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EDITORIAL:

WHO SHOULD PARTICIPATE IN BIOMEDICAL RESEARCH?

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What means *Biomedical Research*? Biomedical Research or experimental medicine consists of basic and applied research aimed at increasing medical knowledge and understanding [1]. It has two main domains: *preclinical research and clinical research*. Preclinical research aims are to generate a better understanding of diseases and new strategies for treatments. Almost all this research are carried out on animals. Clinical research aim is to assess new treatments for diseases. This research is also named *clinical trial* and it is carried out in a group of human participants. Because of some risks and bad consequences of this practice, questions are how to find human participants and how to motivate them to be subjects in research? Or, who should be human participants in research? When we think about Biomedical Research or Experimentation, usually we think in negative terms, like discrimination, violation of rights or ethical rules, something bad, complex and quite difficult to be well understood. And also, because of our background in this field, given by mass-media especially, to the most part of people, the first feeling is that researchers use people for knowledge, they do something bad to sick, or poor, or disabled people. Because we have many histories presented to people! But, actually, the dilemma is that even not participate in research is a bad thing. In this short essay, I will try to argue the situation of HIV patients rejected from research, in the 1980s. I was inspired by the movie *Dallas Buyers Club* (2013), an American biographical drama film. In this movie, we can see the history of an AIDS patient diagnosed in the mid 1980s when HIV/AIDS treatments were under-researched, while this disease was not understood and highly stigmatized.

Why these patients cannot participate as subjects in Human Research, even if they want it? Because they were considered as *vulnerable groups*, and vulnerable groups cannot participate in no research. These are rules and guidelines for researchers. What define a `vulnerable group` in terms of

participating in human research? The first thing should be the capacity to understand information and to give the Informed Consent.

Informed consent is a decision to participate in research, taken by a competent individual who has received the necessary information, who has adequately understood the information and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation [2]. Vulnerable groups include children, the mentally disabled, prisoners, minorities and people in developing countries. But even patients with AIDS were considered as vulnerable or pregnant women.

Why these patients are considered as vulnerable groups? They are in a special condition, it is true. But they are able to understand all information and they also can make choices for themselves. Nevertheless, they seem like are discriminated because of their illness or their special condition.

Ethical issues or conflicts are between (1) the duty to protect the vulnerable from abuse and exploitation and (2) the aspiration to benefit them or society through needed research. We need to make sure that the protection is not excessive, or in our case discriminating.

Research participation has to be voluntary. And they wanted to participate. Their participation doesn't violate their autonomy and does not affect their freedom to choose what they consider to be good for them. If they cannot act for their interests, because the participation is forbidden for their groups, they are discriminated on their illness and on their group membership. Certainly without research, the health condition and the quality of these patients of life cannot be improved. Also, without data to support new treatments, each intervention is an experiment with a single subject.

What these patients did? First, they tried to find their own solutions, as the movie present: they went in Mexico or Japan and brought untested drugs, and used them, in their desperate trying to survive. Then, they asked to authorities for participation access to research. They assailed federal regulations aimed at protecting research participants as obstacles rather than safety measures. Because they viewed protectionism as discriminatory on that it prevented them from getting experimental interventions that they wanted. And the exclusion or limited access to trials is harmful and unjust for them. As a conclusion, research and researchers were perceived not as necessarily harmful but a societal good and as opportunity to treatment [3].

This issue of Studia Universitatis Babeș-Bolyai - Bioethica, presents topics and case reports of bioethical reflection in the different medical research area: legal medicine case reports, pharmacy, patient's rights, neurology, transplantations, eco-ethics and mentally disabled people issues. All these topics

argue about the necessity of ethics, rules, and transparency in our life. Without ethics and thinking, the medical progress is not for all us, but only for some people who use the medical progress in their own purposes. Bioethics issues and all topics in this publication concern all us; they are about our lives and about risks and consequences of medical decisions that do not involve us.

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