Health research committees: their authority, fundamental responsibility and the need for them to undergo periodical audits

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Abstract

Research ethics must include theoretical and practical dimensions. The first one is structured by regulations and policies, and the second dimension refers to how the committee interprets and applies those regulations and policies. This article analyses the operation of the committees at a practical level. Given that the evaluation and judgement of research protocols is a process that requires full awareness, its omission entails important implications for health research.

KEY WORDS: Ethics committees. Ethics. Bioethics Audit. Medical research.

Introduction

Ethics is the study of the behavior of humans regarding the responsibility they have to choose (when a choice is possible) on what is good or better or optimal for the construction of a common good that is truly beneficial for our society. That common good is built through elections-decisions based on values such as solidarity, responsibility and trust.¹ The word responsibility means choosing the option that is good, better or optimal because it agrees with the principles that spontaneously question us; and this is so owing to the fact that we are aware that we know the conditions we live in and the protagonists who act in the society we create together.

Consequently, responsibility implies that we are in a situation where we have two or more options and that there are other people whose good we must take into account when making our choice. Those other people legitimately claim that the chosen option should also be the good, best or optimal one for all.² To help us choosing, in the committees in question, we have a set of international and national acceptance regulations

and guidelines. Regulations and guidelines deriving from the convention and human will, and accepted after having been rationally analyzed and deciding that they are good for individual and common good, and that serve to guide the work of committees.

In Mexico, the evaluation of research protocols that involve humans as research subjects is carried out through independent groups: the research committees (RC)³ and the research ethics committees (REC).⁴ In their protocol review work, much of their responsibilities are the same. RCs assess and rule that the research protocol has a clear scientific objective, that the proposed methodology has sufficient power to reach the study objective, that the data analysis plan is appropriate to the nature of variables and objectives, in addition to assessing social, scientific and clinical relevance of the protocol.³ In turn, RECs evaluate and rule, from the ethical point of view, the purposes, objectives and methods presented in the research protocol.⁵ In addition to both these committees, another works independently: the biosafety committee. This committee reviews and analyzes the research protocols that involve genetic engineering techniques,

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use of radioactive isotopes and ionizing or electromagnetic radiation-generating devices.³

The work of the committees is indisputably important and necessary because, theoretically, it ensures that clinical research proposals are ethical.⁶ However, we cannot ignore that, in the practice of the committees, there are still issues that should be resolved; for example, some researchers argue that committees are not held accountable for the decisions and suggestions they issue, others point out that unjustified or inadequately justified decisions are common, and some more argue that the committees reject research protocols with exploratory (when the literature review produced insufficient elements to establish an *a priori* hypothesis⁷) or inductive approaches (by means of which the hypothesis is obtained *a posteriori*, i.e., based on the observation of particular cases⁷) due to the lack of hypotheses.

There are some who point out that the committees have shown incompetence to understand and properly evaluate research protocols that propose “novel” or modern scientific methodologies. The consequence of committees operating under the shadow of ignorance and incompetence has a clear social cost, since when rejecting research protocols with scientific validity and with social, scientific and clinical importance, health and wellbeing improvements of the population are delayed or prevented; more precisely, they delay or hinder the improvement of the individual and collective good that are health services.

The regulatory dimension

The regulatory area is made up of the international ethical guidelines (e.g., the Belmont Report, the Declaration of Helsinki, the rules of the Council for International Organizations of Medical Sciences, the International Declaration on Human Genetic Data, etc.), national regulations specific to each country and the regulations of each institution or establishment where health research on is carried out. The latter two should be consistent with international provisions. The regulatory dimension derives from the standard and human will, and its purposes are:

- To protect the rights and interests of research subjects.
- To provide an analytical framework that guides RC and REC members in the review and assessment of protocols.

In Mexico, there are national guidelines for the integration and operation of RCs³ and RECs⁵, which are

aligned with the operational guidelines issued by the World Health Organization.^{8,9} They are a set of objective directives that specify how RCs and RECs should be integrated and operate; e.g., regarding the latter, among its attributions, the following are stipulated:⁵

- “Advise the managers of establishments and institutions for the issuance of opinions... regarding the approval of research protocols at the units under their responsibility”.
- “Help in the application of the Law, the Regulation and other applicable provisions in matters of health research”.
- “Contribute to safeguard the dignity, rights, safety and well-being of all current or potential research participants”.

According to these directives, RECs operation is the central role of their work; through them, RECs exercise power and moral authority to assess and rule on health research.

Those who lead and make up RCs and RECs should understand that the regulatory scope (codes, declarations, regulations), though indispensable, is not exhaustive. Just to illustrate: none of the mentioned regulations consider the implications of order values (those that create and maintain and make the common good progress), such as responsibility, reciprocity and social covenant. If committees would adopt these values, their operation in the regulatory field would contribute to the common good, expressed as the generation of valid knowledge with the potential to produce substantial social benefits.

Although RC and REC members operate under a system of rules, they require properly contextualized deliberation,¹ which implies knowledge of regulations, understanding of ethical principles, familiarization with the strengths and weaknesses of the different study designs and knowing or being interested in knowing the subject of the protocol they evaluate. All this with the purpose to truly understand the subject that is addressed in the protocol, in order for the operation of the committees to be rational and responsible and their authority to be legitimately exercised when issuing a ruling. Otherwise, the practice of committees will be rigid, unfair, irrational and irresponsible, which are characteristics typical of a system of force and arbitrariness. This becomes evident when committee members misinterpret that which the authors have stated in their protocol, when the deliberation process is influenced by personal interests, when their judgments are guided by the projection of personal experiences or expectations and when a standardized

review is carried out for all protocols, even if they have different methodological approaches.

In the absence of rationality and responsibility, the authority of the committees will be illegitimate and has not to be obeyed by those who submitted research protocols for ruling. In fact, these investigators have the obligation to prudently object that committees that do not operate rationally and responsibly continue in business.

The practical dimension

The practical dimension we refer to has to do with the *ethos* or usual nature of a person; this includes the way of thinking and being, in the light of the emotions that the individual feels, of the expectations, values and interests that motivate him and the way they influence on his judgments and decisions.¹ Hence the regulations and guidelines that guide the work of the committees are understood and complied with differently, both by each one of their members and by the committee as a whole. Therefore, the members of RCs and RECs should make a constant effort to educate their emotions, feelings and thoughts, and harmonize them with the expectations of rationality and accountability that have been delegated to the authority for the issuance of judgments and rulings. It is required for each member of a committee to deploy the formally dynamic structure of human consciousness, with the purpose to achieve truly ethical judgments and not technical judgments, convenience or utility judgements that harm the interests of the people who will be affected by the committee's decisions.

To illustrate the importance of the practical dimension, here is an example: even when there are rigorous construction regulations and architectural standards, which the State has issued for the construction of buildings, several new properties collapsed in Mexico with the earthquakes of recent years. The architectural structures of those collapsed buildings are a testimony of the practical dimension, of the nature or way of thinking and being of those who designed and built them: architects, engineers, construction workers. Extrapolating this example to the work of the committees, in their operation, they cannot be simple followers of objective regulations, because by doing it they undermine or weaken science credibility.

A characteristic feature attributed to committees is their "autonomy", although, in real life, their conformation and operation are directly linked to the authority of the institution they serve.^{3,5} It should be noted that their autonomy is granted and clearly delimited by the guidelines and directives of the field they operate in. Autonomy does not mean that committees can do whatever they want or whatever they can think of, because if they did, their acts would be arbitrary and their operation illegitimate. Autonomy of the committees is different from the autonomy of people who voluntarily decide, after being duly informed, to participate in an investigation. It has been shown that implementing an audit system to examine the work of committees would help, not to prosecute the committees and their members, but to discover areas for change and improvement¹⁰

Conclusion

Currently, RCs and REC play a central role and have great power and authority over health research, and it is therefore important that they operate clearly and transparently. The research protocol review process is a serious matter that should be fairly conducted. It is desirable that committee members fully comply with their personal responsibility and that committees, as entities, fulfill their social responsibility, hence the imperious need to regularly assess RCs and RECs through audits.

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