Editorial

Respect for autonomy and free consent in research using archived biological material

The relationship between the principles of the respect for autonomy and free consent and research involving human beings began to gain visibility as international documents of great impact and credibility began to be developed collectively by the community of nations, governments and scientific organizations commanding respectability on a global level. This process began with the Nuremberg Code (1947), gained force with the Universal Declaration of Human Rights (United Nations - UN, 1948), continued with the Helsinki Declaration (World Medical Association, 1964) and the Belmont Report (Government of the United States, 1974-78) and, most recently, the Universal Declaration on Bioethics and Human Rights (United Nations Educational, Scientific and Cultural Organization – UNESCO, 2005). The last of these contained 28 articles and was unanimously acclaimed by 191 countries. In this declaration, the growing importance of the concept of autonomy in the context of contemporary ethics has led to the term being broken down into no less than five different principles, defined as follows: Autonomy and individual responsibility (article 5); Consent (article 6); Persons without the capacity to consent (article 7); Respect for human vulnerability and personal integrity (article 8); and Privacy and confidentiality (article 9)[1].

The historical roots of autonomy were planted at the start of the Middle Ages, between the fourth and fifth centuries, against a background of Christian theological discussions between Pelagius and Augustine of Hippo on the subject of "free will," which was understood at that time not only as a human being's capacity to do good but also to choose good[2]. Ten centuries later, with the emergence of Protestantism, Martin Luther and John Calvin respectively developed the concept of liberty and individualism/individuality in the context of the relationship between Christians and their God. In the 18th century, the ideas of the philosopher Immanuel Kant, who was also a Protestant, made a decisive contribution to what autonomy is understood to mean today, on the basis of studies that separated God from the domain of reason. In common with what can be observed in practices related to capitalism, as has been suggested by Max Weber[3], autonomy also has a Protestant basis founded on the individual rights of people to freely take their own decisions and by doing so exercise their rights.

In the specific context of research with human beings, the chapter that deals with respect for autonomy and people's free choice to participate or not has special importance for the field of biomedical ethics. Specifically in Brazil, public regulation of scientific research involving human beings began with a resolution by the National Health Council (Conselho Nacional de Saúde) passed in 1988[4] which, however, was not as well received or understood as had been hoped at the time. Some years later, however, in 1996 the National Health Council passed resolution number 196 changing the scenario and creating the system of Research Ethics Committees and a National Research Ethics Commission[5], which was gradually assimilated by the scientific community, providing the country with a formal, more reliable structure for ethical control of biological research.

Within the wide spectrum of topics covered by the regulations in Brazil, one of the subjects that has caused most controversy is the need, or lack of, for patients to sign free and informed consent forms (FICF) even in cases of archived biological material. In order to clear up areas of doubt, the National Health Council passed resolution 347 in 2005, supplementary to 196/96, regulating the storage and usage of biological material in research projects[6]. This document, which is still in force, deals specifically with projects that involve storage or use of materials stored during earlier research and states that research protocols which will involve the use of such material must include, among other features, mechanisms which guarantee the possibility of making contact with donors to provide them with information which may be in their interests (...) or in order to obtain specific consent for use in further projects. A different point in the resolution states that, in cases in which it is impossible to obtain specific consent for further research (the donor has died, previous attempts at contact have failed or others), explanations should be presented as part of the protocol for appreciation by the ethics committee, which may or may not waive individual consent.

Within the Brazilian Ministry of Health, discussions are in the very final phases about issuing a ministerial directive to create new national guidelines for biorepositories and biobanks for human biological material destined for research, to substitute resolution 347/2005 mentioned above. In line with international developments on the expanded concept of autonomy, future guidelines will make it explicit that storage and administration of biological material is not the same as donation; this material is and always will be the property of the individual from which it originated and must only be used after free and informed consent has been granted, including in cases of subsequent experiments for which the material is once more needed.

A study published by Duque, Ramalho and Casali-da-Costa[7] is one example of how good research, even in conditions that were not conducive to acquiring consent, can be conducted at relatively low cost, respecting rigorously prevailing bioethical dictates. In their retrospective study of 155 cases of patients with cancer of the colon, operated between 2000 and 2004, they were able to obtain FICFs in no less than 74% of cases, by means of initial telephone contact complemented by postal consignment of two copies of the consent form and an envelope for returning the signed form. This number remains a little below the 90% achieved in Holland by Vermeulen et al.[8] in a study using genetic material that had been stored for 10 years, but is superior to the 68% achieved in the United Kingdom by Furness et al[9] for a study of patients given kidney transplantation followed by biopsy.

Not content with this result which, although positive, was not absolute, the researchers from the Instituto Nacional do Câncer (INCA) went further, in exemplary compliance with the prevailing national guidelines for the sector: they formally requested FICF waivers from their institutional ethics committee for the cases in which it had not been possible to obtain consent, duly documenting each case and the reasons. This request was granted by the Committee.

This, therefore, appears to be the correct path indicated by bioethics. Nevertheless, in an important study recently published in Europe, Nordic authors worked to explore in greater depth the relationship between the new biobanks and research ethics, claiming that the central question is not to consent or not to consent, but how to promote and protect the interests of those individuals who contribute to research, whilst also benefiting society and future patients[10]. They also claim that the pros and cons related to the subject indicate that we should seek an appropriate focus for each specific context or situation, because no single model is capable of covering all of the different situations with which we are faced in this complex field. They proposed four alternatives to informed consent which will undoubtedly be analyzed by bioethics experts from now on: broad consent, the confidentiality/privacy approach, submission to the researcher, and conditioned authorization.

Ethics, like science, is glacial. But despite being glacial, it changes over time, with the customs that operate within different human societies and with the dynamics of the concrete reality of which, whether we like it or not, we are all a part.

Volnei Garrafa

Professor Titular, Coordenador da Cátedra UNESCO e do Programa de Pós-Graduação em Bioética da Universidade de Brasília; Membro do *International Bioethics Committee* da UNESCO; Brasília, DF

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