INFORMED CONSENT: THE COMPLIANCE OF THE ARMENIAN LEGISLATION TO THE OVIEDO CONVENTION

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Introduction. The patient's consent is an important ethical and legal principle and presumption for any intervention on his body as a whole. For a person to decide on medical intervention, he must be informed about the problem and its possible solutions, risks, and conditions.

Informed consent is a fundamental ethical principle in the field of biomedicine which implies the prior consent of the patient for any permissible medical or other intervention on the patient's body. It is based on the constitutional value, the principle of respect for human dignity. No purpose, especially scientific research, can justify medical intervenetion on a person without his consent. In biomedical activity, it is a general rule, from which deviation should be applied only in exceptional cases, and then only for the benefit of the patient. Informed consent is not a burden for the doctor, but a way to make the patient responsible for his health, insuring the doctor from further risks. It pursues three main goals. The requirement to obtain the patient's consent before medical intervention, in addition to respecting the patient's dignity, physical integrity, and autonomy, aims to create a relationship of trust between the doctor and the patient with the prospect of increasing the effectiveness of the medical intervention, as well as to avoid causing consequences for the patient that he is not ready to accept and bear. That is why the doctor can deviate from the performance of these duties towards the patient only in exceptional cases, acting in the best interest of the patient. In addition, the autonomy of the patient's will and self-determination in a certain matter prevails over the medical intervention by the doctor for any purpose, including saving the patient's life. Medical intervention without patient intervention, among others, violates the right to the physical integrity of a person. The person giving the consent, that is, the holder of the right, is the patient. In all other cases, when the patient does not express his consent, or rather, third parties make that decision instead of him, is an exception to the general rule. These are the cases when the patient's rights are exercised by third parties, for example, representatives based on the law, civil law transaction, or court act, or the cases where the medical worker acts based on the need to provide emergency care. In all mentioned cases, the universal condition "best interest of the patient" is an important guarantee for ensuring the patient's rights. For example, in the case of a child or incapacitated persons, the rights of representatives are exercised on behalf of the right holder and for the benefit of the right holder. That is why it is important to ensure that there is no conflict between the interests

of the patient and his representative. Expressing the simple word "yes" is not enough for consent. For the patient's consent to be valid, the following elements must be present at the same time: A necessary condition for expressing consent is the patient's ability to give consent. To decide for medical intervention, the patient must be informed about the problem and its possible solutions, risks, and conditions. When making that decision, one should not be under the influence of deception, violence, or threats. The European Charter of Patient Rights, defining the right to information, took into account not only the patient's information about his health, the necessary medical care, and methods but also the medical care and service providers, and the available medical services.

Methodology. The title of the study expresses the preference for method selection. The literature was studied from a comparative perspective, to highlight the current state of informed consent from the perspective of the legal and health systems. However, other methods of study, which are familiar in social science, have been used. It is important to use the comparative method, the main purpose of which is to understand the patterns and features of informed consent in the given legal system. The systemic method allows us to understand, interpret, and describe the system in which a certain level of development of informed consent was possible and due to which informed consent took a certain form. In addition to the ones listed, abstraction, generalization, induction deduction, and other scientific methods were also used.

Literature review. For the work, a study of theoretical and practical literature, materials, and publications available in Armenian, Russian, and English was carried out. Considerable monographs, articles, empirical studies, judicial precedents (case law), and publications were referenced. To increase the research value, it was also important to study the existing positions, views, and opinions in related sciences and their comparison.

Scientific novelty. Informed consent is the minimum ethical and legal standard to ensure respect for human dignity, autonomy, and integrity in the field of biomedicine. The rule provides legal framework securing both patients and doctors. Namely, it stipulates the duty of health and medical professionals. The article is the first in it kind analyzing the legislation of the Republic of Armenia from the point of view of its compliance with European human rights standards. The main sources of such standards are the European Convention on Human Rights, the case law of the European Court of Human Rights, the Oviedo Convention, etc. Based on the conclusions made as a result of the research, concrete recommendations are made to improve the national legislation to approximate it with the European standards.

Analysis. An overview of the legislative framework allows to considering the following. The Armenian Constitution amended in 2015 guarantees the fundamental right of every individual to personal (physical and mental) integrity (Art. 25). Yet, the content of this article has not found any interpretation in the case law of the national judiciary it

shall be interpreted according to the practice of bodies operating based on ratified international treaties on human rights, as required by the Constitution [Article 81, Constitution, 2015]. The Constitution specifies the rule of integrity about informed consent only in the case of scientific, medical, or other experimentation, highlighting the requirement that the subject understands the consequences of such experiments. Accordingly, explicit voluntary consent must be obtained before any such experiments. The Law on Medical Aid and Services to the Population serves as a framework law (*lex generalis*) in healthcare intended to regulate the organization of medical care and services and to safeguard the exercise of constitutional rights to the protection of human health. The last considerable amendments to the Law were made in May 2020.

Rigth to information

Content of the information

The Armenian Law on Medical Care and Services to the Population (hereinafter Law on Medical Care) enumerates and provides a list of patient rights, including the right to information. The patient's right to information is ensured by Articles 14, 15, and 16 of the Armenian Law on Medical Care. Those articles stipulate the scope and the content of information related to health status and contend with the management of health-related information by the patient. Article 15(1) of the Law envisages that every person (patient) shall have the right to receive (…) information on his/her health condition, disease diagnosis, medical care and services provided (in the past or currently), including the choice of treatment methods, the implementation progress and outcomes, and the related risks.

Several parts of Article 14 and Article 15 entirely are dedicated to information rights including the right to information about diagnosis, health status, treatment recommendations and alternatives, and details about medical care and services provided currently or in the past. Other details that are covered include provisions addressing information rights regarding the progress of a treatment plan, outcomes, related risks, and payment amounts and details. According to the European standard, the scope of information covered by "informed consent" is extended to the information related to the concrete medical intervention, its purpose, nature, consequences, risks, and other information necessary to freely decide on the intervention [R. Andorno, 2005; V.L. Raposo, E. Osuna, 2013].

Except in emergencies, impossibility, or refusal of the patient to be informed, a doctor is required to give the patient fair information, clear and appropriate on the serious risks associated with the proposed investigations and care. Moreover, this obligation is not waived by the mere fact that these risks occur only exceptionally. The French courts, for example, pay increasing attention to the duty of informing the patient of exceptional risks [Garay Al. 2002]. The decision for intervention largely depends on the gravity of the risks and consequently therapeutic alternatives to the proposed treatment. The Law serves as a guideline for its general stakeholders and in that sense, there is, arguably, an impor-

tant omission regarding the importance of providing patients with appropriate information on the gravity of risks and alternatives to proposed treatments. Informed consent is the process of allowing to a person receiving health services to make a choice more suitable for him. In this regard, the appropriateness of information possesses both material and formal aspects. Consent is not valid without prior information. However, there is no provision envisaging negative consequences or sanctions for the failure to provide appropriate information and obtain consent for treatment.

Limitations. The will of the patient to disclose relevant information. In local legal traditions coming from the Continental legal system, the right of an individual to exercise his or her rights includes the possibility that the right-holder might willingly refuse to exercise the right in question. In line with this concept, Article 14 of the Law on Medical Care sets out that every patient has the right "to refuse information related to his health conditions, including on medical care and services" (Art. 14, para 1, part 11). Comparative legal research of European countries reveals that the legitimate aim of the forgoing right is to ensure the interest of the patient by omitting from harming the patient by information on a serious diagnosis or prognosis (except for cases of risks of contamination for third parties. Accordingly, only the patient, but not the proxy or representative, is entitled to this right. The Armenian Law is not clear in this sense and this right as a general matter could be entrusted to the patient's proxy or representatives [CoE report, 2022, 13-18].

Impossibility and emergency. The Armenian health-related legislation does not envisage any grounds allowing doctors to make an exception for providing information directly to the patient or delaying the provision of such information. This raises several ethical issues because, practically speaking, many doctors have been accustomed to sharing information first with relatives and family - especially in the case of serious diseases such as cancer. Legislative standards do not prohibit or sanction placebo information. In the Armenian health-related legislation there is no mention of exceptions to the doctors' duty to provide information. Such exceptions are set out only for the doctor's duty to obtain patient consent before any medical intervention, but there is no clarity concerning prior or subsequent information. No exception is set out from the doctor's duty to inform the patient of prior consent which is in line with European jurisprudence [ECtHR case, Mayboroda v, Ukraine]. However, this is not appropriate when it comes to the exercise of the same duty towards representatives or proxies. For example, in the case of a serious genetic disorder, the information should be disclosed to the patient and their family member. The absence of the provision reflects the ethical perspective that the conventional patient waiver could jeopardize the essence of that right especially when the doctor-patient relationship is influenced by traditions and an orientation based on human rights.

Modalities. The Armenian health legislation remains silent concerning the details around the modalities of informing the patient. Only Article 15 of the Law requires that

information be provided in an accessible manner, but does not clarify criteria for accessibility. Information within the "informed consent" concept means information not only dully provided but adequately perceived. For giving consent to an intervention, the patient must receive clear information adapted to the patient's degree of understanding. The practitioner should provide the information in respect of the patient intellectual abilities and the socio-cultural level. Those abilities vary with age, mental situation (for stress, choc, etc.), nature of the situation (cancer, stroke, heart attack), and other situations. This requirement derives from the general principles of the law of equality and non-discrimination and the idea of ensuring equal access to healthcare.

Right to consent. Characteristics of consent. Armenian health-related legislation does not specify characteristics that must be fulfilled for consent to be valid. Those guarantees are established in the Civil Code because patient-doctor relationships are qualified as private-law relationships. Indeed, it is worth noting explicitly that important aspects of doctor-patient relationships are considered to be subsidized by the civil-law regulations because they are classified as private-law relations, similar to capacity, competencies, transactions (contracts, agreements), and forms of transactions. In the condition of weak case law on the matter, the forgoing relations never receive an appropriate judicial description and hence qualifications. Besides, Article 1 of the Civil Code provides that relations pertaining to the exercise and protection of inalienable human rights and freedoms and other intangible assets shall be regulated by civil legislation and other legal acts unless otherwise derived from the essence of these relations [Civil Code of Armenia, 1999].

The relationship between medical care and service is based on the patient's trust in the doctor and full disclosure. In the context of Continental (Civil law) traditions, it means that any agreement between parties could be abrogated if one party loses trust in the other parties. In the case of an entity delivering healthcare services, this prerogative is strictly limited to the patient and is subject to legal regulation. The same is related to the form of consent as a unilateral transaction in the sense of civil law [Graziadei, M., 2014].

Prior consent: general rule. The Armenian Law does not however provide any other requirement to the consent such as free of coercion, or prior information to the consent as the Oviedo Convention does. According to European standards, the information should be prior to consent and hence to an intervention in the health field. The prior element requires that the information for medical decision-making should be provided sufficiently in advance by providing the person concerned with adequate time for accepting or rejecting the medical intervention or other activity.

Free and informed consent. Article 16(1) of the Armenian Law on Medical Care defines that a person's written consent to a medical intervention is a necessary condition. Article 14 of the Law provides that the patient has the right to refuse to receive medical care and services. Exceptions to the mentioned rules serve the cases prescribed by Article

24 of this Law (a threat to the person's life and diseases posing a danger to the surrounddings). The consent is free, given voluntarily, and without coercion, intimidation, or manipulation. Hence, the consent should be free from coercion or undue influence. It aims to respect individual autonomy and to ensure that people have freely chosen a course of action. The practitioner should respect the patient's will and autonomy after having been informed about the consequences of his/her choice.

The Armenian constitution requires informed consent only when a person is to be subjected to scientific, medical, or other experiments without his or her freely and clearly expressed consent (Article 25(4)). Health-related legislation does not elaborate on the elements of the freely expressed consent which means civil-law regulations are applicable by analogy. The Armenian civil law would consider the consent to medical intervention as a transaction whereas consent in health law is more than a civil-law transacttion aimed at the "establishment, amendment or termination of civil rights and obligetions" (Article 289 of the Civil code). Besides, the requirements extended to the transacttions are usually not applicable to the consent and the Civil code does not provide special rules adapted to the bioethical requirements and principles of the consent. For example, civil law provisions on types of transactions (bilateral, multilateral, or unilateral), forms of transactions, invalidity of transactions, etc. Namely, if the consent is a unilateral transaction that means it creates obligations only for the person who has entered into the transaction – for the patient. If the consent is a bilateral transaction that means creating obligations for both sides, neither case is applicable here as free, informed, and prior consent of the patient serves as a pre-condition for any medical intervention. However, it is important to notice that in the existing regulation, the Civil Code reserves the right to regulate the protection of subjective rights exercised in healthcare and biomedicine, including issues related to legal capacity.

In sense of the Article 5 of the Oviedo Convention, informed consent is the duty of the medical service provider to collect the given patient's agreement before any intervention to body integrity. It creates no obligation for the patient who is free to withdraw their consent at any time unless the doctor believes that at the time of withdrawal, the patient lacked capacity.

The interference with the patient's physical integrity could be justified by the consideration laid down in Article 25(2) of the Constitution such as state security, preventing or disclosing crimes, protecting public order, health and morals, or the basic rights and freedoms of others. For example, in the case of the COVID-19 virus, the interference could be justified by public health considerations and the necessity to control the spreading of infectious diseases.

The Armenian legislation imposes limited grounds for the intervention without respecting the informed consent rule. Moreover, this provision prescribes only the reasons

for intervention but does not provide additional conditions for making exceptions such as intervention should be proportionate to his situation.

The general purpose of the international standards pertaining to rights to information is to provide the patient with the information necessary and appropriate for medical decision-making [Sox, et al., 2024]. Contrary, in the Armenian legal system no clear link exists between the general right to medical information, the right to consent prior to any medical intervention, and the provision of full information as a necessary precondition to obtaining consent. Hence, the articles of the Armenian legislation cover the information that is protected by Article 5 and Article 10 of the Oviedo Convention without making a clear distinction between them.

Forms of consent. Article 16() of the Law states "A person's written consent to a medical intervention shall be a necessary condition, except for cases stipulated by Article 24 of this Law". The Armenian law (Article 16) envisages that the consent is of written form without making any exceptions from the rule as the exceptions stipulated in Article 16 concern intervention without consent.

Consent could be express or implied. The Armenian Law does not differ amongst varieties and types of explicit and implicit consent. Express written consent is normally considered the most undisputable form of consent and so the safest course of action is to ask the applicant to sign a consent. Taking into account the invasive and irreversible character of the expected intervention and the substantive consequences of it, the implied consent legally could not be sufficient in the particular case (for example, in the case of heart surgery or organ transplantation).

The written form requirement for all types of medical investigation is not itself in contradiction with the Oviedo convention. Nevertheless, limitation to only a written form of consent could cause several problems and lead to violations of patient rights. It does not provide responsiveness to all existing cases when the nature of the intervention does not require major formalities. This requirement can cause problems when it does not take into consideration the nature of the intervention. The form of informed consent should be proportionate to the nature of the intervention.

This might also create risks in the case when the practitioner would avoids anytime the informed consent rules when he does not have sufficient time and means to collect it in writing. Hence, the patient will be deprived of the right to physical integrity at any time when there would be a possibility to consent but not enough time for forming it in writing. Besides, while evaluating consent, the judge cannot limit himself only to the formal aspect of express consent but also can assess the totality of the facts on the records. The written form of the consent is supplementary to what is agreed between the doctor and patient for disclosing the expressed will based on the provided information.

The principle of medical intervention either with written consent or without consent set out in the Armenian health legislation is not adaptable for a variety of cases faced by the doctors in practice. It does not also envisage the possibility of taking into account the patient's previously expressed wishes, which is one of the novelties of the Oviedo Convention [Koch, et al., 2016, 79-81]. It is in the patient's best interests that the decision-maker must determine and consider there the patient's past and present wishes and feelings. However, no answer is provided when previously expressed wishes conflict with best interests [Smith, et al., 2013].

Limits to the rule. Armenian Law on Medical Care set out the principle of informed consent as a general rule (Article 16) except for the cases when consent for medical intervenetion is not required by Article 24, such as a threat to the person's life (1), and conditions posing a danger to the surroundings (2).

In emergencies, when a decision must be made urgently for the sake of the patient's health or life, or in case of impossibility, when the patient is not able to participate in decision-making, and the patient's representative is not available, physicians may initiate treatment without prior informed consent. In such situations, the physician should inform the patient or the representative at the earliest opportunity and obtain consent for ongoing treatment in keeping with these guidelines.

Protection of persons not able to consent. Article 15(2) of the Law on Medical Care provides a general rule for providing information in case of children and incapacitated persons. According to the Law, as a rule, the right to information should be provided to the lawful representative of these individuals, rather than to a child regardless of age. The same holds for persons legally declared as incapable.

On an exceptional basis, the information could be provided to the child holding the underlying information rights if the following circumstances are met simultaneously: the child, in the doctor's opinion, is capable of evaluating his or her health condition; such information will not harm the child; such information will facilitate the provision of medical care and services; and the lawful representatives do not object to the provision of information (except for a person declared as incapable under the procedure defined by law or a child who has reached the age of 16).

Article 16 of the Law provides that the opinion of a person who has not reached the age of 16 or has been declared incapable according to procedures defined by law shall be taken into consideration nevertheless.

The wording of the current regulations presupposes that even in the cases when the child's consent could be collected, it is subject to the will of the lawful representative. That simply means the lawful representative can oppose without any justification the provision of information to the child notwithstanding grounds that recognized by law to do

so. Here, it is worth noting that the Armenian health-related legislation does not provide a mechanism for balancing the conflict of interest between the right-holder and the lawful representative. This concern is equally relevant in the case of a person deemed to be incapable: persons with mental health issues receiving treatment and care in psychiatric and social care institutions are usually neglected by their guardians. Moreover, the guardians are granted the prerogative of managing the property and the income of the incapable persons, including their pension, and in general to manage them in contrary or not in the interest of the ward.

The wording of Article 14 (3) of the Law on Medical Care supports the general rule that the provision of information on health status should be provided not to the child but rather to its lawful representative or, in the absence thereof, a contact person authorized by the lawful representative. In the exceptional case, in particular, when the conditions stipulated by Paragraph 2 of Article 14 have been met, information could be provided to both the children and the lawful representatives. Meanwhile, it should be noted that the wording of Article 14, especially its third paragraph lacks clarity.

In this regard, certain regulations related to the issue have been fixed in the Law on Psychiatric Care and Service of Armenia. Specifically, according to Article 17(1), psychiatric care and service are provided when a person with mental health issues or that person's legal representative provides written informed consent except for the cases provided for by this Law.

According to the second part of the same Article, a child who has reached the age of 16 or a person declared incapable under the law can give his/her written informed consent to receive or reject psychiatric intervention, except in cases provided for by law, if:

(i) In the opinion of the doctor or psychiatrist, the child who has reached the age of 16, or the person declared incapable by the law can understand the consequences of the psychiatric intervention or its lack thereof;

(ii) that information will not cause harm to the child who has reached the age of 16, or the person declared incapable under the law;

(iii) will facilitate the provision of psychiatric care and service.

Regarding the legislative provision, it should be noted that it does not support the requirement to obtain the informed consent of the incapable person and the minor as patients. According to the assessment of the Constitutional Court, based on the application of the Human Rights Defender, the involvement of the legal representative is justified only based on subsidiarity that is if the bearer of the mental health right does not have the legal capacity to execute his fundamental right to mental integrity. This also applies to cases when it appears that the person can execute this right, but by doing so, may cause harm to his mental health. The Constitutional Court stressed that it is necessary to conduct a professional assessment of a person's ability to independently exercise his/her

mental health and fundamental rights. The Constitutional Court also stressed that the principle of subsidiarity should also apply in the case of minors.

It is important to take into account the principle that is provided for by international treaties, which state that the ability of any patient - not only those with mental health issues - to give informed consent for medical intervention should be assessed by the healthcare provider on a case-by-case basis. The necessary precondition of such consent is the appropriate fulfillment by the healthcare provider of his duty to inform, taking into account the abilities of the patient, and the specifics of the given case. Therefore, from the point of view of the assessment of the legal capacity to of patients to express their will, its proper implementation is extremely important from both a medical and a legal context. This proves once again that such legislative solutions should not be raised only as formalities, but also in terms of ensuring their effective application. This is especially important in as much as, in considering the vulnerability of persons recognized to be incapable, in certain cases, in the event, the guardians do not pursue the best interests of their wards, conflicts of interests may develop between the persons recognized as incapable and their guardians.

Studies and the recorded systemic and continuous problems prove that the institution of guardianship does not always reliably serve its purpose. Thus, there is a need for new institutions and new mechanisms to assist persons with mental health issues in their decision-making process.

Limitations to consent: Article 16(5) Law on Medical Aid provides that the doctor can act without patient consent, relying on medical experts or even on his medical opinion alone, based on best interests of the patient, so long as the following conditions are met:

- the doctor believes that the medical intervention cannot be delayed (thereby establishing the basis for declaring an "emergency" situation;
- the patient's condition does not enable the patient to express his/her will;
- no lawful representative or contact person can be found.

According to European standards, the doctor can act without prior patient consent in cases when the circumstances require prompt medical intervention to serve the benefit of the health of the patient regardless of the fact whether or not the patient can express his/her will [Derse, 1999, 307-325]. The Armenian Law combines impossibility and emergency as grounds for providing medical care and services without prior consent.

In the case of Article 8 of the Oviedo Convention, the impossibility of receiving the patient's consent concerns the timeframe for obtaining consent rather than the capacity of the patient to express his will. Hence, the current regulation existing in Armenian law does not provide for a possibility for medical intervention without the patient's consent in case of a grave situation that requires prompt reaction.

The foregoing conditions do not concern the cases set out in Article 24, in particular, in case of a threat to the person's life, by the procedure defined by the Government (1); and in case of diseases posing a danger to the surroundings, in the procedure defined by law (2). It might be that in the absence of ethics-based medical practice of informed consent, this exception to the rule on consent, even in cases when it is possible to obtain consent in a timely matter, represents a regulation that reflects the direct interest of the patient to remain alive, even though it also represents a violation of the right to personal integrity from the European standards perspective.

Free, informed consent is one of the fundamental and key principles of bioethics, medical ethics, and medical law alongside patient autonomy, which is defined as respect for the right of patients to determine, among other things, what is to be done to them, including which treatments will or will not be accepted. The principle requiring free, informed consent is based on the constitutional value of the principle of respect for human dignity. Thus, prior, informed consent of the patient is necessary for any medical intervention on the patient's body except under emergency circumstances that require prompt intervention for the sake of the patient.

As a general rule, informed consent before any intervention is required whenever it is possible. Hence the mere intent to save the life of the patient does not serve as sufficient grounds to create an exception to the general rule.

Protection of public health: Restriction of human rights is permitted within individual cases and for reasons reflecting public interests. Human Rights limitation clauses might similarly serve as grounds for restricting human rights both in regular times and during emergencies. The Oviedo convention allows restriction of informed consent (Articles 5 and 6) in case of interest of public safety, for the prevention of crime, for the protection of public health, or the protection of the rights and freedoms of others (Article 26 of the Oviedo Convention). Article 25(2) of the Armenian Constitution provides more extensive grounds for restricting the right to physical and mental integrity, and hence to the right to informed consent. The reasons reflecting public interests are state security, preventing or disclosing crimes, protecting public order, health and morals, or the basic rights and freedoms of others. At the level of legislative acts, the Law on Medical Care provides exceptions from the general rule of informed consent but no indication is made about the grounds and conditions of their restrictions.

The Armenian health legislation does not provide any regulations allowing the appliers of the law to implement necessary measures for ensuring human rights in medical practice. For restriction of human rights in line with European standards, a state should respect several requirements, namely, to implement the restrictive measure: by the law; in the interest of a legitimate objective of general interest; necessary in a democratic socie-

ty; in the absence of less intrusive and restrictive measures available to reach the same objective; based on evidence and rather than arbitrary or discriminatory.

Conclusion. To conclude, it should be noted that there are various contradictions between national law and European standards in the field of biomedicine. Those contradictions are not in compliance with the human rights requirement as they do not secure the granting of an effective remedy before a national authority. Despite in case of conflict between the norms of international treaties ratified by the Republic of Armenia and those of laws, the norms of international treaties shall apply, the Armenian legislation does not provide an institutional and pecuniary remedy for violations. When the Oviedo Convention is adopted, the legislature should bring national laws and bylaws in compliance with standards enshrined in the Convention, and medical, healthcare professionals should apply them into their practice as legal and ethical rules.

***References*:**

1. The Constitution of Armenia, 2015; available at www.president.am/en/constitution-2015.
2. The Armenian Law on Medical Care and Services to the Population, 1996, updated in 2020; available at https://cis-legislation.com/document.fwx?rgn=3059, March 24, 2024.
3. Andorno, Roberto. "The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law " 2, no. 4 (2005): 133-143. doi.org/10.1515/jibl.2005.2.4.133;
4. Raposo, V., Osuna, E. (2013). European Convention of Human Rights and Biomedicine. Beran, R. Legal and Forensic Medicine. Springer, Berlin, doi.org/10.1007/978-3-642-32338-6_98:
5. Garay Alain. "The New French Legislation Relating to Patients' Rights and the Quality of the Health Care System." European Journal of Health Law 9, no. 4 (2002): 361–79. http://www.jstor.org/stable/45442571.
6. Compliance of the RA law on informed consent with the general human rights principles enshrined in the Oviedo Convention and its Additional Protocols, in Protection of Human Rights in Biomedicine: Concept Report, 2022, available at https://rm.coe.int/concept-report-eng-final-2787-5493-6582-1/1680aa2d74.
7. Judgment of the European Court of Human Rights within the case of Mayboroda v. Ukraine (application no. 14709/07), 2023.
8. The Civil Code of Armenia, The English version is available at https://www.translation-centre.am/pdf/Translat/HH_Codes/CIVIL_CODE_en.pdf, March 23, 2024.
9. Graziadei, Michele, 'Virtue and Utility: Fiduciary Law in Civil Law and Common Law Jurisdictions', in Andrew S. Gold, and Paul B. Miller (eds), Philosophical Foundations of Fiduciary Law (Oxford, 2014; online ed., Oxford Academic, 23 Oct. 2014),
10. Sox, Harold C., Michael C. Higgins, Douglas K. Owens, and Gillian Sanders Schmidler. Medical decision making. John Wiley & Sons, 2024.
11. Koch, Peter M., and Harvey Berman. "The Failure of an Ideal: Autonomy and Previously Expressed Wishes." AJOB Neuroscience 7, no. 1 (2016): 79-81.
12. Smith, Alexander K., Bernard Lo, and Rebecca Sudore. "When previously expressed wishes conflict with best interests." JAMA internal medicine 173, no. 13 (2013): 1241-1245.
Derse, Arthur R. "Law and ethics in emergency medicine." Emergency Medicine Clinics of North America 17, no. 2 (1999): 307-325.

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Informed consent: the compliance of the Armenian legislation to the Oviedo convention

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The article is dedicated to the issues of informed consent, the provisions of regulation by legislation, their specificities related to children, and persons with disabilities, in times of emergencies, and cases when consent cannot be obtained due to the inability of the patient, the impossibility of the circumstances and the urgency of the situation.

The informed consent rule invokes the duty of health and medical professionals, especially of professionals responsible for healthcare management and governance.

The purpose of the article is to analyze the legislation of the Republic of Armenia from the point of view of its compliance with European human rights standards. The main sources of such standards are the European Convention on Human Rights, the case law of the European Court of Human Rights, the Oviedo Convention, etc. Based on the conclusions made as a result of the research, concrete recommendations are made to improve the national legislation to approximate it with the European standards.