

# Constitutional and legal status of the subject during biomedical research

Serhii S. Pyroha<sup>1</sup>, Bohdana B. Shandra<sup>2</sup>, Ruslana P. Naturkach<sup>2</sup>, Maryna G. Kohut<sup>2</sup>

<sup>1</sup>AUGUSTIN VOLOSHIN CARPATHIAN UNIVERSITY, UZHGOROD, UKRAINE

<sup>2</sup>UZHGOROD NATIONAL UNIVERSITY, UZHGOROD, UKRAINE

## ABSTRACT

**Aim:** To find out the peculiarities of constitutional and legal status of the subject during biomedical research.

**Materials and methods:** A synergistic approach helps predict possible fluctuations and vectors of development, taking into account various social and technical processes of influence on the status of the subject; comprehensive – involves the analysis of the research subject within the framework of a combination of different scientific schools, concepts and methods and provides opportunities for the development of unified standards, benchmarks, principles and general norms of legal regulation.

**Conclusions:** The constitutional-legal status of the subject is the position of the subject (patient, object of research) established and established by the norms of constitutional law, which distinguishes him as a special subject of legal relations in the process of conducting biomedical research and consists of a set of rights and obligations and specifics of the legal liability of its participants.

**KEY WORDS:** human rights and freedoms, law, biomedical research, human rights protection, subject during biomedical research

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## INTRODUCTION

The second half of the 20th and the beginning of the 21st century were characterized by serious scientific and technical discoveries in the field of biology and medicine, and the rapid rise of medical technologies to a qualitatively new level. Cloning, genetic engineering, organ and tissue transplantation – this is not a complete list of research that can change the life of mankind and find the possibility of treating many diseases. Scientific research in the field of medicine today represents the most important sphere of human activity, the main goal of which is to preserve the life and health of people. In recent years, medical science has made great strides; it has become capable of penetrating the deep processes occurring in the human body, influencing reproductive health, dying processes, genetic status, etc. The objective emergence of completely new knowledge-intensive technologies, the expansion of the horizons of human activity in the field of medical and biological sciences gives rise to the emergence of new relationships between researcher and subject, which undoubtedly leads to the need for legal regulation of these relations, the emergence of new profound scientific developments that can influence the formation of adequate legislative bases in this area [1].

At the present stage, our society, having gone through a serious path of development, is forced to admit that there are a lot of issues the solution of which is not yet within the control of man. Each new evolutionary stage is accompanied by the emergence of a mass of new diseases and viruses that claim many lives and pose a serious threat. HIV (AIDS), cancer, COVID are just the tip of the iceberg of the most serious diseases, the treatment of which is not yet possible even in our time of rapid development of science [2].

Disappointing statistics inevitably emphasize the clear need to combat these diseases and search for fundamental means of their prevention, diagnosis and treatment. In this regard, this area is one of the priority tasks of modern medicine, the implementation of which, in turn, is unthinkable without conducting experimental studies with human participation [3].

In order to test the theoretical principles put forward by scientists, with a view to testing them in practice and ensuring the safety of the developed treatment methods, the need invariably arises to conduct biomedical experiments on humans. At the same time, to date, legal science has not formed a final position on the issue of protecting human rights in their implementation. Conducting experimental research is

very closely interconnected with interference in the sphere of private interests of a person, with the right to life, personal integrity, respect for private life, which necessitates detailed regulation of the possibility of permissible interference in this area, as well as the development, taking into account humanistic trends, theoretical and legal the basics of the relationship with the subject during the study [4].

The need for a serious and more careful consideration of the legal relations that arise during biomedical research involving humans is thus determined by the dynamic development of science and the corresponding complication of social relations. In this regard, the study of these relations should be based on ensuring human rights, which in itself, to one degree or another, is a manifestation of the multifaceted and multidimensional principle of humanism, which, in essence, implies considering a person as the highest value. It is the extent to which the implementation of human rights and freedoms, their recognition and maximum respect will occur that directly determines whether our state will truly be legal [5].

## AIM

The aim is to find out the peculiarities of constitutional and legal status of the subject during biomedical research.

## MATERIALS AND METHODS

The research methodology is based on a complex of methodological approaches and methods of scientific knowledge of social phenomena and processes.

A synergistic approach helps predict possible fluctuations and vectors of development, taking into account various social and technical processes of influence on the status of the subject; comprehensive - involves the analysis of the research subject within the framework of a combination of different scientific schools, concepts and methods and provides opportunities for the development of unified standards, benchmarks, principles and general norms of legal regulation; humanistic - normalizes manifestations of coercion in the construction of the constitutional system and human value in the theory of constitutionalism in the formation and functioning of the system for the protection of the rights of the subject; posthumanistic - revealed through the positioning of changes in the status of the subject as an alternative transformation that has already taken root in the constitutional and legal reality. A complex of methods was used, among which: dialectical - when analyzing the phenomenon through its normative-legal

and law enforcement genesis; transcendental - to reflect the dominance of the primacy of human interests in the functioning of the system for the protection of the subject's rights; hermeneutic - when interpreting normative legal acts, proposals for improving the conceptual and categorical apparatus; constitutional comparativistics - when distinguishing a group of states according to the level of technology implementation, which makes it possible to reflect the connection between the status of the subject and the democracy of the government; legal forecasting - to determine the prospects for the further development of constitutional law in the modern conditions of constitutionalism, to identify directions for the development of the status of the subject.

## REVIEW AND DISCUSSION

Analyzing the ethical aspects of conducting research on humans in the 1970s, G. Jonas noted that the time will soon come when the scientific community will have to overcome the huge temptation to move to regular, daily experiments on the human body. Becoming an ordinary event, such experiments will bring great danger to humanity [6]. Even half a century ago, the basic norm of the Nuremberg Code of 1947 regarding the possibility of conducting an experiment on a person only in case of extreme necessity was an absolute imperative of the scientific ethos, the internal moral censorship of world science did not allow it to be reconsidered [7].

The Geneva Declaration of 1948, adopted by the World Medical Assembly, and the 1949 International Code of Medical Ethics assume, at least implicitly, that an experiment on a person is possible only in the absence of another alternative to obtaining knowledge of great importance to society. As we have already noted, these normative acts do not contain a definition of a medical experiment, but the principles laid down in them have a direct impact on the ethics of its conduct. Fundamental knowledge is an indisputable value of society and often serves as a justification for risking the physical and social well-being of mankind. In any scientific research, there are ethical principles that regulate the scientist's attitude to the subject of his activity. For a scientist who works in the field of experimental medicine, the object of research is a person, and the ethical norms laid down in the process of their interaction are a guarantee of the success of future results [7].

In the context of the topic of our study, we note that scholars in the field of constitutional law have sufficiently investigated the issue of the constitutional and legal status of a person and a citizen, but little attention has been paid to the study of the constitutional and legal status of an object in the field of biomedical research.

It should be noted that among legal theoreticians and constitutionalists, there is no unified view regarding the understanding of the concept of "legal status" and its components (sub judice). So, in particular, the category "status" translated from the Latin language means the position, condition of something or anyone: "status of a person", "status of an individual", "status of a citizen", "status of an organ" [8]. In modern domestic explanatory dictionaries, you can find such a definition of status as: "legal status of persons or organizations, institutions, etc.; the position of an individual or a group of individuals in relation to other individuals or groups in the social system; the position of its subjects, the totality of their rights and obligations established by the norms of law" [2].

Undoubtedly, one should fully agree with the statement of one of the leading researchers in the field of constitutional law, M. Gromovchuk, that the concept of "status" is one of the basic concepts in legal science, as it allows determining the place of legal subjects in the system of social relations, their rights and obligations relationships with other subjects [9-11]. Status in constitutional law has several expressions depending on the role it plays in determining and fixing the position of participants in constitutional-legal relations and approaches to its characteristics. But in any of its manifestations, the constitutional and legal status has the qualities of stability, relative stability, internal coherence and systemic significance [12]. In the science of constitutional law, status is a theoretical construction that combines normative characteristics, theoretical ideas and the practice of implementing legal institutions [13]. The term "status" is widely used both in legislation and in special legal literature [12-15].

According to the successful statement of Z. Makarova, the actual legal category "constitutional and legal status" allows to establish the place of one or another institution in the system of distribution of power, to show all the multifaceted relationships between this institution and other government institutions [14].

Starting to solve one of the tasks of our research, it is necessary, first of all, to reveal the meaning of more general legal definitions - "legal status", "constitutional status" and "constitutional-legal status". Note that the existence of several approaches to the definition of scientific terminology is a generally accepted phenomenon both in legal science and in constitutional law. Therefore, to reveal the issue of the constitutional and legal status of the subject in a biomedical experiment, it is necessary first of all to use the terminological apparatus, while it is important to outline the key theoretical and methodological approaches to its analysis.

Many domestic and foreign researchers (Y. Bysaga, D. Byelov, M. Savchyn, M. Matuzov, A. Lebedev, Y. Todyka, N. Shuklina), the term "legal status" and "legal provision" are usually used as synonyms and used to characterize the subject's place in legal society. At the same time, A. Syrota notes in this regard that: "Despite the different approaches to this phenomenon, the difference in views on the concept of this legal phenomenon, all authors are united in the fact that the legal status of any subject of legal relations is reflecting and enshrining in law its real, factual position in the system of social relations" [15].

In constitutional law, the status category was most fully explored by N. Bohdanova, who pointed out that status in constitutional law has several incarnations depending on the role it plays in defining and fixing the participants of constitutional-legal relations and approaches to its characterization. In any of its manifestations, the constitutional-legal status has such qualities as: stability, relative constancy, internal consistency and system-forming significance [13].

It should be noted that both legal theorists and constitutionalists do not have a single point of view in the understanding of such a category as "legal status". Thus, in the dictionary of terms from constitutional law, the term "legal status" is defined as the set of rights, duties and responsibilities of its subjects - citizens, authorities, institutions, organizations, etc., established by law. [16]. Here P. Shlyakhtun understands the term "constitutional status" as the set of rights, duties and responsibilities of a subject of constitutional law established by the norms of the constitution [2].

V. Chetvernin defines legal status as "a legally established permanent position of a subject of a certain type in society and the state. Legal status, in his opinion, consists of primary rights and legal obligations. In other words, the rights and obligations that constitute the legal status of an entity are such rights and obligations that are constantly, always present in every entity of a certain type" [17].

N. Onishchenko under the category "legal status" understands the system of legislatively established and state-guaranteed rights, freedoms, legal interests and obligations of the subject of public relations [18]. V. Korelsky considers legal status as a multifaceted category, which, firstly, has a general, universal character, includes the statuses of various subjects of legal relations: the state, society, individuals, etc.; secondly, it reflects the individual characteristics of the subjects and their real position in the system of multifaceted social relations; thirdly, legal status cannot be realized without duties corresponding to rights, without legal responsibility in necessary cases, without legal guarantees; fourth, the

legal status category defines the rights and obligations of subjects in a systematic way, which makes it possible to carry out a comparative analysis of statuses [19].

It should be noted that in the scientific legal literature the legal status of subjects is distinguished: a) natural persons; b) legal entities; c) the state; d) foreigners, stateless persons; e) status of refugees; e) status of Ukrainian citizens residing abroad; g) professional and job status [20].

Thus, legal status can be defined as the legally established position of the subject, therefore legal sources sometimes also speak of legal status. However, in our dissertation research, we will consider the legal status.

Investigating the general theoretical principles of the legal status of a legal entity, I. Okunev singles out such components as: 1) legal personality; 2) the system of rights, obligations and legal interests; 3) system of guarantees of rights and obligations of legal subjects; 4) legal responsibility. At the same time, the researcher believes that this construction of legal status: firstly, can have a universal character, which allows it to be formed on the basis of the construction of the legal status of a legal subject of a specific field of law; secondly, it is capable of acting as a universal basis for legal regulation of the legal status of a legal entity; thirdly, it can be applied to specific types of legal status of legal subjects [21].

A. Kolodiy and A. Oliynyk adhere to the position according to which they consider the most complete structure of legal status, which contains the following elements: 1) statutory legal norms and legal relations; 2) subjective rights, freedoms and legal obligations; 3) citizenship; 4) legal principles and legal guarantees; 5) legitimate interests; 6) legal personality; 7) legal responsibility [22].

At the same time, we share the position of B. Daminov, who believes that the constitutional status is determined by the normative characteristics enshrined in the Constitution, for subjects of legal relations of the same kind (type), it is general. The constitutional-legal status is broader in content than the constitutional one and involves characteristics contained, in addition to the Constitution, in the norms of other sources of constitutional law. This type of status takes into account the specific characteristics of subjects of legal relations of the same kind (type) and in this sense it is synonymous with a special legal status. The latter is characterized by the greatest breadth of parameters, determined by the sources of various branches of law. Therefore, the most general scope has a legal status, the basis of which is the constitutional-legal status, the core of which is the constitutional status [23].

As we have already seen from the above, for almost all branches of law, the concept of "status of the subject of law" is one of the main ones, it reveals the main branch institu-

tions, since the concepts of "subject of law" and "subject of legal relations" are considered identical. We believe that this approach should be used in the study of the problem of the constitutional and legal status of the probationer.

The constitutional-legal status of the subject can be characterized from the point of view of constitutional-legal, administrative-legal, criminal-legal, family-legal, civil-legal and other branches of law. But at the same time, taking into account the object of our research, the constitutional and legal status of the subject will be analyzed. Taking into account the above, depending on the typological or individual characteristics that individuals have as subjects of law, normative legal acts, which provide for statuses, completeness of legal status, they are divided into certain types. Namely: a) general is a legal status provided by the constitutional law for any person or citizen; b) special – prescribed by separate legal acts for certain categories of people or citizens (judges, prosecutors, teachers); individual – legal status provided by individual legal acts for a specific person [22].

Thus, the general constitutional and legal status of a probationer is determined by the general status of a person and a citizen, because in constitutional legislation, with few exceptions, there are almost no norms that directly mention the rights of a probationer. And the general theory of law does not develop the features of a special subject of law, which is, due to the peculiarity of its legal nature, the subject. In Chapter II of the Constitution of Ukraine "Rights, Freedoms and Duties of Man and Citizen" the term "undertrial" does not appear at all. In the norms, the probationer acts as the subject of legal relations and is included in the terms "everyone", "everybody", "citizen".

## CONCLUSIONS

The next type of constitutional and legal status is the special status of a probationer, which is established by the norms of the relevant branches of law (administrative, criminal, civil, medical, etc.) and international legal acts that regulate the variety of spheres of public life in which the probationer participates, as well as conditions that affect its legal status. That is why the special status of the subject, which distinguishes him as a special subject of legal relations, is based on the sign of participation in biomedical research. However, the understanding of the limits of this feature and, accordingly, of legal personality has led to fairly significant variations in different areas of law. That is, different branches of law use several concepts that characterize a person according to this feature, namely: subject, patient, object of research, and in this connection approach the issue of legal personality of the specified categories of persons in different ways.

Thus, the constitutional-legal status of the subject is the position of the subject (patient, object of research) established and established by the norms of constitutional law, which distinguishes him as a special

subject of legal relations in the process of conducting biomedical research and consists of a set of rights and obligations and specifics of the legal liability of its participants.

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## CONFLICT OF INTEREST

The Authors declare no conflict of interest

## CORRESPONDING AUTHOR



**Serhii S. Pyroha**



Voloshin Carpathian University



4 Hoydy st, 88000 Uzhhorod, Ukraine



e-mail: [belov\\_dimon@yahoo.com](mailto:belov_dimon@yahoo.com)

## ORCID AND CONTRIBUTIONSHIP

Serhii S. Pyroha: 0000-0002-7093-3207  

Bohdana B. Shandra: 0000-0003-4104-2744  

Ruslana P. Naturkach: 0000-0002-3324-2040  

Maryna G. Kohut: 0000-0001-7885-7416  

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