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Participation and education: the Declaration of Helsinki in today's context

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For 60 years, the *Declaration of Helsinki* has established itself as a primary document for translating fundamental ethical principles into research practice. In October 2024, after a two-and-a-half-year revision process, a new version[1] was presented, incorporating modifications that reflect the current social context and the challenges of a globalized world in which individuals and communities expect and demand adequate and effective responses to their health problems.

With a broader participation of countries and actors than on previous occasions, this version's generation provides greater legitimacy to its contents. The document is no longer addressed exclusively to physicians but to all professionals involved in the research process. This implies a shared responsibility among different sectors, including researchers from different disciplines and editors and managers of medical publications, scientific and academic entities, patient associations, funders, and government agencies.

Those included in a study are no longer called subjects but participants. Although this change may seem minor or just language, it underscores the active role of people in research, recognizing them as integral parts of the study as well in the definition of priorities, the design of the study, its implementation, and the dissemination of results. While this aims to foster greater collaboration and transparency, it has challenges in practice. Its implementation may encounter financial constraints that hinder collaboration with patients early in a research study, disagreements may arise over priorities and outcome measures to be selected, and a lack of research methodology expertise may hinder the work. Also, the participation of patients as partners may bias recruitment if they choose to invite participants based on their perception of who needs or deserves certain treatment. In addition, contrary to the purpose of safeguarding rights, some community members may feel pressured to participate in the study. Finally, there is the possibility of creating a false impression of diversity by including people from marginalized groups without addressing underlying inequalities (tokenism).[2]

Furthermore, the new version of the *Declaration* no longer speaks only of welfare, a term that can be imprecise, but includes an explicit mention of the rights of individuals. This concept is better defined and established by the international legal framework.[3]

In the same sense of encouraging the participation of individuals, the new Declaration provides for several points to promote involvement in research, avoiding the violation of rights in low-income countries, which for various reasons are often excluded from this activity.[4]

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Concerning emerging issues in the current context, the focus on individual health is broadened to include public health, highlighting the need to respect ethical principles even in emergencies, such as the COVID-19 pandemic; reference is made to environmental care issues and the growing problem of the proliferation of data and its diversified use is addressed. The latter refers to the secondary use of data and the general protection of personal information. In this context, a critical role is given to Research Ethics Committees (RECs), which can allow or disallow data use without a prior informed consent process.

It is relevant to highlight some specific modifications from the point of view of child research and the editorial role of a pediatric journal.

The first is the new approach to considering vulnerability. The notion of vulnerability is fundamental both in the conception of research studies and in their conduct and supervision; however, it has been proposed to move from considering it as a definite concept, which implies delineating vulnerable groups or individuals, to an analytical one, in which it is crucial to define and analyze the types and sources of vulnerability.[5] This version of the Declaration reflects this change of vision, considering vulnerability no longer as a characteristic of individuals but as a dynamic and variable situation that affects both individuals and communities. Thus, the participation of all individuals and communities is promoted, taking care of the rights of the participants but promoting their inclusion since the exclusion of people in vulnerable situations from research studies does not allow for adequate responses to their problems. In other words, a misunderstood protectionism ultimately perpetuates inequity, constituting an ethical problem.

Another point of particular interest for our patients, children, is the use of placebos as comparators in research studies, a subject of long-standing controversy in general and very notably in those situations in which placebo administration involves pain.[6,7]

The new version of the Declaration provides some flexibility in the exceptions for its use or even using other comparators that are not the best available treatment option. For this reason, it is crucial to have well-prepared RECs that are commensurate with the responsibility given to them, as they are the ones who may or may not endorse these exceptions. Also, in agreement, the need for continuing education in research ethics for all those involved is emphasized.

This update is a reaffirmation of the promotion of ethical principles in research, providing guidance on their application in the face of current challenges, emphasizing collaboration and joint responsibility. If the spirit of this new version of the document had to be defined in two words, they would be participation and education. This includes everyone who deals with health from different roles and levels. It is, undoubtedly, a call to educate ourselves on practicing the traditional principles of autonomy, beneficence, nonmaleficence, and justice in an ever-changing world. ■

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