participant and the research team also hampers other essential ethical aspects, such as detailed assessment of capacity to consent. Thus, when implementing eConsent, mechanisms should be established for a remote and ethical assessment of capacity. For example, researchers may use a progressive approach, gradually presenting information and seeking confirmation at different stages of the process, ensuring participant comprehension. Another option is to incorporate an online conversation system to address any queries or provide clarifications [9]. Teleconsent is another innovative alternative that integrates the eConsent process into a remote session and has shown effectiveness in enhancing recruitment while preserving human interaction [20]. By adopting these measures, researchers can ensure participants have a clear understanding of the study throughout the consent process.

Another ethical dilemma of eConsent is the verification of participant identity in virtual

contexts. Electronic signatures have been considered a solution to this issue in contexts like the United States and Europe, where legislation establishes that an electronic signature is unique to an individual and organizations can use it to verify a person's identity [6]. However, a study on the informed consent process in the United States showed that some presidents of ethics review boards believe that electronic signatures should be limited to minimal-risk studies, while others expressed doubts regarding the acceptance and legal validity of this method [11].

This issue is also a challenge in low- and middle-income countries, where foolproof systems can be costly, leaving participants vulnerable to identify theft. This can have profound ethical and methodological implications, potentially introducing biases that could cause invalid research results. Identity verification when using eConsent continues to be a challenge in most contexts, requiring safer solutions with future advancements in technology, such as using facial recognition for identity verification. The use of eConsent could also lead to inequities or discrimination in opportunities to participate in research, as it is likely to exclude individuals who lack internet access due to limited economic resources, limited digital literacy, residence in remote areas [21], or who simply do not like or trust a virtual approach [22,23]. Therefore, studies using eConsent must outline in their methods how this risk of selection bias will be mitigated and their implications for the study results. Moreover, protection of participant confidentiality and privacy delivered and received digitally can also be a challenge due to potential data breaches or improper use of information [24]. Researchers must favor virtual platforms that enable anonymization and demonstrate safe data processing and storage [6].

Final considerations

The use of eConsent in healthcare research has significantly grown in recent years, presenting the research community with advantages, but also ethical challenges. Ethical risks include providing insufficient information for participants, limitations in the assessment of consent capacity, communication barriers between researcher and participants, selection bias, participant identification issues, and confidentiality and privacy concerns. We argue that researchers and ethics committees should proactively anticipate these problems and implement measures to protect participants and mitigate such risks. Specific ethical regulations are necessary to guide and ensure the proper use of this digital tool. This will not only help protect the rights and welfare of research participants but also promote responsible and ethical use of research resources, fostering trust in research practices and promoting a responsible research conduct in the digital age.

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Participation of the authors
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