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Editorial:

INFORMED CONSENT FORM FOR PARTICIPANTS IN MEDICAL RESEARCH: DETAILED OR GENERAL INFORMATION?

MARIA ALUAŞ

The Informed Consent is one of the most debated topics in Medical Ethics in the last five decades. Should or not patients be informed about medical interventions, treatments, and possible risks of medical acts on their bodies? This question was debated and detailed on all sides. The second development on these topics was on what information should be put on the Informed Consent form: should it contain all relevant information for the patient, in order to make an informed decision for his/her state of health or only the main and general information? In the daily medical practice there are many issues with the adequate quantity of information for the patient and if the Informed Consent Form is too long or to complex, the patient does not read all the information. Usually health care professionals are saying that patients are signing Consent Forms, but they do not read them and do not understand them.

Major strengths of a long and complete Informed Consent form are: it should be clear, complete, and meaningful; information is given in a comprehensive way, logically and structured. By complete information we mean the information on: proposed surgery interventions, the possible side effects associated with interventions, medication and consequences of this kind of intervention, risks and benefits of intervention, other options instead of participating in study, duration and constraints associated with, and follow-up program. Also it describes the purpose of the study, reasons to participate, the necessity of the study and procedures to be followed such they

are proposed. It refers also information about statement of confidentiality, research funding and conflict of interest. Every detail they need to know is here, including costs and expenses for participation and possible compensation, or contact information.

Before making any decision, participants must to discuss with an investigator, review the information, and have the opportunity to ask any question they may have. They also will keep a copy of the signed and dated consent form. In our understanding, this is a very important fact, to provide the patient with a copy of the Informed Consent form. After the procedure, the patient can read it again, if he/she need to, any time or he/she can ask details or explanations to doctor if it necessary, in order to avoid bad consequences or complications that can result from the medical act.

As **weaknesses of a complete consent form**, we can notice that it is too long and too detailed, information is repeated and participants won't have the patience to read so many pages and to try to understand all information. If they sign a general form and a detailed form later, as a part of the same medical act it could be a good option. In this way, the information could be understood such as the details about the necessity of the medical act and its consequences.

Ethical justifications for detailed informed consent form. We recognize the right of participants to be informed, to can decide for themselves and to have control over what happens with their health. If they are adequately informed and they keep a certain control of their life, they are autonomous and their lives are considered valuable. Respecting the autonomy means to recognize that they are persons and they will decide freely and without constraints and coercions what to do in the future, to accept to be part in a study or to refuse if it is considered too dangerous for them at this moment.

We must to involve all concerned in decision by informing them about all they need to know in order to take a good decision for them, for their family, according their life projects. If the study is meant to serve a social good, to enhance the health care of other people participants must to know that they will help society and they collaborate with researchers in order to obtain results for other patients in the same health condition. This collaboration presume

engagement and investment, but in the same time it is very important to respect all participants as persons with dignity and rights, because we, as individuals, can have different views about health, freedom, social good and social values life and its purpose.

The participant is an individual and he or she can have its own priorities, its own hierarchy of values in the life and personal values could be more important than social ones. Participants must to have a priority on expressing their own wishes, fears and concerns about what will happen with them, because they are the main subjects of research study; it is about their body, their heath condition and their life; and not inform them means not recognize their voice as a priority and not recognize them as our equals, or as persons.

Another ethical justification is to avoid and to minimize the possibility of exploitation in research, especially from Wertheimer point of view: an unfair distribution of benefits (Emanuel, Wendler and Grady). The question is who benefits are more important, participants or society? We believe participants should have more benefits than society, but this purpose is difficult to be guarantee from the beginning of the study. This is the reason for why the informed consent process is so important in research. If participants decide by themselves that participating is the right choice even if it could be possible not to have many benefits for them, if they want to do a sort of sacrifice for social good, research can initiate or continue, but they must to decide what they want to do with their lives and not others.

The requirements on **voluntary** and **informed** consent are also important, because participants need to know that they have a choice to do, and they can quit the project at any time, to ask questions they may have about the study, and they have the possibility to be assisted by research protection advocate. They must to feel protected and to have control on what will happen in their lives.

This issue of *Studia Universitatis Babeş-Bolyai Bioethica* presents articles related most to research practice and presents different relevant nuances of these realities. We believe this is the right way and process to obtain results and to act correctly and assumed in a researcher work.

BIBLIOGRAPHY

Wertheimer A. (1996) Exploitation. Princeton, NJ, USA: Princeton University Press
Emanuel E.J., Wendler D., Grady C. (2000) What Makes Clinical Research Ethical? JAMA, 283:2701