

В практике биомедицинских исследований постоянно возникают ситуации, когда исследовательские стратегии не могут быть однозначно определены как с позиции существующих норм, так и с позиции реализованных прецедентов. Зачастую имеет место либо абсолютная новизна случая (ситуации), либо множественность трактовок предмета, которые предполагают личный выбор исследователя. Но возможно ли опираться на индивидуальный выбор, когда речь идет о жизни людей, ценностях их здоровья и благополучия?! Именно в таких ситуациях биоэтическая экспертиза становится не просто процессуальным действием, но жизненно важным руководством для развития науки.

Еще одним проявлением неоднозначности биомедицинского исследования, продуцирующим необходимость биоэтической экспертизы, становится противоречивость интересов (устремлений) сторон, принимающих в нем участие. Сторонами исследования является далеко не только исследователь (научный коллектив) и собственно исследуемая группа, здесь задействованы и интересы организации исследователя, и заказчики-спонсоры, и представители этического комитета, и интересы науки, а также ценности и реалии социума. При этом каждая из сторон имеет свои, не совпадающие с другими, цели, потребности, ожидания, что порождает многообразные конфликты, требующие многостороннего регулирования. Таким образом, роль биоэтической экспертизы трудно недооценить.

В сложившейся практике биоэтическую экспертизу осуществляют этические комитеты, формирование и действие которых пока, к сожалению, далеко не всегда отвечает запросам и нуждам современных биомедицинских исследований. Во-первых, этические комитеты европейской модели имеют только совещательно-консультативный характер. Во-вторых, не существует единой выверенной практики формирования национальной структуры этических комитетов, а также единой практики оспаривания решений локальных этических комитетов. В-третьих, участие в этических комитетах представителей социо-гуманитарного знания не является абсолютной нормой и общеобязательной практикой. В четвертых, в практике работы этических комитетов преобладает рассмотрение научной, инструментальной и процессуальной составляющей исследования и в меньшей степени – ценностно-мировоззренческой. Таким образом, несмотря на широкое обсуждение вопросов биоэтической экспертизы, ее адекватное воплощение пока не реализовано.

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## **THE ROLE OF BIOETHICAL EXPERTISE IN BIOMEDICAL RESEARCH**

The article considers the core aspects of the bioethical expertise in the field of biomedicine research. The author stresses the importance of humanistic component of expertise, assesses the activities of ethics committees.

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## **SYSTEMIC APPROACH IN BIOETHICS AND HUMAN SECURITY CONCEPTS**

The discipline of Bioethics, founded more than 40 years ago by American biologist Van Rensselaer Potter as a “Bridge to the Future” - an appropriate set of theoretical and practical methods and tools to counter the global problems, becomes at the beginning of XXI century more actual than never as an element which catalyzes and generates macro-systemic social, economic and political changes and permutations in conditions of aggravation of global multiaspectual crisis. Bioethics, actually, deals with correlation and adaptation of social mentality, of social moral and value systems to most fundamental needs of contemporary human civilization as the necessity to survive in sustainable conditions, by overcoming global menaces and to assure global security for a better future of the offspring of contemporary humankind.

In the same time, the concept of Human security, from the perspective of defining of its basic components: liberty of necessities and liberty of fear, strongly supports the fulfilling of most important social and political objectives and purposes of bioethics. The liberty of necessities become an achievable goal, as a state where the specific needs of human being (physiological, spiritual and social political) will not impede anymore his personal progress as a source of insecurity, impoverishment and pauperization. The freedom of fear is, moreover a psycho-emotional state of the human being, allowing him to be exempted of worry and dread of future as a natural outcome of implementation of sustainable and rational, equitable and participative policies and strategies.

Bioethical methodology as a set of applicable tools which can be used in political and social scientific researches, generates a new and original forms of scientific interest, which can identify and develop many other principles and roles of new global governing, being in correlation with moral and noospheric research standards, with the emerging purpose to offer a viable possibility for humankind to qualitatively survive in the context of contemporary environmental, economic, political and moral global crises.

A systemic approach in the analysis on political and most general social scopes of bioethical conception as well as of human security theory, shows that both are involved in the activity of solving of one of the major contemporary problems on the global scale which may generate several types of global crises: the defining and optimization of the perspectives and potential of further development and modernization of the world system of international relations and

of human civilization as a whole, from the point of view of social, political, economic, environmental factors. In this context, the question of optimization of the global crises becomes relevant, considering that social-political interests as core of political system have a crucial role for establishing and activating synergistic mechanisms in international relations which can become a trigger for maximization of benefits by using of biggest part of mankind intellectual and human potential in the perspective of overcoming global crisis.

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### **СИСТЕМНЫЙ ПОДХОД В КОНЦЕПЦИЯХ БИОЭТИКИ И БЕЗОПАСНОСТИ ЧЕЛОВЕКА**

Системный подход создает веские предпосылки для эффективного и взаимосвязанного внедрения методологий биоэтики и безопасности человека в условиях необходимости преодоления глобального кризиса, обеспечивая свободу, права и развитие личности.

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### **NEWEST HISTORY IS BIOETHICAL RENAISSANCE AGE**

Today's era is called the era of postmodernism. However, after this era invariably come next. What is it called?

Each period (era) of human existence, characterized by its own ideology, its own set of axiological; their failures and successes. So the characteristic features of Postmodernism could be called human awareness the vulnerability of Nature. Humanity at this time appeared before the fact of opening the dangerous knowledge. The knowledge that has evolved much faster than other areas of science, which caused considerable social and legal imbalance. As a result of these discoveries may suffer not only the man himself, but the planet Earth. The main question asked by mankind at this stage of existence, is the question of «What to do?» (What do you do with all that we could open or invent, etc.) and «how to be on?» (How to ensure the safety of human existence).

Staying in these meditations from the beginning of 20 years of the XX century, mankind has gradually come to the conclusion about the need to ensure in all ways the survival of planet Earth, and, of course, part of it - man. Because, there was a new knowledge – Bioethics, which permeates all spheres of society. In XXI century, in 2005, theoretical concepts for the preservation of the planet at the legal level were enshrined in the Universal Declaration on Bioethics and Human Rights. As of today bioethical paradigm increasingly penetrates the consciousness of humanity. Given that bioethical philosophy is gaining momentum and has the feedback from society – that it will be the philosophy of the future. This era should rightly be called the Bioethical renaissance age.

Bioethical renaissance age characterized by the following features.

1. As well as the classical Renaissance was characterized by an appeal to the values of Antiquity, and the Bioethical renaissance age characteristic bioethical treatment, regeneration, property, characteristic of Ancient age (era to 6 century AD), for example, conducting a conversation today about Life ethics, Global Ethics, we can not access the basic eternal human values, which are cultivated since the days of the Indian Vedas.

2. The main leitmotif of XXI century – to save the planet Earth. This is especially significant was after a series of ecological catastrophes on a planetary scale, which led to irreversible environmental changes of the planet; epidemics provoked by man. And if the previous Modernism and Postmodernism age can be best summarized the thesis: «We can not wait for the mercy of Nature, take them from her – our task», the Bioethical renaissance age thesis should be something like: «Each age acquiring new ideas, gets new eyes». Realizing that the anthropocentric conception of philosophy is extensive in nature and consumer society comes to the idea of replacing it with ecocentric paradigm of thinking, by which there is a chance to delay the collapse of the entire planet; the need to take the co-evolutionary way.

3. In addition to the international legal acts, at the national level are also accepted in the relevant provisions of the security of the existence of the ecosystem (prohibiting the experiments of the human genome, including the conduct of human cloning).

I am convinced that in XXI century, when access to the dangerous knowledge of overly open, there should be a certain system of checks and balances, which is Bioethics with its axiology.

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### **НОВЕЙШАЯ ИСТОРИЯ – ЭПОХА БИОЭТИЧЕСКОГО ВОЗРОЖДЕНИЯ**

По мнению автора, на смену современной эпохи постмодернизма придет эпоха Биоэтического Возрождения, основным лейтмотивом которой будет сохранение Земли, коэволюционный путь существования человечества, экоцентрическая парадигма мировоззрения, которая сменит потребительский антропоцентризм, возвращение к вечным ценностям Природы.