EDITORIAL

INFORMED CONCENT

Despite the available legislation, which recommends the use of the term Free and Informed Consent (BRASIL, 1996) in Brazil there is yet no consensus on translation to "informed consent", being widely accepted the term "consentimento informado" which, as a fact, has not much sense in Portuguese. Post-information consent and Consciente consent are two possible versions, althoguynb incomplete. A better possibility is "Term of Consent" which is adopted by many Universities and Research institutions.

If the versiuon to Portuguese arises some polemics, the contents of the Term of Consent reveal additional problems.

In the ethical relation in research, the basic principle is guarantee to the subject full freedom to deliberteo in his/her participation in the study. More than that, scientists must recognize that the subject (the individual) is free to take the decision regarding his/her participation in the study and that such decision should be take without any sort of embarassment (GRUPO, 1995). In this connection, the Term of Consent plays an important role not only as a concret intrument of information but also as a legal document endorsing an agreement among parts. For that, some requisites are essential. Hewlett (1996) state that the consent is moraly acceptable only when it is based in four elements: information, competence, understanding and willigliness. It is interesting to note that the Brazilian legislation request only a simple consent in which the right of refuse is the essential requisit (MUÑOZ, 2004). Therefore, there are many way to approach the content of this document and to understand its process. Nonethless, these approaches are circumscribed by the Resolution nº 196 of the National Health

Counsil (CONEP). However, its content do not plecrude a more detailed discussion on this issue.

The process of consent involves two main factors. One is the interlocution with the object of consent, the other is the document of consent. The former is more imporant and the latter is a necessary consequence. The explanation, the information and the way this is done aims to guarantee, essentialy, the autonomy of the individual in taking an option to participate or not, since the document he/she signs – the Term of Consent – is the legal representantion of his/her autonomy.

Therefore, the content of the consent process becomes essential to the attainement of the ethical rule. In this connection, there arises some difficulty in to establish a level of communication that allows the explicitation of the autonomy of the individual facing a varied array of different understandings and perceptions on science and, in this case, in biomedical sciences. However, it is necessary to seek clarity of content to attain the requisits of full information, of structural competence, of understanding whithin the individual's reference frame and, ultimately, allowing the expression of his/her willingliness.

The Resoulution n° 196 of the National Health Counsil (BRASIL, 1996) in quite clear in the requirements to structure a Term of Consent – it is a document that explicit the agreement of the subject of the study or his/her legal representative, free of faults (simulation, fraud or mistake), dependency, subordination or intimidation, after a complete and detailed explanation on the nature of the study, its objectives, methods, expected benefits, potential risks, and the anoyance that may accompaign. However, if one take a look to the consent documents of the average research institutions in this country, the conclusion is that, even complaying with the legal requirements, little importance is granted to the clarity of its content. Most documents are intended only to comply with the legal needs and to guarantee that nothing if left to allow a legal claim against the scientist or the research institution. Certainly, this late concern is an important topic that is addressed in the terms and it arises as a sign of evolution in the concept of citizenship. However, to offer the individual a ample cenario of the study and its surroundings should be the main focus of the document. Thus, scientists must change their understanding on the objective and the focus of such document.

As previously mentioned, the Term of Consent is not just a bureocratic document. Its content should not only aim to please the members of the Ethical Committee. Of course, it should comply

with the legal requirements, but one should remember that the target of the Term of Consent is the individual. In this regard, a direct, fluent and acssessible language is essential, complying with all the requirements mentioned in the Resolution n°196. Among these requirements, two are to be mentioned due to the difficulty of scientists to face them – resulting in diferent problems. The first is related to the explanation of the study, its objective and methods. In this topic the problem is that scientists commonly reduce the explanation of a complex methodology into a few lines of poor understanding. This is a real problem and in order to solve this, scientists should improve their communication skills or seek assistance of other professional to offer something satisfactory to the individual. Next is the problem of the benefits, embarrassments and risks. This is another rank of difficulty since, in many cases, more than the satisfactory translation of the scientific knowledge, it is necessary some sort of argumentation without, in any case, to scracth the autonomy of the individual. In this regard, a better preparation of scientist, maily in humanistic sciences, can offer them conditions to cope with these difficulties. Indeed, unfortunately, humanistic sciences have been a neglected area in the formation of professionals of biological and health sciences in the last decades and the problems previously mentioned are a reflect of this.

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