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SPECIAL FEATURES OF THE LEGAL STATUS OF THE RESEARCH SUBJECT IN CLINICAL TESTING OF MEDICINES

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Viacheslav I. Borysov[1], Olena I. Antoniuk[2], Ivan I. Vyshnyvetskyy[3]
[1]SCIENTIFIC AND RESEARCH INSTITUTE OF PROVIDING LEGAL FRAMEWORK FOR THE INNOVATIVE DEVELOPMENT OF NATIONAL ACADEMY OF LAW SCIENCES OF UKRAINE, KHARKIV, UKRAINE
[2]SUPREME COURT, KYIV, UKRAINE
[3]BOGOMOLETS NATIONAL MEDICAL UNIVERSITY, UKRAINIAN ASSOCIATION OF CLINICAL RESEARCH, KYIV, UKRAINE

ABSTRACT

Introduction: The issue of the content of the legal status of the research subject in clinical testing of medicines and its distinction from the patient's legal status is of practical importance, related to the observance of ethical standards in the field of clinical trials, as well as ensuring the balance of public and private interests in this field. Although the subject of this study and the patient being treated are usually united in the intention to overcome the disease, these processes have different essence. The regulation of the legal status of the research subject should be done by legal means that are relevant to the nature of such trials and ensure the effective protection and security of the interests of these subjects. Normative regulation of the legal status of the research subject, unlike the patient, is insufficiently structured and characterized by fragmentation thus requires the doctrinal elaboration.

The aim: The aim is to determine specific features of the legal status of the research subject and its difference from the patient's legal status being provided with medical care; to reason about the necessity and content of propositions to amend the current legislation of Ukraine in order to ensure the rights and legitimate interests of the research subjects.

Materials and methods: The authors used the judgements of the European Court of Human Rights (ECHR) on medical research, international and national regulatory acts, publications of scholars in the field of medical law. The research was carried out on the basis of the systematic approach using the methods of dialectical and formal logic, general scientific and specific legal methods of research.

Conclusions: With the aim to ensure the proper legal protection of the rights and legal interests of the subjects of clinical trials the authors provided arguments for the need to amend the current legislation of Ukraine in order to correspond the international legal acts and ethical standards.

KEY WORDS: a researcher, clinical testing, research subject, a patient, medicines

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INTRODUCTION

Clinical testing of medicines should be a matter of particular concern for the lawmaker, since they relate to the verification of the efficiency of medicines that have not been formally approved for the use in the provision of medical care. Such activities are accompanied by the risks to a human being involved in the clinical testing. The assessment of these risks and the establishment of an effective mechanism for the protection and security of the rights of the research subjects, based primarily on international ethical principles for ensuring protection of the rights, safety and well-being of the research subjects, depend on the state. Legal regulation of the research subjects and their guarantees should, primarily, take into account the nature of the clinical testing and also make it impossible to falsify the data of the clinical testing in order to provide effective medical help for future patients.

Analysis of national and international legislation and doctrine indicates that the research subject is often identified with the patient being treated. As a consequence, legal regulation of the research subject's rights uses legal means borrowed from the legal regulation of the patient's rights (without adaptation to the specifics of legal relations in the field of clinical testing); some aspects of such relations are left behind the attention of the lawmaker, or they are regulated by reference to normative acts, which provide medical care and do not take into account the specifics of the clinical testing. Because of the lack of legal protection, the research subjects become more vulnerable and receive no real legal protection, even having available legal means that do not work due to their incorrect perception by the subjects of legal enforcement. As a result, a person becomes even weaker subject of legal relations in the health care sector that affect the inalienable rights to life and health. These issues are not of the sufficient attention in the scientific literature. Considering this, the legal status of the research subject requires comprehensive doctrinal study.

THE AIM

The aim of the study is to determine specific features of the legal status of the research subject and its difference from

the patient's legal status being provided with medical help, to justify the necessity and content of proposals to amend the current legislation of Ukraine in order to ensure the rights and legal interests of the research subjects and legal certainty.

MATERIALS AND METHODS

To achieve the goals of the study, the authors have analyzed statistical data of clinical testing in Ukraine and have studied global and national tendencies in the field of such probations. The authors have analyzed the judgments of the European Court of Human Rights (hereinafter referred to as the ECHR) in cases pertaining to the topic of the study. Besides, the authors of the research have studied international and national legal acts regulating the procedure of clinical testing conducting.

The relevance of this research was determined by studying and analyzing of the publications of foreign and national researchers on the protection and security of the rights of the research subjects.

While studying the content of legal provisions and concepts contained in international and national regulatory acts and ethical standards, the authors of the paper have used the methods of theoretical analysis and synthesis. Certain issues required the use of systematic analysis method, first of all, in determining the balance between human rights and legitimate interests in the health care sector.

Formal and legal analysis of the international and national legislation provisions on the legal status of the research subject, its rights, as well as the legal means of its ensuring and differences from the legal status of the patient, allowed us to identify shortcomings in national legislation and to propose an improvements of legal regulation, in particular, on regulating specific features of keeping primary medical records during clinical testing, on specifying the definition of criminal illegal act in determining violation of the procedure for clinical testing conducting. The comparative and legal method was used in the analysis of specific features of regulating the issue of the access to the opportunity of using medicines that are being registered or undergoing clinical testing, as well as the peculiarities of ensuring the confidentiality of information about the research subjects.

In solving the objectives of the study, the authors have also used such methods as formal and logical (for distinguishing the rights of the research subject, delimitating the clinical testing from medical care), functional (in determining the impact of the clinical testing on the content of the rights of the subjects involved in the clinical testing), sociological (in analyzing the causes of the negative dynamics in the number of clinical testing in Ukraine) and others.

REVIEW AND DISCUSSION

Clinical testing of medicines is of considerable social and economic importance [1, 2]. Although, according to the statistics only 5% of all medicines under development actually reach the pharmaceutical market, but the costs of their clinical testing are annually increased by an average of 7.5%. Annual growth of the medicinal products' market is forecasted at 7.8%. If the participation in clinical testing for the research subjects is free of charge, the large amounts of money are spent on clinical trials each year. The range of costs on clinical testing at three stages is estimated between US $ 75 million and US $ 4 billion, depending on the country of conduction and the nature of the testing [3].

Having significant potential in the field of clinical testing, the annual number of such testing in Ukraine indicates negative tendency.

According to the World Clinical Trials Market Survey for 1999-2018, the number of trials in Ukraine is 0.75% (3 347 trials over the indicated period) of the total number of trials in the world, which is lower than, in particular, in Romania, Turkey, Mexico, Egypt, Greece, Bulgaria, New Zealand, Thailand, Hungary, Brazil. Among the leaders in the number of clinical testing is the United States, which conducts 26.53% of clinical trials in the world (120 654 trials), Japan ranks second with an indicator of 8.99% (40 895 trials), in the PRC this figure is 7.69% (34 954 trials), in Germany – 7.51% (34 143 trials) of the global clinical trial volume. Since 2015, the largest increase in clinical testing has been observed in the PRC and Japan [4].

Since 2017, there has been a decrease in the number of clinical testing in Ukraine, which is due to several reasons. For example, according to the survey conducted in January 2018 by the Ukrainian Association of Clinical Researchers (UACR) on the reasons that prevent Ukraine from becoming more attractive in the global clinical trial market, with 286 of clinical research representatives taking part in this survey, 35% of respondents consider such reasons in the insufficient legal normalization of the procedure of clinical testing conducting on the basis of state and municipal treatment-and-prophylactic institutions, 27% – in low education of the population, negative attitude to clinical testing, 10% – in undeveloped medical infrastructure, outdated logistics of health care facilities, 9% – in undeveloped research business environment (small number of Ukrainian CROs, SMOs, vendors, etc.), 7% – in imperfect work of regulatory agency, 6% – in a small number of physicians who are fluent in English, 5% – in the legal insecurity of researchers, 1% – in the low qualification of Ukrainian physicians [5].

This paper focuses on specific features of the legal status of the research subject in the clinical testing of medicinal products and its differences from the legal status of the patient.

A human being in the process of involving into clinical testing, as well as in the course of medical care, enters into legal relations with the health care facility, but the identity of the subject composition does not determine the same content and object of legal relations.

I. Ya. Seniuta believes that the participant of the experiment (the patient) has dual nature, is both the subject and quasi-object, because he acts as the research subject. The scholar offers to regulate the status of the subjects of legal relationship related to the conduction of medical experi-

ments by law act [6, p. 47-48].

The issue of legal provision for the protection and security of the rights and interests of the research subjects is relevant to many world countries and is addressed differently [7, 8]. The specific feature of legal regulation of these relations in Ukraine is to determine the detailed procedure for conducting clinical testing at the by-law level act, although at the level of law it is stated that clinical testing of medicines is conducted in accordance with the law [9]. Besides, the identification of a clinical testing subject with a patient (which is incorrect because the latter term means an individual seeking medical care and/or who is provided with such assistance [11]), is common in national law [10] and the scientific literature, namely a clinical testing is often considered as the provision of medical care using innovative medicines.

However, clinical testing of medicines is not the type of medical care. Such trials are primarily conducted to improve the effectiveness of medical care for future patients [12-14].

Clinical testing is the scientific study of an unregistered medicinal product for the purpose of establishing or confirming the efficiency and safety of a medicinal product [10, 15]. Medical care is the activity of professionally trained medical workers, directed on the prevention, diagnosis, treatment and rehabilitation of illnesses, injuries, poisonings and pathological conditions, as well as pregnancy and childbirth [11].

For example, the World Medical Association Declaration of Helsinki – "Ethical Principles for Medical Research Involving Human Subjects" [16] uses the term "medical research" that does not cover medical care. The paragraph 7 of the Declaration states the primary purpose of medical research involving human objects, which is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). The paragraph 16 of this Declaration states that research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

The Article 2 of Regulation (EU) No. 536/2014 of the European Parliament and of the European Council of 16 April 2014 "On clinical trials on medicinal products for human use" [17] states that clinical study means investigation in relation to humans intended: to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; to identify any adverse reactions to one or more medicinal products; or to study the absorption, distribution, metabolism and excretion of one or more medicinal products with the objective of ascertaining the safety and/or efficacy of those medicinal products. According to the Article 3 of the Regulation, a clinical testing is aimed to receive reliable and robust data.

Medical care is provided according to the medical evidence by professionally trained medical workers who are employed by the licensed healthcare institutions and individuals having appropriate license and able to stay in civil and legal relations with health care institutions [11].

Requirements for researchers and places for trials are different from the mentioned above. For example, it is obligatory to have the Ethics Committee that operates in the medical-preventive institution, to have the base for providing emergency medical care to patients at such institution, conditions for storage of medicinal products and documentation of clinical research, medical documentation in the archives for at least 15 years upon the testing completion, the ability to involve the required number of the research subjects according to the clinical trial minutes [10].

Despite the indicated differences in the scientific literature, the right to participate in a medical experiment refers to the rights of the patient [18, p. 93; 19], and legal relationship concerning the carrying out of medical experiments are considered as a component of legal relations in the field of providing medical care [6, p. 44].

Besides already made comments about the incorrectness of this approach, it should be noted that the patient is the person who addressed for medical care, whereas clinical testing should be conducted with the participation of a healthy patient.

It is advisably to note that international ethical rules and regulations, as well as the national law require researchers to obtain the informed consent of the subject involved in the clinical testing, or of the person authorized to make the relevant decision instead on behalf of that subject, explaining the research nature of the process, they are involved in (the Art. 7 of the International Covenant on Civil and Political Rights [20], paragraph 1 of the Nuremberg Code of 1947 [21], the Art. 4 of the European Charter of Patients' Rights [22], paragraph 30 of the Preamble and paragraph 21 of the Art. 2, of Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014, paragraph 4.8 of the Integrated Addendum to ICH E6 (R1) "Guideline on Good Clinical Practice E6 (R2)" of 09 November 2016 [23], paragraph 1.28, subparagraph 4.8.1 of the Instruction "Medicinal products. Appropriate clinical practice. ST-NMOZU 42-7.0: 2008" [24]).

The state is obliged to provide access to human beings for information about the risks to life and health connected with his participation in the experiment [19].

In view of the clinical testing and medical care are different activities undertaken by the medical-preventive institutions, then the legal status of the research subject cannot be determined on the basis of the provisions on the rights of the person as a patient in the provision of medical care. The research subject should not be considered as a patient or a quasi-patient.

Unlike the patient, the research subject is not entitled to choose a physician, since the candidate of a researcher is chosen by sponsors and is stated during the examination of the materials of the clinical testing. The researcher can be not only a full-time physician of a medical-preventive institution, but also an employee of the department of a higher medical educational institution, if there is a contract of cooperation between this higher medical educational

institution and the medical-preventive institution, where the trial is planned.

Besides, since clinical trials have predominantly "blind" nature (one or more parties to the trial do not know which medicine are intended for the research subject), some of the research subjects may also take registered medicines for the comparison purposes. The clinical testing itself must be carrying out according to the research protocol, so the research subject, unlike the patient, does not have the right to choose the methods of clinical testing applied to him.

The scientific literature argues that the appointment only of placebo for the patients in the control group within the clinical trial, may limit their right to receive the best treatment available today, and also contradicts the state guarantees for realizing citizens' rights in the health care sector by providing them guaranteed level of health care [25, p. 17].

At the same time clinical testing has the research nature that the researcher must explain to the subjects involved in such research. Therefore, the use of placebo or another medicine in allowed cases for research purposes according to the clinical testing protocol is not the violation of the individual's right to the best available treatment.

Any scientific study requires accurate data record and definitions of the used concepts. Clinical testing is not the exception, this requirement is crucial. It affects the life and health of not only the subject, but many people who may be offered medical care in the future with the use of medicines that shall undergo the appropriate probation.

Therefore, particular attention during the normative regulation of the clinical testing, as well as its conduction, is primarily paid to the initial documents filled in by the researcher, recording information about the results of the research. Although the clinical trial is not a medical aid, the researcher keeps primary medical records in regard to the subject.

The data provided in the individual registration forms should correspond to the original documents, they were transferred from; the differences should be explained [24].

Primary medical records include original documents, data and records, in particular, medical cards of hospital patients, medical cards of ambulant cases, laboratory records, service notes, diaries of the research subjects or questionnaires, journals of issuing medicinal products, etc. [10].

Normatively defined statutory forms of hospital patients' medical cards and medical cards of ambulant cases, as well as instructions for filling them in [26] do not provide the possibility of keeping relevant primary medical documents within the clinical trial, do not take into account the normatively defined features of storage and archiving of medical records of the research subjects, and therefore need to be modified in accordance with the specific features of clinical testing.

While determining an individual's legal status in the health care sector, we should take into account the diversity of legal options available in this sector.

For example, the European Charter of Patients' Rights provides, among other rights, the right to use modern technology that, in turn, provides the availability of medical care, including diagnostic and treatment procedures and medicinal products that meet international standards.

The realization of this right is ensured, in particular, through the use of Internet technologies, the introduction of innovative methods of treatment and new equipment, electronic histories of diseases, patients' personal cards on data medium, telemedicine [27, p.70-73].

Although the definition of this right does not textually refer to the possibility of participating in clinical testing, however, this right is interpreted more broadly in the scientific literature, and the term "right to innovation" is used to refer to it, which includes such components as: 1) the right to medical and biological experiment; 2) the right to reproductive technology; 3) the right to donate; 4) the right to therapeutic cloning; 5) the right to sex reversal [28, p. 145].

However, such right is not specified in national law [11] among citizens' rights in the health care sector.

The use of biomedical experiments on humans is permitted for public benefit, in terms that they are scientifically substantiated, the potential success benefit over the risk of causing serious health or life consequences, and the preservation of medical secrecy if necessary [11].

At the same time, the possibility of applying new methods of prevention, diagnostics, treatment, rehabilitation and medicines, which are under consideration but still not approved, is regulatory provided in the interests of cure of a person after receiving his/her written consent.

The right of the patient to access experimental treatment and medicinal products in different countries find their place in different laws.

For example, the European Court of Human Rights (ECHR) considered the case of "Hristozov and others v. Bulgaria" [29], where ten applicants with cancer complained that they were denied access to unauthorized experimental cancer medicines. The Bulgarian legislation provides the granting of an appropriate authorization only if the medicinal products are authorized in another state. Applicants asked to allow the use of medicinal products that were permitted in some states only for "charitable research use" and therefore, they were denied in the authorization. The ECHR in its decision of 13 November 2012 pointed out that there was no violation of the Art. 8 in this case, which provides the right to respect private and family life, the Convention for the Protection of Human Rights and Fundamental Freedoms [30] (hereinafter referred to as the Convention). The ECHR noted that there was a restriction on the right to respect the private life of the applicants, but provided the possibility of using unauthorized medicine under certain conditions. The ECHR stated that it could not be argued that the authorities denying applicants the access to the remedy, if it could potentially save their lives, which effectiveness is still dubious, thus increased the applicants' suffering. The Article 3 of the Convention does not oblige the Member States to eliminate differences in levels of health care in different countries.

In another case of "Durizotto v. Italy" [29], being considered in the ECHR, the Italian national courts refused to grant the

applicant's daughter permission to undergo charitable research for the treatment of her disease through the medicine treatment, which was under clinical trial, and had limited access to it, which the applicant regarded as discriminatory. The ECHR in its judgment of 6 May 2014 (admissibility decision), noted that the Scientific Committee set up by the Italian Ministry of Health had a negative attitude to the therapeutic method and the scientific value of the therapy. Therefore, the interference into the right to respect the private life of the applicant's daughter, which was to refuse to grant her request for such therapy, was necessary in a democratic society and pursued a legitimate aim of protecting the health and was consistent with that purpose.

Therefore, a person's right to being applied new methods of prevention, diagnosis, treatment, rehabilitation and medicines that have not been approved for use, is not absolute in the interests of the person's care.

The issues of the application of medical secrecy norms to clinical trial's subjects are of particular interest. The content of medical secrecy indicates that physicians both during medical care and clinical testing must respect it.

The right to secrecy about the state of health, the fact of seeking medical assistance, the diagnosis, as well as the information obtained during the medical examination is guaranteed in Ukraine [9]. During clinical testing, the information about the research subject is kept confidential and processed within the clinical trial in an impersonal form. Ensuring the confidentiality of documents that can identify the research subject is the necessary condition for protecting his or her rights [10].

These prescriptions of national law are important because, in case of the absence of such norms, the research subject may have been denied the confidentiality of the information about the trial, in particular on grounds of public interest in accessing the data on the safety and efficiency of medicines that were examined.

For example, the ECHR judgment in the case of Gillberg v. Sweden of 22 November 2010 and the Grand Chamber of 3 April 2012 [31] gave priority to public interests. The lawfulness of criminal prosecution of the researcher by the state for refusing to disclose information about clinical trials was considered in this case. The resolution of this case was primarily based on the inaccuracy of the clinical testing and medical care, which established the essence of confidentiality of clinical trial's information in this case for the ECHR. The applicant in this case, a professor of the University, was responsible for the research project on the syndrome of hyperactivity and attention deficit of children in 1977-1992. The University Ethics Committee determined the confidentiality of participant information as a precondition for this project that could only be accessed to the researcher and his staff, so he gave obligation to patients and their parents to keep this information. In 2002, a scholar from another university and a pediatrician asked for access to research materials, and the university refused them. The Administrative Court of Appeal, examining the complaint for this refusal, concluded that the applicants had demonstrated a legitimate interest and should have access to the material on terms that would include restrictions on its use and the prohibition on the removal of copies from the university premises. The applicant refused to disclose the material and he was sentenced for probation and ordered to pay a fine.

The ECHR noted in this case that, although, at first glance, it had posed serious ethical concerns regarding medical research, public access to information and the interests of children involved into the research, the only question that arises, is whether the applicant's conviction and sentence for failure to perform his duties were compatible with the Convention. Regardless of whether the applicant considered that the disclosure decisions were based on wrong or insufficient grounds, it was important that the applicant intentionally failed to fulfill the obligations imposed by the court decisions during the long period of time.

The Grand Chamber of the ECHR noted that the applicant was an official exercising public authority in a public institution. He was not a pediatrician or psychiatrist and did not represent children or parents. The materials which the applicant refused to provide belonged to the university and contained official documents that were subject to the principle of public access under the Law on Freedom of the Press and the Privacy Act. The legislation did not allow the agreement of a state agency or a third part, which in advance excludes the right of public access to official documents. The applicant, who was not empowered by the research participants with the powers of their physician, had no obligation to keep professional secrecy. The Grand Chamber of the ECHR emphasized that there was no breach of the confidentiality of the provided information, since it was a matter of research rather than treatment.

Having analyzed this judgement, Professor Erwin Deutsch criticized the ECHR judgement. E. Deutsch pointed out that the promise of keeping information secret is one of the fundamental tenets of European privacy law. If the subjects were aware that the promise could "fall back" under the Swedish Security Act, they would probably never have agreed to participate in the experiment. The right not to undergo the medical experiments without informed consent is one of the general rules of international law. The relation to a promise in such a delicate area was obvious to Gillberg, and he had the right to fulfill it, according to E. Deutsch. The ECHR had to rule in favor of the plaintiff, since the European law has the priority over the Swedish law, and the promise to keep information secret cannot be amended by national law [31].

Paragraph 2 of the Good Clinical Practice of the International Conference on the Harmonization of Technical Requirements for the Registration of Medicinal Products for Human Use (ICH GCP) "Guidelines for Proper Clinical Practice E6(R2)" provides that the rights, safety and prosperity of the research subject is of paramount importance and should prevail over the interests of science and society (subparagraph 2.3), the confidentiality of records allowing to identify the research subjects must be ensured with respect for the right to private life and the protection of privacy in accordance with the applicable regulatory requirements (subparagraph 2. 11).

The case covered above involved the criminal prosecution of the researcher for non-disclosure of information, including failure to provide access to clinical testing documents, which was qualified by national court as abuse of official position.

Criminal liability for the violation of the procedure for conducting clinical trials is established in Ukraine, which is defined in the Criminal Code separately from criminal liability for improper performance of professional duties by a medical or pharmaceutical employee. Besides, the criminal offense of the rights and legitimate interests of persons participating in a clinical testing (rather than patients receiving medical care) was called "Patient's Rights Violation". There is also a criminal liability for illegal conduction of medical, biological, psychological or other experiments on a person, if it poses a danger to the life or health of the last. Criminal offenses of failure to perform or improper performance of professional duties by a medical or pharmaceutical employee as a result of negligent or dishonest attitude, if it has caused grave consequences for the patient, as well as for conducting clinical testing of medicines without the written consent of the patient or his legal representative, or concerning a minor or incapable person, if these actions resulted in the death of the patient or other serious consequences, are related to criminal offenses against person's life and health [32].

Deliberate violation of the established procedure of pre-clinical study, clinical testing of medicinal products, falsification of their results, as well as violation of the established procedure of state registration of medicines belong to criminal offenses in the sphere of narcotic drugs circulation, psychotropic substances, their analogues or precursors and other criminal offenses against the health of the population of Ukraine. Sanction for such actions that did not cause the death of the victim or other grave consequences, is imprisonment for a term from three to five years with deprivation of the right to occupy certain positions or to be involved in certain activities for a term from one to three years. In case of these measures, imprisonment is for a term from eight to ten years with deprivation of the right to occupy certain positions or to be involved in certain activities for a term from two to three years [32]. The legislation of other European countries does not contain analogues of criminal liability for such actions. At the same time, the legislative definition of the mentioned criminal offense does not fully comply with the principle of legal security, which is an element of the rule of law and guarantees the subjects of legal relations the opportunity to predict the legal consequences of their behavior. Criminal liability for any deliberate violation of the clinical trial procedure (for example, breach of reporting deadlines for at least one day or reporting about certain circumstances), even if there are no grave consequences, does not coincide with the provided punishment.

As stated in the decision No. 15-rp / 2004 of November 2, 2004 of the Constitutional Court of Ukraine [33], the issue of fairness is conformity of punishment to the committed crime; the category of justice implies that the punishment for a crime must be reasonable to the crime arising from the rule of law principle, from the essence of the constitutional rights and freedoms of individuals and citizens, in particular the right to liberty.

The ECHR stated in its judgment in the case of "Soldatenko v. Ukraine" of 23 October 2008 [34] that, when it comes to deprivation of liberty, it is extremely important to ensure a general principle of legal security. In case if national law provides the possibility to deprive liberty, such law must be sufficiently accessible, clearly formulated and foreseeable in application to eliminate any risk of arbitrariness (paragraph 111).

Observance of the requirement of clarity and ambiguity of the norms establishing criminal liability, as stated by the Constitutional Court of Ukraine in its judgment of February 1, 2019 No. 1-r / 2019 [35], is especially important in regard to the specifics of the criminal law and the consequences of criminal prosecution related to possible significant restrictions on human rights and freedoms.

For example, clinical trials in Ukraine highlight the following: 1) violations that adversely affect the rights, safety or health of the subjects and (or) affect the quality and integrity of clinical testing data (inconsistency, falsification of data, lack of primary medical records, and numerous significant observations) that may be used to suspend or suspend a clinical testing; 2) defects that may adversely affect the rights, safety and health of the subjects and (or) the quality and integrity of the clinical trial data (deviations from the clinical trial protocol and / or numerical insignificant comments) and are subject to timely correction by providing written notification of their removal to the state enterprise "State Expert Center of the Ministry of Health of Ukraine"; 3) disadvantages that do not affect the rights, safety and health of the subjects and (or) cannot affect the quality and integrity of the clinical trial data and must be corrected [10].

For example, we would like to distinguish the following in accordance to clinical testing in Ukraine: 1) violations that adversely affect the rights, safety or health of the research subjects and (or) affect the quality and integrity of clinical trial data (inconsistency, falsification of data, lack of primary medical records, and numerous significant observations) that may be the reason for partial or complete stop of a clinical trial; 2) shortcomings that may adversely affect the rights, safety and health of the research subjects and (or) the quality and integrity of the clinical trial data (deviations from the clinical trial minutes and / or numerical insignificant comments) and are subject to timely correction by providing written notification of their removal to the state enterprise "State Expert Center of the Ministry of Health of Ukraine"; 3) disadvantages that do not affect the rights, safety and health of the research subjects and (or) can not affect the quality and integrity of the clinical trial data and must be corrected [10].

Therefore, it is inconsistent to provide criminal liability for the violation of the procedure for conducting clinical testing without determining the content of such violation in the definition of a criminal offense, whereas a special regulatory act distinguishes between violations and shortcomings [10]. The latter are also violations, misconduct, but by their nature and consequences they are not critical and should be corrected and taken into account in future medical and professional work.

The results of the research have proven that national

legislation and scientific doctrine are mistaken for treating clinical testing as medical care and defining the rights of the research subject as a kind of patient's rights. It has been substantiated that the legal status of the research subject should be determined separately from the legal status of the individual as a patient, by using special measures of legal protection of a human being as researched experimental medicinal product during the trial. Compulsory ground of the research of subject's rights is the state control over such activities and solution of safety issues of the research subject according to the principle of advantage of the potential success over the risk of serious harm to health or life, as well as in terms of maintaining the necessary privacy. The findings of the study can be used in further research on human rights in the health care sector, enforcement practice and while improving the current legislation.

CONCLUSIONS

Understanding the essence of clinical testing is the key to the proper legal protection and security of human rights and legitimate interests, as well as to the balance between public and private interests in the field of clinical testing of medicines, which directly affect the development of this vital area.

Human rights of the research subject differ from the human rights of the patient while providing medical care. Both groups of the rights belong to human rights in the health care sector.

The research subject shall have the right: 1) to participate voluntarily in the clinical testing, including to refuse to participate in the trial at any time, without explanation, without any sanctions or restrictions; 2) to obtain information on the nature and possible consequences of the trial, the properties of the medicinal product, its expected efficacy, the degree of risk, and other information to be provided for him under the legislation and agreed by the draft informed consent; 3) to privacy of the documents that can identify the person being examined; 4) to suspend the clinical testing or its separate stages in case of the threat to the health or life of such subject in relation to its conduction; 5) to the early termination of the clinical trial or its separate stages in case of the threat to the health or life of such subject in regard to its conduction, as well as in case of the absence or insufficient effectiveness of its action, violation of ethical standards; 6) to insure his life and health; 7) to address the sponsor, the state enterprise "State Expert Center of the Ministry of Health of Ukraine", the Commission on Ethics at the medical and preventive institution, the Ministry of Health and to court in case of the violation of the rights.

The forms of the medical card of the hospital patient and the medical card of the ambulant case and the instructions for filling them in need to be modified in order to determine the peculiarities of keeping the forms of primary medical documents during clinical testing.

While determining the objective aspect of the violation of the procedure of pre-clinical study, clinical testing and state registration of medicinal products in the criminal law, we must clearly state the action which implies criminal liability. Criminal liability should be provided for such violations that negatively affect the rights, safety or health of the subjects, the quality and integrity of the clinical trial data.

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Authors' contributions:
According to the order of the Authorship.

ORCID numbers:
Viacheslav I. Borysov: 0000-0001-5807-2849
Olena I. Antoniuk: 0000-0003-1825-3981
Ivan I. Vyshnyvetskyy: 0000-0001-7228-3052

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CORRESPONDING AUTHOR
Vyacheslav I. Borisov,
Academician Stashis Scientific Research Institute
for the Study of Crime Problems
National Academy of Law Sciences of Ukraine,
Kharkiv, Ukraine
tel. +380689886921
e-mail: borisov_v.i@ukr.net

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