Research and research ethics committees and the obligation for them to operate in accordance with the principle of the social covenant

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Abstract

The relationship between the social covenant, ethics and scientific research is highly important for society. Economic prosperity and better health are two of the main reasons why society supports science, without society itself being able to determine the nature of the research that is to be implemented; this is decided by Research Committees (RCs) and Research Ethics Committees (RECs). This article analyzes how the work of RCs and RECs must have a social covenant and represent the interests of society in order to promote its trust in research.

KEY WORDS: Research Committees. Ethics Committees. Social covenant. Ethics. Mexico.

Los comités de investigación y ética en investigación y la obligación de que operen de acuerdo con el principio de la alianza social

Resumen

La relación entre alianza social, ética e investigación científica es extremadamente importante para la sociedad. La prosperidad económica y la mejor salud son dos de las principales razones por las cuales la sociedad apoya a la ciencia, sin que la sociedad misma pueda determinar la naturaleza de las investigaciones que serán implementadas; esto último lo deciden los comités de investigación (CI) y los comités de ética en investigación (CEI). En este artículo se analiza cómo el trabajo de los CI y CEI debe tener una alianza social y representar los intereses de la sociedad para promover la confianza de esta en la investigación.

PALABRAS CLAVE: Comités de investigación. Comités de ética. Alianza social. Ética. México.

Introducción

The implicit existence of the social covenant is precisely the reason why the ancient Greeks called ethics “the political science” (*episteme politike*), that is, the science of the city or the science to be a good citizen.¹ In modern world society, science, as a systematic process of rationality, increases its importance when it involves research, because it brings

about practical benefits for society in general. In turn, society, through public policy decisions, assigns economic resources to research in order to accelerate scientific progress, without being able to determine the nature of the research that will be implemented; the latter is decided by research committees (RCs) together with research ethics committees (RECs). To the extent that the work of RCs and RECs is an activity carried out by humans, the decisions of the

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Date of reception: 05-09-2019

Date of acceptance: 30-09-2019

DOI: 10.24875/GMM.M20000355

Gac Med Mex. 2020;156:138-141

Contents available at PubMed

www.gacetamedicademexico.com

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committees will reflect the emotions, values and beliefs of their members, which affects the way science is perceived and implemented and how investigations are loyal to the social covenant.

The social covenant, a science-inherent principle

The word covenant derives from *convenire*, Latin word that means to come together, to agree. The dictionary of the Royal Spanish Academy defines the Spanish word for covenant, *alianza*, as the "action of forming alliances".² Researchers and members of the RCs and RECs must regard loyalty as the obligation that gives meaning to the social covenant. Therefore, they have fiduciary responsibilities. The responsible fulfillment of the fundamental commitments (where loyalty emanates from) by researchers and RCs and RECs strengthens society's confidence in scientific research. When one of the parties' own interest threatens or violates the legitimate benefits of the other, the primary objective of scientific research is impinged: the generation of valid information, with or without immediate practical ramifications, to the benefit of society.^{3,4}

Currently, by law, only research proposals approved by RCs and RECs can be implemented in Mexico. Decision-making by RC and REC members in the assessment of research projects comprises more than theoretical obligations expressed in the law, in regulations and in ethical principles, it involves the character traits of the RC and REC members as well.⁵ Hence, it is not surprising that the work of RCs and RECs can sometimes be controversial, especially when they reject research protocols with innovative ideas and with the possibility of generating results that would improve the country's health system, because RC and REC members do not understand the methods whereby the investigations will be carried out. This rupture between the social covenant and the RCs and RECs also occurs when they cease to function as a critical body with clear social responsibility and bias their judgments in deference to a researcher or group of researchers who are perceived with authority or reputation.

When RCs and RECs evade their responsibility with the social covenant in the evaluation of research protocols, they abandon the probability of promoting improvements in health, wellbeing or knowledge of the population. The following is a real and current example where the social covenant is dodged:

- Multicenter research protocol of descriptive, exploratory, retrospective cross-sectional design,

which raises an original and relevant research question for the improvement of the quality of life of adolescent women with intellectual disability. As part of the data collection techniques, the methodology refers to the review of medical records with the sole purpose of generating information regarding menstrual hygiene of this group of women. The protocol properly specifies how the anonymity and confidentiality of personal data will be maintained. In their written ruling, the RC and the REC of the hospital considered that the research proposal was scientifically relevant, that it was methodologically well designed and that it met the ethical requirements; however, they rejected the protocol, arguing that hysterectomies had never been practiced in women with intellectual disability in the hospital.

Considering the assertion by the RC and REC that no hysterectomy was found in women with intellectual disability, we might ask ourselves, how did they guarantee the scientific rigor and validity of the results of their search? Is it justified that the RC and REC members implemented the research by their own initiative without prior authorization from the authors of the protocol? How did they maintain scientific and ethical rigor without having followed the protocol they ultimately did not approve?

By offering their services, RCs and RECs are accepting a fiduciary responsibility and the responsibility to act in accordance with nationally and internationally established criteria. Their action becomes idiosyncratic when it does not proceed in agreement with these responsibilities, which, consequently, prevents the accomplishment of the benefits that the social covenant entails for society.

Authorship and its relationship with the social covenant

An author is considered as a collaborator who has made substantive intellectual contributions to the protocol of an investigation, and then to the article where the results will be published. Anyone who appears as an author must assume responsibility for the following three conditions:⁶

1. Making important contributions to the design or data collection or analysis.
2. Performing a critical and substantial review of intellectual content.
3. Approving the finished work.

The names of collaborators who do not meet the three authorship criteria should appear in the Acknowledgments section.⁶

Authorship entails important implications and, consequently, academic, social and economic pressures that exacerbate deeply established anxieties in individuals and that, when interacting with each person's nature, define an area of possible behaviors. In hospital units, directors or heads of clinical research and researchers are simultaneously required to maximize scientific productivity. This powerful pressure is what, in many cases, defines scientific research practice morals (from Latin *moralis*, that which is customary²). The following is real case that illustrates a common and generalized practice:

- A multicenter sectoral investigation must have the approval of the RCs and RECs of each participating center. A prerequisite demanded by directors or heads of clinical research (in order for the project to be able to be submitted for evaluation by the RCs and RECs of the corresponding hospitals) is that the protocol has to mention a doctor or health professional serving at the potentially participating hospital as a “responsible researcher”, with the instruction that this “responsible researcher” should appear as an author. This requirement is established in the forms (of each invited hospital) the researcher must complete to submit the protocol for evaluation by the committees. Although this is the prevailing morals, i.e., that which is customary, an ethical infraction occurs due to the fact that these “responsible researchers” of participating hospitals, which will appear in the list of authors, sometimes only favor or allow access to information or databases or medical records, which are activities that do not justify assuming the role of an author in an investigation. However, failure to comply with this prerequisite makes for a protocol to be rejected since the beginning under the argument that “their hospitals are not only providers of data or samples”.

Unjustified authorship gives rise to a series of ethical deliberations: on one hand, it is always a lie and, therefore, an ethical infraction, since an individual obtains credit for something he has not done and can use to obtain a personal benefit. On the other hand, it is a testimony of the nature or way of thinking and being of the agents involved, in the light of the expectations, values and interests that motivate them, and in the way this influences their judgments and decisions.⁵ Furthermore, it represents a strong longing for increasing

productivity (to publish at all costs), which undermines the scientific foundation on which research should be based: the responsible search for the truth. By rejecting a protocol whose legitimate authors refuse to obey the mandate of assigning a spurious authorship, RCs and RECs cease to promote the generation of scientific knowledge they are bound to by the social covenant.

RCs and RECs professional loyalty

In Mexico, the groups that independently assess research protocols are three: RCs, RECs and biosafety committees.^{7,8} We have focused this article on the former two because they generally assess the largest number of protocols and for having overlapping functions. Briefly: for a REC to determine that a research proposal is ethical, it must evaluate its social and scientific importance, its validity and methodological plausibility, the appropriateness of the selection criteria, the risk/benefit ratio and the informed consent documents,^{4,9} which are criteria that also have to be examined by the RC.⁷ The reason why there must be two groups with overlapping activities is not defined. The essence of the work of the RECs should not be restricted to the informed consent of the research subjects.^{4,9} And the methodological aspects assessed by RCs are not alien to ethics either.⁴ Research ethics is immersed in research itself; hence, both RCs and RECs duty is to maintain high ethical standards, nationally and internationally defined, in the conduction of an investigation in order for it to meet its purpose: the social covenant.

Prior to being implemented, multicenter studies must be approved by the RCs and RECs of each participating center. The variety of arguments to reject or approve an investigation with modifications indicates how the RCs and RECs of different centers see the same proposal. The differences in justifications depend on the RCs and RECs nature or way of being. To illustrate this, let's go back to the first case, given that it is about a multi-center research proposal:

- In one hospital, the RC and REC rejected the protocol because of “never having performed hysterectomies in women with intellectual disability”; in another, it was objected due to “the possible existence of risky situations for the hospital”. Both hospitals are medical care and research reference centers; other hospitals approved the proposal. By denying the research proposal, RCs and RECs violated their professional loyalty (immersed in the social covenant) by conferring

primacy to the interests of the hospitals they belong to, instead of considering the interests of the population of women who would benefit from the research outcomes. The best interest of patients may not be that of the hospital, which could be more interested in avoiding legal aspects, or judgments or opinions of the scientific or medical community itself.

In sum, RCs and RECs will contribute little to the improvement of individual and collective health and wellbeing in health services if they do not understand the nature of their work and its relationship with the social covenant. Professional loyalty emerges from the nature (*ethos*) of each member of the RCs and RECs and from the fundamental commitments they individually and as a whole have with society.

Conclusion

Although there are national guidelines for the integration and operation of RECs and RCs, current

reality of the tasks of the committees underscores the need of changes in order to favor for them to operate in accordance with the social covenant and scientific research ethics.

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