

## Editorial:

# ETHICAL JUSTIFICATION OF BIOMEDICAL RESEARCH

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What is biomedical research and why biomedical research concern all us? Before starting to talk about contemporary ethical concern regarding biomedical research, let's define the concepts. According to the Stedman's Medical Dictionary<sup>1</sup>, "research" refers to the "organized quest for new knowledge and better understanding, the natural world or determinants of health and disease".

Biomedical research or experimental medicine is an applied research with the purpose to increase medical knowledge. Medical research has two arm: *preclinical* research and *clinical* research. *Preclinical* research aims to generate a better understanding of diseases and new strategies for treatments, *clinical* research evaluates new treatments for safety and efficacy<sup>2</sup>.

This kind of research generated many ethical concerns and critics from its very beginnings as a method, because participants in this research were enrolled in fraudulent ways without telling them the whole truth about what will happen to them during the research phases.

The main question focus in our editorial is on the difference between medical practice and research. Robert J. Levine<sup>3</sup> (2008) discusses several ways in which the two fields conflict. He mentions a list of conflicts between Medical

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<sup>1</sup> Stendman's Medical Dictionary for the Health Professions and Nursing. 7<sup>th</sup> Edition. Wolters Kluwer Health, Lippincott Williams & Wilkins, 2012, p. 1450.

<sup>2</sup> J. Pierce, G. Randels, *Biomedical Research*, in "Contemporary Bioethics", Oxford University Press, 2010, pp. 487-506.

<sup>3</sup> R. L. Levine, *The Nature, Scope, and Justification of Clinical Research*, in "The Oxford Textbook of Clinical Research Ethics", Oxford University Press, 2008, pp. 211-222.

Practice and Research. Thus, the practice of medicine is not scientifically based, the physicians practice model is the authority; the researcher practice is to learn and to tell the truth. In the tradition of medicine, the physician does not tell the truth to the patient about diagnosis or prognosis, unless he/she is certain that this is good for the patient. The physician should keep the confidentiality of what the patient told him/her. Instead, the researcher's motivation is to publish findings of their research. The physician treats the patient, the researcher should respect the protocol and the randomized controlled study. The researcher enrolls the participant in the study only after the participant gave the Informed Consent. In the medical practice, there are some situations when the physician should treat the patient even without Informed Consent (i.e. emergencies).

We consider that the researcher has always a hypothesis of the research, he/she is looking to confirm or not this hypothesis, but the physician does not have a hypothesis. He/she always should listen and talk to every patient without presumptions or hypothesis. In the end, we can see a difference between the Institutional Review Board (IRB) in research and in medical practice: the approval of the IRB in a clinical study is always mandatory, but in the medical practice, the ethics committee or ethics consultant's opinion is not mandatory, having only a role to orientate the physician.

Both, the participant in the biomedical research and the patient should be informed about the meaning and the purpose of their participation or treatment, they should understand exactly what kind of treatments they are doing and also they should agree with the treatment or the research freely. But, both medical practice and biomedical research still face many issues and concerns and we are far from finding a good solution for everyone interested in these fields.

This issue of *Studia Universitatis Babeş-Bolyai – Bioethica* cover topics both from medical practice and research and all articles are focused on developing new ideas, understandings and realities. Our conclusion is that we need to find more professionals from the biomedical field interested on ethics and how to manage ethically their everyday practice.

**Bibliography:**

- Stendman's Medical Dictionary for the Health Professions and Nursing*. 7th Edition.  
Wolters Kluwer Health, Lippincott Williams & Wilkins, 2012, p. 1450.
- J. Pierce, G. Randels, *Biomedical Research*, in "Contemporary Bioethics", Oxford University Press, 2010, pp. 487-506.
- R. L. Levine, *The Nature, Scope, and Justification of Clinical Research*, in "The Oxford Textbook of Clinical Research Ethics", Oxford University Press, 2008, pp. 211-222.