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EXPERIENCE REPORT

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Ethics in medical research and the essential bureaucracy of ethics committees: an experience report

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Abstract

Since October 1996, Brazil has a new regulation on research involving human beings, it is the Resolution nº 196 of 1996 of the National Health Council, instance in which the National Research Ethics Commission and the Ethics Committees were created in Research – EC. This resolution says that each and every research project, in any area, involving human beings must contain an analysis of ethical aspects – carried out by the researcher himself – and be approved by the Research Ethics Committee. Research involving human beings is understood to be that which, individually or collectively, directly or indirectly involves human beings, in their entirety or parts of them. This article reports the difficulties in developing a research project that will later be approved by an EC, but with an emphasis on why these difficulties exist.

Keywords: Bioethics. Medical ethics. Bureaucracies. Ethics Committee.

Introduction

Advances in science and technology have been progressively impacting people's daily lives **[1]**. The evolution of scientific knowledge brings with it an extremely important issue, ethics in medical research **[2,3]**. Ethics in research involving human beings arose from the need to conduct research actions while maintaining not only the safety, rights and dignity of the researcher, but mainly of the research participant due to the unpredictability of the consequences of an investigation **[4]**.

In order for there to be a prior assessment in relation to the aspects presented by the researcher and the feasibility or otherwise of carrying out certain research involving human beings, the Ethics Committees (EC) were created, which aim at greater responsibility and respect for the participant of the research, act based on the National Health Council Resolution 196/96 **[4]**. The principles that underlie research ethics are listed in this resolution, which are autonomy, beneficence, non-maleficence, justice and equity towards the subject involved, emphasizing that the subject must be informed of the risks and benefits to which it will be exposed (National Health Council) **[5]**.

Issues related to research with human beings encompass the ethical consequences of decisions, researchers, institutions and especially the participants involved. It arises in the context after the Second World War, under the inspiration of normative documents such as the Nuremberg Code and the Declaration of Human Rights (1948), among others, with the purpose of establishing guidelines for research in the health area, aiming to ensure the integrity of persons subjected to medical experiments. Later, it started to involve the Social Sciences and Humanities, which claimed specific normative guidelines for the singularities of the area **[6]**.

The claim of ethics in research is based on the ethical foundations of human dignity, freedom and diversity of individuals and social groups, as well as principles of integrity, transparency and responsibility in conducting research and its results **[7]**.

Based on this, the present study aimed to carry out an experience report based on ethics in medical research and the essential bureaucracy of ethics committees.

Experience report

For some researchers, ethics committees are

targets of much criticism due to bureaucracy, and the number of documents required, but mainly to the Informed Consent (IC). However, nowadays, all the bureaucracy involved in a research project is essential in the field of medical research and publications.

As an effective member of the EC, the big impasse is the elaboration of the IC, mainly referring to the basement in the smallest details that involve its elaboration. But it is necessary to clarify that it is, mainly, in the IC that are the essential and legal parameters for the approval of research involving human beings. The IC must be formulated by the researcher, signed by an autonomous and capable person, the decision taken after an informative and deliberative process, aiming at the aceptance of a specific treatment or experimentation, aware of the nature, consequences, and risks (Resolution 466/12). There are special situations in which the IC can be waived (Resolution 196/96), and it must be replaced by a justification that explains why there is no need or impossibility of obtaining it, and the EC will assess its relevance.

The explanation for so many demands dates back to World War II as cited previously. However, over time, potential emotional, and cognitive risks or risks derived from situations that are created in the process of obtaining information, for participants, older or younger, needed to be considered. As mentioned by Amorim et al 2019 **[7]**, risks of personal shocks can derive from embarrassment, clash of cultures, language, and attitudes. Total respect for human dignity should be the concern of researchers in education. This implies guaranteeing the individual inviolability and personal integrity of research participants, who must be protected against personal harm and excess tension. These concerns extend to the publication and socialization of research when it is necessary to guarantee the confidentiality and integrity of the participants so as not to cause any damage, of any nature, to those who collaborated with the data collection. The identification of participants by the way the research is reported can generate undesirable personal or professional effects. Taking care that this does not happen is an ethical issue **[8]**.

To understand the seriousness of research with human beings, a mere questionnaire can generate insecurity, feelings of offense, invasion of privacy, feelings of inferiority, aggression, anger, anguish, malaise, and even cause depression and cognitive shocks. When designing a question or questionnaire item, it is necessary to consider who it is addressed to and the possible effects of the question, and not just consider the interests of the research and the researcher. These are legitimate reactions that must be perceived, considered, and handled with care.

The National Council of Ethics in Research (CONEP) and the ECs have a multidisciplinary composition with the participation of researchers, bioethics scholars, jurists, health professionals, social, human and exact sciences and user representatives. EC members, as well as researchers, must register on Brazil Platform (national and unified database of research records involving human beings in the EC/CONEP system). It allows the surveys to be monitored in their different stages, from their submission to their approval by the EC and CONEP, when necessary, even allowing the monitoring in the field phase and the sending of partial and final reports. The researcher must register on the platform describing preliminary information, study area, study design/financial support, study design and other information, complete and click on the "send project to EC" icon.

Projects arrive at the secretariat appointed by the EC, which distributes them to its members and coordinator, and everyone receives notice of issues on the platform by email. The rapporteurs receive the project and after analysis they issue their opinion. After the drafting of the report by the rapporteur, the projects are forwarded for evaluation by the other members of the EC, in a monthly or biweekly meeting, depending on the number of projects to be analyzed. The meetings must have more than half of the collegiate to deliberate and/or approve research projects and must be recorded in minutes, with the signature of all those present. The submission of the protocol to an EC does not depend on the level of the research, and it may be a work for the conclusion of an undergraduate, scientific initiation or doctoral course and of academic or operational interest.

The institutional EC must review all research protocols involving human beings, being primarily responsible for decisions on the ethics of the research to be carried out in the institution, in order to guarantee and protect the integrity and rights of the volunteers participating in said researches. It will also have a consultative and educational role, encouraging reflection on ethics in science, as well as the attribution of receiving complaints and requesting their investigation. The presentation of research to the community is carried out in congresses, seminars and scientific publications.

Development

Between 1945 and 1949, in the city of Nuremberg,

12 trials were held for the crimes of World War II **[6]**. The first of them analyzed medical research with human beings in Nazi concentration camps. In 1947, the Nuremberg Code was elaborated, to guarantee that principles of human rights, in particular the dignity of the human person and the autonomy of the will, become central aspects in any scientific research involving people **[9]**.

The first article of that Code was an immediate response to the judgments of war, stressing that the voluntary consent of the human being is "essential" **[9]**. The other articles corroborate the idea that the participant can abandon the study without reprisals, that the human trial should be preceded by animal experiments and that research with risk of death should be avoided **[1-3]**.

Still, it was only in 1964 that the World Medical Association proposed the Declaration of Helsinki, an international reference document to regulate ethics in health research **[9]**. The Declaration of Helsinki, more focused on biomedical research, reaffirmed the importance of ethical principles such as consent, dignity, and integrity of participants. In the review of the document, carried out in Tokyo (1975), the need to create Ethics Committees was indicated. In 1966, Henry Beecher, when reviewing 22 publications on research with human beings, warned that scientific practice was still far from humanist values and internationally agreed to ethical precepts **[10]**.

An example of this was the fact that higher risk research is carried out with people in vulnerable situations, such as prisoners, asylum inmates, children with mental disabilities, and elderly people with dementia **[9]**. In Brazil, the ethical review of research with human beings is carried out through the Research Ethics Committee/National Research Ethics Commission - EC/CONEP system (Brazil Platform). CONEP, based in Brasília, is one of the Commissions of the National Health Council, linked to the Ministry of Health **[11]**. CONEP was created by National health council Resolution No. 196/1996 and has the function of elaborating and implementing norms and regulatory guidelines for research involving human beings, both for biomedical research and research in Human, Social, and Applied Social Sciences (Council National Health Council) **[12]**.

It also has a consultative, deliberative, normative, and educational role, working together with a network of EC organized in the institutions where the research is carried out **[13]**. Research ethics committees are responsible for the ethical evaluation of research projects; moreover, they must inform and educate their members and the community about their role in social control (National Health Council) **[14]**.

Conclusion

As presented, it is assumed that all research involving human beings must have the dignity of the human person as a fundamental principle. The bureaucratic factor becomes extremely necessary, as it implies respect, from consent to participate in the research, to the careful assessment of potential risks to participants, the commitment to individual, social and collective benefit, as well as respect for human rights and human rights. autonomy of will. It is necessary to clarify that ECs are not just committees of researchers, but a representative group of society and, more than that, they are responsible for ensuring, through the approval or disapproval of a research project, the dignity of the participant, the use of high standards of research, integrity, honesty, transparency, and truth, defense of democratic values, justice, and equity and social responsibility that involves research itself.

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Conflict of interest

The authors declare no conflict of interest.

Similarity check

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