Arch Argent Pediatr 2024;122(3):e202310277

Ethical approval for all studies involving human participants, especially in pediatrics

Fernando Ferrero[a]

Whenever we write an article, we want to make sure that the title expresses its content and/or the message it is trying to convey as faithfully as possible. This time, I had no choice but to paraphrase the title of an excellent editorial by John Fletcher in the *CMAJ*.[1] I could not think of other more forceful wording that would otherwise reflect the need described by Fletcher.

It is striking that, even now in 2024, there is still conflict about whether an investigation should or should not be submitted for evaluation by a Research Ethics Committee (REC) before conducting it.

Surely, nowadays, no one would question the need for prior ethical approval for a study involving a pharmacological intervention versus placebo, sponsored by the pharmaceutical industry. However, outside of this very clear example, everything seems that could be discussed: What if 2 drugs are compared and both have an approved indication? What if the study is initiated by an investigator from an academic institution? What if only data from clinical patient records are used?

History has demonstrated that the risks to study participants do not depend exclusively on the study design or kind of sponsor. The paradigm of this is evidenced by the Tuskegee Study, a strictly observational, government-sponsored study that became a shame for the scientific community.[2]

Even today, some investigators, out of ignorance, disinterest, or self-sufficiency, search the depths of regulations to see if their research can be considered to be "...*limited to the study of health systems, official public health programs, or public health surveillance,*"[3] and should therefore be exempt from prior ethical approval. They cannot understand that if they intend to send their results to a scientific journal (thus seeking the generalization of such knowledge), it is most likely to be research; otherwise, their report should be limited to the authorities of the institution where they work.

But, most importantly, if there is the slightest doubt as to whether or not research requires prior ethical approval, a REC must necessarily be consulted.[3]

Along this line of thought, no one doubts anymore that, in order to publish a case report, the authorization of the patient or their legal representatives is required in order to use their health information. However, when someone wishes to publish studies based on "data" from patients who received "standard of care" and which have been obtained from their medical records, it would seem that such authorization is unnecessary. Unfortunately, it is often forgotten that these "data" do not belong to the investigators or the institution where the patient was treated; these data belong to the patient and, in order to use them in a study, permission must be requested.

doi: http://dx.doi.org/10.5546/aap.2023-10277.eng

To cite: Ferrero F. Ethical approval for all studies involving human participants, especially in pediatrics. *Arch Argent Pediatr* 2024;122(3):e202310277.

[a] Editor, Archivos Argentinos de Pediatría.

Correspondence to *Fernando Ferrero: fferrero.publicaciones@sap.org.ar*

Most likely, many times, contacting hundreds of patients seen several years ago can be extremely difficult. It is also true that the study may be relevant enough to justify that it should still be carried out if any information that may identify individuals is adequately disassociated. But only a REC can and should monitor these concerns: the relevance and feasibility of the study, the qualification of the investigators, and the appropriateness of the mechanism used to protect the data and patients' privacy. Only the REC can authorize the use of patient information for research purposes.

The terrible circumstances that gave rise to the Nuremberg Code[4] and the Belmont Report[5] clearly showed that, when it comes to research involving human participants (or their data), it is always important to have the perspective of someone who is independent from the investigator.

Research Ethics Committees are the bodies on which society rests its responsibility to look after the interests of research participants. The goal of conducting an ethical evaluation for a study is to prevent the possibility of any harm to participants. If done later, after the study has been completed, it will probably be too late.

Scientific journals also have a responsibility to look after the interests of people who participate (whether aware of it or not) in research. Their responsibility is not to publish any study that has not been clearly conducted in an ethical manner.

Both the Declaration of Helsinki ("*Principle 36: Reports of research not in accordance with the principles of this Declaration should not be accepted for publication"*)[6] and the regulations of the International Committee of Medical Journal Editors (ICMJE) (journals should encourage authors to state "*whether procedures were conducted in accordance with the ethical standards of the committee responsible for human research and the Declaration of Helsinki*")[7] establish that any study that did not follow the ethical standards should not be accepted for publication. The Argentine regulations follow the same principles ("*Editors of scientific journals should not publish results of studies conducted in disregard of ethical standards"*).[3]

Moreover, keeping in mind that any study evaluation must be conducted prior to its development, the Committee on Publication Ethics has also clearly stated that retrospective ethical approval is not acceptable.[8]

Finally, since this is a pediatric scientific journal, it should not be forgotten that studies in children and adolescents involve a vulnerable population that requires additional protection and reinforcement of all ethical guarantees.

Following a path that began decades ago, *Archivos Argentinos de Pediatria* maintains and renews its commitment not to accept study manuscripts that fail to comply with the corresponding ethical approval. ■

REFERENCES

1. Fletcher J. Ethical approval for all studies involving human participants. *CMAJ.* 2015;187(2):91.
2. Tobin MJ. Fiftieth Anniversary of Uncovering the Tuskegee Syphilis Study: The Story and Timeless Lessons. *Am J Respir Crit Care Med.* 2022;205(10):1145-58.
3. Argentina. Ministerio de Salud. Resolución 1480/2011. Guía para la investigación en salud humana. Buenos Aires, 13 de septiembre de 2011. [Accessed on: October 17th, 2023]. Available at: https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-1480-2011-187206/actualizacion
4. International Tribunal of Nuremberg. The Nuremberg Code (1947). International Research Code of Ethics. Permissible Medical Experiments. *BMJ.* 1996;313:1448.
5. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. [Accessed on: October 31st, 2023]. Available at: https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf
6. Asociación Médica Mundial. Declaración de Helsinki de la AMM – Principios éticos para las investigaciones médicas en seres humanos. 64ª Asamblea General, Fortaleza, Brasil, octubre 2013. [Accessed on: October 17th, 2023]. Available at: https://www.wma.net/es/policies-post/declaracion-de-helsinki-de-la-amm-principios-eticos-para-las-investigaciones-medicas-en-seres-humanos/
7. International Committee of Medical Journal Editors. Preparing a Manuscript for Submission to a Medical Journal. [Accessed on: October 31st, 2023]. Available at: https://www.icmje.org/recommendations/browse/manuscript-preparation/preparing-for-submission.html#d
8. Committee on Publication Ethics. Retrospective ethical approval? [Accessed on: October 19th, 2023]. Available at: https://publicationethics.org/case/retrospective-ethical-approval