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# Protection of Human Rights in Biomedicine

## Concept Report

Comparative analysis of the compliance of the national legislation of Armenia in the field of biomedicine with European Human rights and ethical standards enshrined in the Oviedo Convention on Human Rights and Biomedicine

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This Concept Report on Comparative analysis of the compliance of the national legislation of Armenia in the field of biomedicine with European Human rights and ethical standards enshrined in the Convention on Human Rights and Biomedicine (Oviedo Convention) is prepared in the framework of the Council of Europe cooperation Project on "Protection of Human Rights in Biomedicine" by a group of national and international experts with the help and support of the Council of Europe Office in Yerevan and the Secretariat of the Committee on Bioethics (DH-BIO) of the Council of Europe.

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# Contents

# Summary

This report is an expert examination of legislation related to biomedicine of the Republic of Armenia (RA) in relation with the principles enshrined in the Convention on Human Rights and Biomedicine (Oviedo Convention)[1] and its Additional Protocols, concerning informed consent, medical secret and confidentiality, assisted reproduction and embryo protection, genetic testing, biomedical research and transplantation.

The objective of this report and the recommendations it provides are intended to support the national authorities in their effort to bring legal norms and law-enforcement practices in the biomedical field closer to the European human rights and ethical standards preparing the RA for the ratification of Oviedo Convention.

A legal assessment was made of the compliance of the general principles and compatibility of the provisions that govern the RA legislation with those enshrined in the Oviedo Convention and its Additional Protocols. On the basis of this assessment, where necessary, recommendations were formulated to ensure conformity between Armenian legislation and the Oviedo Convention and its Additional Protocol.

It was concluded that, the general principles that govern the Armenian legislation on the above-mentioned topics are mostly in conformity with the Oviedo Convention and its Additional Protocols, but certain potential incompatibilities and legal gaps were identified. Special attention must be devoted on compatibility of the RA legislation on biomedical research with the relevant provisions of the Oviedo Convention and its Additional Protocol.

To ensure compliance with the Oviedo Convention and its Additional Protocols, it is recommended that amendments presented in the Table of Recommendations be considered for the RA legislation, as well as additional measures, procedures and norms laid down in self-regulating mechanisms as standards, guidelines and protocols.

1. Long title "Convention for Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of the Council of Europe (Oviedo Convention)" (ETS no. 164). It was opened for signature on 4 April 1997. https://www.coe.int/en/web/bioethics/oviedo-convention

# Structure of the expert examination

The expert examination was conducted as follows:

**First**, the Council of Europe (CoE) legal requirements concerning the topics to be studied were analyzed. For the purpose of checking the compatibility between Armenian law and CoE standards, we are assuming a comprehensive notion of CoE standards.

The main focus is on the provisions of the Oviedo Convention.

Conformity with the Additional Protocols to the Oviedo Convention were also examined when RA legislation addresses the same topics.

Such analyses also took into account article 8 of the European Convention on Human Rights (ECHR)[2], which works as an umbrella provision, as well as case-law of the European Court of Human Rights (ECHR), when appropriate.

**Second**, a legal assessment was made of the compliance of the **general principles** that govern the RA legislation on informed consent, medical secret and confidentiality, medically assisted procreation, embryo protection, genetic testing, biomedical research and transplantation with the general human rights principles (e.g., primacy of human being, equitable access of appropriate quality; respect for and protection of human dignity, integrity and autonomy; prohibition of financial gain; the misuse of organ and tissue; all forms of discrimination, in particular based on genetic characteristics) enshrined in the Oviedo Convention and its Additional Protocols. In this regard, it should be taken into account that the Additional Protocols are developing the provisions of the Oviedo Convention but are distinct legal instruments. **The ratification of the Convention does not necessarily imply the ratification of the Protocols. By contrast, the ratification of a Protocol requires the previous ratification of the Oviedo Convention.**

Third, a legal assessment was made of the compliance of the provisions of the RA legislation on the above-mentioned topics with the provisions of the Oviedo Convention and its Additional Protocols. This part examined to what extent is the RA legislation compatible with the Oviedo Convention and its Additional Protocols.

Special attention was paid to the provisions of the Oviedo Convention and its Additional Protocols that have not been addressed in the RA legislation revealing the existing legal gaps. Where necessary, recommendations were formulated to ensure compliance with certain provisions, with a view to optimising the protection of the rights and freedoms of the individuals (in particular patients, and when it comes to transplantation donors, potential donors and recipients) in the light of the principles enshrined in the Oviedo Convention and its Additional Protocols. For the sake of convenience all recommendations are also presented in a table appended to this Report.

2. https://www.echr.coe.int/Documents/Convention_ENG.pdf

# 1. Expert examination of the legislation on Informed Consent and the Right to Information of the Republic of Armenia

## ► 1.1. Council of Europe standards

### ► 1.1.1. Introduction

On what concerns the information regarding health, there are two principles in the Oviedo Convention that deserve our special attention:

1) **Informed consent** to an intervention in the health field (as referred in the general rule of Article 5);

2) **Right to information** collected about one's health (as referred in Article 10).

The first case (Consent for an intervention in the health field as referred in the general rule of art. 5 of the Oviedo Convention) it is focused on informed consent to undergo an intervention in healthcare, in accordance with the requirements the CoE standards in this field, taking into account the Oviedo Convention, the European Convention of Human Rights and the case-law of the Strasbourg Court (ECtHR) (when appropriate). Informed consent is a subject pertinent to many different areas in the biomedical arena including healthcare, research, and decision-making at the beginning and end of life. This part is concentrated fundamentally on informed consent for and intervention in the health filed.

As a general rule, Article 5, paragraph 1, of the Oviedo Convention "an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it". On the other hand, it is important to take into consideration that the word "intervention" should be understood in its widest sense, as in Article 4 – that is to say, it covers all medical acts, in particular interventions performed for the purpose of preventive care, diagnosis, treatment, rehabilitation or research.[3]

### ► 1.1.2. Characteristics of consent

Once the patient has been informed, he/she will be able to give his/her consent. This consent must have the following characteristics and features:

*i) Free*: Article 5, paragraph 1, mentions the word "free" that implies that consent shall be given without any pressure, including coercion by the physicians or family members. By implication, conflicts of interest must be disclosed.

*ii) Revocable*: This means that consent may be withdrawn at any time. Nevertheless, this rule does not mean, for example, that the withdrawal of a patient's consent during an operation must always be followed. Professional standards and obligations as well as rules of conduct, which apply in such cases under Article 4, may oblige the doctor to continue with the operation to avoid seriously endangering thehealth of the patient[4].

*iii) Expressed* or implied: The distinction is not regulated in the Oviedo Convention, but the Explanatory Report to the Convention (hereinafter – Explanatory Report) allows for both forms of consent. It explains that express consent may be either verbal or written. Article 5, which lays down the general rule, does not require any particular form.

3. Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine // ETS-No164, paragraph 34 (hereinafter – Explanatory Report).

4.. Explanatory Report, paragraph 38.

The form will largely depend on the nature of the intervention. It is generally accepted that requiring express consent would be inappropriate in many routine situations. The consent is therefore often implicit, as long as the person concerned is appropriately informed. In some cases involving invasive diagnostic acts or treatments, express consent may be required[5].

For this reason, in general, written consent is required in procedures that involve foreseeable risks and potentially negative consequences. It should be borne in mind, however, that in many countries written consent has become standard for all types of procedures and interventions due to a concern about medical liability and malpractice litigation. In these cases, consent may become an instrument of defensive medicine rather than a reflection of patient autonomy and a critical tool to promote it.

## ► Requirements of information prior to consent

The provision of § 2 of Article 5 of the Oviedo Convention demonstrates an important requirement of the information provided: it must be "appropriate". This means the information must be sufficiently clear and suitably worded to be understood by the person who is to undergo the intervention. The patient must be put in a position, through the use of terms he or she can understand, to weigh the indications of the intervention and its purpose against its risks and the burdens that may ensue. A danger that must be avoided, however, is the provision of forms of consent documents that are so detailed and so complex that they become incomprehensible or irrelevant. The question of what kinds of risks are so remote that they need not be reported is a matter of domestic law.

In addition to the comprehensibility of information, *de lege ferenda* it should be noted that the information provided might need to meet additional standards in order to be considered "appropriate". The information should be relevant and articulated in a manner to help the patient to make decisions in accordance with his/her own free will. Furthermore, clinical information should be truthful.

## ►Content of information prior to consent

Article 5, second paragraph, only mentions four items regarding the content of the information: i) purpose of the intervention; ii) nature of the intervention; iii) consequences; iv) risks. Nevertheless, it is important to highlight that this is not an exhaustive list. As the Explanatory Report clarifies, informed consent may entail, according to the circumstances, additional elements in addition to those listed. In order for their consent to be valid, the persons in question must have been informed about the relevant facts regarding the intervention being contemplated . In particular, even though it is not explicitly mentioned in the Convention, a discussion around therapeutic alternatives should be also provided. In this regard, the Explanatory Report points out that information on the risks involved in the intervention or in alternative courses of action must refer to and explain not only the risks inherent in the intervention or types of intervention contemplated, but also to any risks related to the individual characteristics and circumstances of each patient. Such risks, including, for example, but not limited to age or other co-morbidities or pathologies, are often called "personalized risks" and constitute a personalized risk profile. Failure to provide adequate information regarding personalized risks is one is one of the most common legal claims brought against health care providers.

5. Explanatory Report, paragraph 37.

## ► Consent Withdrawal

Article 5, § 3 of the Oviedo Convention also refers to the possibility that the person concerned may freely withdraw consent at any time, in respect to the principle of freedom to consent. As the Explanatory Report clearly refers *the decision of the person concerned shall be respected once he or she has been fully informed of the consequences. However, this principle does not mean, for example, that the withdrawal of a patient's consent during an operation should always be followed. Professional standards and obligations as well as rules of conduct which apply in such cases under Article 4 may oblige the doctor to continue with the operation so as to avoid seriously endangering the health of the patient*[6].

## ► 1.1.3. Limitations to consent

Article 26 of the Convention specifies the conditions under which the exercise of the rights contained in the Convention may be limited. It may also be applied to informed consent.

Article 26(1) of the Oviedo Convention stipulates that "no restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others"[7].

Therefore, to be admissible, restrictions must be prescribed by law and be necessary in a democratic society for the protection of the collective interest in question or for the protection of the rights and freedom of others. These conditions must be interpreted in the light of the criteria established with regard to the same concepts by the case-law of the European Court of Human Rights. In particular, the restrictions must meet the criteria of necessity, proportionality and subsidiarity, taking into account the social and cultural conditions proper to each State. The term "*prescribed by law*" should be interpreted in accordance with the meaning usually given to it by the European Court of Human Rights, that is a formal law is not required and each State may adopt the form of domestic law it considers most appropriate.[8]

## ► Emergency situation

According to Article 8 or the Oviedo Convention "when because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned". In such a case, physicians are allowed to act without consent from the patient or his/her legal representative.

Nevertheless, this provision should be interpreted in a restricted way and limited solely to necessary emergency interventions that cannot be delayed. Interventions for which a delay is acceptable are excluded. However, this possibility is not reserved for life-saving interventions.[9] It is also important to remark that the article specifies that the intervention must be carried out for the immediate benefit of

6. Explanatory Report, paragraph 38.

7. This provision is very similar to Article 8 par. 2 of the European Convention of Human Rights in stating that "there shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others".

8. Explanatory Report, paragraph 159.

9 Explanatory Report, paragraph 58.

the individual concerned.[10] The emergency exemption applies both to persons who are capable and to person who are unable de jure or de facto to give consent e.g. a person in a coma. Even in emergency situations, however, health care professionals must make every reasonable effort to determine and execute what would be the patient's wishes.[11]

### ► 1.1.4. Protection of persons not able to consent

We will refer here exclusively to consent and authorization for medical treatment, which are regulated in Article 6 of the Oviedo Convention. There are other specific provisions in the Oviedo Convention regarding consent for scientific research (article 17) or consent for organ and tissue removal from living donors for transplantation purposes (Article 20).

The Oviedo Convention does not specify when a person is considered not able to consent. This question is left to domestic law. In words of the Explanatory Report, "account has been taken of the diversity of legal systems in Europe: in some countries the patient's capacity to consent must be verified for each intervention taken individually, while in others the system is based on the institution of legal incapacitation, whereby a person may be declared incapable of consenting to one or several types of act. Since the purpose of the Convention is not to introduce a single system for the whole of Europe but to protect persons who are not able to give their consent, the reference in the text to domestic law seems necessary: it is for domestic law in each country to determine, in its own way, whether or not persons are capable of consenting to an intervention and taking account of the need to deprive persons of their capacity for autonomy only where it is necessary in their best interests"[12].

As a general principle, Articles 6(1) states that "an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit". In this sense, the direct benefit of incapable persons is the principle that governs the relationship between the representative of an incapable patient (or an authority, a person or a body provided for by law) and the represented patient. Therefore, the representative's decision-making authority is limited by the need to pursue the direct benefit of the patient. One might legitimately ask whether there ought to be a right of appeal against the decision of the legal representative to authorize or refuse an intervention. The Explanatory Report does not explicitly provide for such a provision. The terms of paragraphs 2 and 3 of this article, however, imply that there is a possibility of appealing to a higher body or authority in the manner provided for in domestic law.[13]

Two additional rules must be taken into account. First, the representative, the authority, the person or the body acting on behalf of the incapable patient shall be given, under the same conditions, the information referred to in Article 5.[14] Second, the authorization may be withdrawn at any time in the best interests of the person concerned.[15] It is, in fact, a duty of the doctor to protect the patient against any decision taken by a person or body whose authorization is required, but which are not in the interestof the patient; in this respect, it is anticipated that national law will provide adequate recourse.[16]

10 Explanatory Report, paragraph 59.

11 Explanatory Report, paragraph 57.

12 Explanatory Report, paragraph 42.

13 Explanatory Report, paragraph 49.

14 Article 6(4) of the Oviedo Convention.

15 Article 6(5) of the Oviedo Convention.

16 Explanatory Report, paragraph 48.

### ► Minors

Article 6(2) of the Oviedo Convention states that "where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law. The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity". In this regard, this provision does not clearly allow minors to make decisions by themselves, but rather includes the maturity as a factor that must increase the importance of the will of the minor in the final decision. However, according to the Explanatory Report, this provision might even lead to the conclusion that the consent of a minor should be necessary, or at least sufficient for some interventions, mirroring with Article 12 of the United Nations Convention on the Rights of the Child. Article 12 stipulates that "States Parties shall assure the child, who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child"[17].

### ► Adults

An analogous provision is laid down for adults in Article 6(3). Indeed, "where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law". In this regard, the term "similar reasons" refers to such situations as accidents or states of coma, for example, where the patient is unable to formulate his or her wishes or to communicate them[18].

Two additional rules deserve mention. First, cases involving recovery of capacity. If adults have been declared incapable but they recover their capacity because for example their illness improves favorably, they are according to Article 5, again deemed capable of consent.[19] Second, with respect to the participation of the incapable person: the individual concerned shall, as far as possible, take part in the authorization procedure. This rule requires that the significance and circumstances of the intervention be explained tothem, and then obtain their opinion[20].

### ► 1.1.5. Protection of persons who have a mental disorder

The Oviedo Convention devotes a specific provision to persons who have a mental disorder. According to Article 7, "subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health".

As noted in the Explanatory Report, a number of member States have laws about the treatment of patients with mental illness of a serious nature who either are compulsorily detained or have a life-threatening medical emergency. They permit intervention for certain serious situations, such as

17 Explanatory Report, paragraph 45.

18 Explanatory Report, paragraph 43.

19 Ibid.

20. Explanatory Report, paragraph 46.

the treatment of a serious somatic illness in a psychotic patient or also for certain serious medical emergencies (for example acute appendicitis, an overdose of medication or the case of a woman with a severe psychotic illness who has a ruptured ectopic pregnancy). In such cases, the legislation permits a life-saving treatment, so long as the physician concerned believes it is proper to do so. The procedure is covered by Article 6 (protection of persons not able to consent) or Article 8 (emergency situations).[21]

On the other hand, it is equally important to point out that protective provisions established by national law must be observed. These provisions include appropriate supervisory, control and appeal procedures, such as mediation, for example, by a judicial authority. This situation should be evaluated in particular in light of the Recommendation No. R(2004) 10 of the Committee of Ministers of the Council of Europe concerning the protection of human rights and dignity persons with mental disorder ,[22] which establishes a number of principles which must be respected during treatment and placement in mental healthcare.

### ► 1.1.6. Previously expressed wishes

According to Article 9 of the Oviedo Convention, the expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account. The article therefore covers not only the emergencies referred to in Article 8 but also situations where individuals have foreseen that they might be unable to give their valid consent, for example in the event of a progressive disease such as senile dementia.[23]

Nevertheless, as the Explanatory Report has underlined, taking previously expressed wishes into account does not mean that they should necessarily be followed. For example, when the wishes were expressed a long time before the intervention and science has since progressed, there may be grounds for not heeding the patient's opinion. The practitioner should thus, as far as possible, be satisfied that the wishes of the patient apply to the present situation and are still valid, taking account in particular of technical progressin medicine[24].

### ► 1.1.7. Health-related information

In the second case referred in the introduction, the right to information regarding the patient´s health (as referred in art. 10) it is relevant to refer that, when dealing with health-related information it is important to make a distinction between the information required to ensure that the person has the possibility to make an informed decision in the terms of Article 5 of the Oviedo Convention and information on the person's health referred to in Article 10.

The Oviedo Convention expressly sets out that the right to information has two complementary components: the right to know and the respect for the wish not to be informed. Indeed, Article 10(2) recognizes that "everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed". The right to know encompasses all information collected about patient's health. In this sense, the Explanatory Report of the Oviedo

21. Explanatory Report, paragraph 53.

22. Available at: https://rm.coe.int/rec-2004-10-em-e/168066c7e1

23. Explanatory Report, paragraph 61

24. Explanatory Report, paragraph 62

Convention includes "diagnosis, prognosis or any other relevant fact".[25]

Regarding patients' wishes not to be informed about certain aspects of patient's health status, the Explanatory Report clarifies that the patient's waiver must not be regarded as an impediment to his or her consent to an intervention; thus, he can validly consent for example to the removal of a cyst despite not wishing to know its nature.[26]

Other conflicts between the doctor's duty to provide care – as laid down in Article 4– and the patient's wish not to know may also arise. For instance, it may be very important for patients to know certain facts about their health, even though they have expressed the wish not to know them. It might also be appropriate to inform an individual that he or she has a particular condition when there is a risk not only to that individual but also to others. At the same time, certain facts concerning the health of a person who has expressed a wish not to be told about them may be of special interest to a third party, as in the case of a disease or a particular condition transmissible to others. According to the Explanatory Report, all these cases should be balanced by internal law.[27]

## ► Exceptions to the duty of information

Therapeutic privilege: According to Article 10(3), in exceptional cases, restrictions may be placed by law on the exercise of the rights to know or wish not to know. These restrictions are to be grounded in the best interests of the patient.

This provision reflects the concept of "therapeutic privilege". In certain cases, the doctor's duty to provide information (as covered under Article 4 as well) conflicts with the interests of the patient's health. It is for domestic law, taking account of the social and cultural background, to solve this conflict. Where appropriate under judicial control, domestic law may sometimes justify the doctor withholding some information or, in any event, disclosing it with circumspection ("therapeutic necessity"). The physician may not ordinarily undertake the decision to withhold information from a patient on his or her own.

While establishing the right to privacy of information in the health field, the first paragraph of Article 10 establishes reaffirms the principle introduced in Article 8 of the European Convention on Human Rights and reiterated in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. It should be pointed out that, under Article 6 of the latter Convention, personal data concerning health constitute a special category of data and are as such subject to special rules.[28]

The right to respect for private life in relation to information about his/her health in what respects medical confidentiality and medical secret shall be analyzed separately in next chapter (Chapter 2).

25. Explanatory Report, paragraph 66.

26. Explanatory Report, paragraph 67.

27. Explanatory Report, paragraph 70.

28. Explanatory Report, paragraph 63.

# 1.2. Compliance of the RA law on informed consent with the general human rights principles enshrined in the Oviedo Convention and its Additional Protocols

## ►Armenian Legislation applicable

- Armenian Constitution (art. 25, 4)
- Law on Medical Care (art. 14, 8, 9, 11, 12, 13; art. 15, art. 16, art. 24, art. 25)

On what concerns the information regarding health, there are two principles in the Oviedo Convention that deserve our special attention:

1. **Consent** for an intervention in the health field (as referred in the general rule of art. 5);
2. **Right to information** regarding the patient´s health (as referred in art. 10).

In the first case (**Consent** for an intervention in the health field as referred in the general rule of art. 5 of the Oviedo Convention) the general requirements ( consent must be free and informed) are met:

- Expressed consent required for research (art. 25, 4 of the Armenian Constitution);
- General rule of consent (art. 14, 1 p. 8; 16, 1 Law on Medical Care and Services to the Population);
- Exceptions to the informed consent rule (art. 24, 1; art. 16, 5 Law on Medical Care and Services to the Population);
- Withrawal of consent (art. 25, 1; art. 14, 1 p.3 Law on Medical Care and Services to the Population).
- Protection of persons not able to consent (art. 16, 3 and 4; art. 15, 2 Law on Medical Care and Services to the Population);

In the second case (**Right to information** regarding the patient´s health (as referred in art. 10 of the Oviedo Convention) the following requirements are met:

- Right to know (art. 14, 13; art. 15, 1 Law on Medical Care and Services to the Population);
- Right not to know (art. 14, 1 p. 11 Law on Medical Care and Services to the Population);

## ► Analysis

Following the amendments of 2015, the Armenian Constitution guaranteed the fundamental right of every individual to physical and mental integrity (Art. 25). It shall be interpreted according to the practice of bodies operating on the basis of ratified international treaties on human rights, as required by the Constitution (Art. 81).

The Constitution specifies the rule of integrity with regard to informed consent only in the case of scientific, medical or other experimentation, highlighting the requirement that the subject understand the consequences of such experiments. Accordingly, explicit voluntary consent must be obtained prior to any such experiments.

The Law on Medical care and services to the Population is a general 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 amendments to the Law were made in May of 2020.

Nevertheless, the Law remains silent concerning the details around to the provision of information to the patient in order to obtain explicit voluntary consent. No legislative provision envisages negative consequences or sanctions for the failure to provide appropriate information and obtain consent for treatment.

The law serves as a guideline for its general stakeholders and in that sense, there is, arguably, an important omission regarding the importance of providing patients with full information on alternatives to proposed treatments.

In the RA legislation, no mention regarding exceptions to the doctors' duty to provide information prior to consent is made. 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: the right of an individual to exercise his or her personal rights includes the possibility that the right-holder might willingly refuse to exercise the right in question. Article 14 of the Law on Medical aid stipulates that every patient has the right "to refuse information related to his health conditions, including on medical care and services".

The absence of the provision clearly reflects the ethical perspective that the conventional patient waiver could jeopardize the core essence of that right especially when the doctor-patient relationship is influenced by traditions and an orientation based on human rights.

The RA Law does not specify conditions 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 substituted by the Civil-law-regulations because they are classified as private-law relations, similar to capacity, competencies, transactions (contracts, agreement), 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.

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 in the event that 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 sense of civil law.

The RA Law on Medical Care requires a written form for consent (Article 16) except for the cases when consent for medical intervention is not required (Article 24), such as a threat to the person's life (1), and conditions posing a danger to the surroundings (2).

The stipulation of written form for all types of medical investigation is not itself in contradiction with the Oviedo convention. Nevertheless, this requirement can cause problems when it does not take into consideration the nature of the intervention. Besides, the Law does not differ amongst varieties and types of explicit and implicit consent. The form of informed consent depends on the nature of the intervention. Considering the invasive and irreversible character of some interventions 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).

Article 14 of the Law on Medical Care provides a general rule for providing information in the case of children and incapacitated persons. According to the Law, as a rule, the right to information should be transferred to the lawful representative of these individuals, rather than to a child regardless of age. The same holds true for persons legally declared 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 (with the exception of 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 nevertheless shall be taken into consideration.

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 are 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 aid 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 authorization 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 not able to consent in accordance with 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 in accordance with the law has the capacity to 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 in accordance with the law;

(iii) will facilitate the provision of easing the delivery 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 on the basis of 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 has the capacity to execute this right, but by doing so, may cause harm to his own 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 fundamental rights. The Constitutional Court also stressed that the principle of subsidiarity should also apply in the case of minors.

It is important to consider the principle that is provided for by international treaties, which states that 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, considering 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 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 inasmuch 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.

Article 16(5) Law on Medical care provides that the doctor can act without patient consent, relying on medical experts or even on his medical opinion alone, on the basis of the 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 a contact person can be found.

As explained above, according to the Oviedo Convention, the doctor can act without prior patient consent in cases when the circumstances require prompt medical intervention to serve the best interests of the patient even though the patient is unable to express his/her will. The Law does not distinguish between grounds for impossibility and grounds for emergency for providing medical care and services without prior consent except in the case of a threat to the person's life. 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 the Armenian law does not provide for a possibility for medical intervention without the patient's consent in case of a grave situation that requires a prompt reaction.

The foregoing conditions do not concern the cases that are set out in Article 24, in particular, in case of a threat to the person's life, in accordance with 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 manner, 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 or other permissible intervention on the patient's body except under extra-ordinary emergency circumstances that requires prompt intervention for the sake of patient.

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

In what concerns the second issue – the right to information regarding the patient´s health, the patient's right to information is ensured by Articles 14, 15, and 16 of the RA Law on Medical care and services to the Population. 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.

The RA Law on medical care provides a list of patient rights, including the right to information. Nevertheless, the general scope and content of the rights in question are ambiguous. Moreover, there is no clear link 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.

The RA Law on Medical Care follows the example of the Oviedo Convention by setting out a right to know and wish to not know information related to a patient's health status (Art. 14, para 1, part 11). Several parts of article 14 and article 15 entirely are dedicated to information rights including the right to information about a 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.

Article 15 of the Law requires that information be provided in an accessible manner but does not clarify the criteria for accessibility.

The RA legislation does not envisage any grounds allowing doctors to make an exception with respect to providing information directly to the patient. 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 (i.e. incomplete information used in the best interest of the patient).

## ► Conclusions

- The principles of informed consent are reflected in the RA legislation.
- It has not been found in the Armenian legislation any provisions that may conflict with Oviedo Convention.
- There are some concepts and provisions that could be improved and better clarified.
- It is envisaged that the ratification of the Oviedo Convention, which will entail the commitment to implement the Convention will provide the country with the tools to introduce the missing provisions in the national legislation.

## ►Recommendations

Requirements and conditions regarding information should be provided for in the law in order to enable the implementation of the principle (i.e. a clear and understandable informed consent framework including a better elaboration on the protection of persons not able to consent and the inclusion of provisions regarding the emergency situations, previously expressed wishes).

Those provisions regarding people who cannot consent should be clarified.

In this sense it is encouraged and recommended, to proceed with a review of the legislation regarding informed consent in view of its implementation according to the Convention standards.

# 2. Expert examination of the legislation on Medical Confidentiality and Medical Secret of the Republic of Armenia

## ► 2.1. Council of Europe standards

### ► 2.1.1. Introduction

Medical secret and confidentiality are the two sides of the same coin. In fact, medical confidentiality is a professional duty that derives from the patients' right to confidentiality of health information. Indeed, all patients have a right to privacy and a reasonable expectation that healthcare professionals will rigorously maintain confidentiality of their personal information. Each patient's right to privacy and the correlative practitioner's duty to maintain confidentiality apply regardless of the form in which the information is communicated. Nevertheless, the right to confidentiality is not an absolute right, but may be waived in certain cases, which will be studied below.

It is important to bear in mind that the Oviedo Convention devotes only one generic provision to the right to confidentiality (Art. 10).

### ► 2.1.2. Article 8 of the European Convention on Human Rights and its application within the European Court of Human Rights case-law

The right to confidentiality is relevant to the right to privacy. Historically privacy has been considered as a mere non-interference right by any particular nor public authority in the terms provided by Article 8 of the 1950 *Convention for the Protection of Human Rights and Fundamental Freedoms* (hereinafter, ECHR). This umbrella provision ('right to respect for private and family life') has historically been the legal basis for the European Court of Human Rights in order to protect the confidentiality of patient data[29].

In this regard, the Court has acknowledged that the protection of personal data, including health-related information, is of fundamental importance to the enjoyment of the right to respect for his or her private and family life guaranteed by Article 8 of the Convention. Respecting the confidentiality of health-related data is an essential principle in the legal systems of all the Contracting Parties to the Convention. The disclosure of such data may seriously affect a person's private and family life, as well as their social and employment situation, by exposing them to opprobrium and the risk of ostracism. Respecting the confidentiality of health data is crucial not only for the protection of a patient's privacy but also for the maintenance of that person's confidence in the medical profession and in the health services in general. Without such protection, those in need of medical assistance may be deterred from seeking appropriate treatment, thereby endangering their own health.[30]

In general terms, it can be concluded that, according to the Court, medical data which are lawfully processed by healthcare professionals may not be transferred to law enforcement authorities unless

29. See inter alia the following ECtHR judgments regarding health data protection: *Z. v. Finland* (Judgment of 25 February 1997), *M.S. v. Sweden* (Judgment of 27 August 1997), *Roche v. the United Kingdom* (Judgment of 19 October 2005), *Panteleyenko v. Ukraine* (Judgment of 29 June 2006), *L.L. v. France* (Judgment of 10 October 2006), *I. v. Finland* (Judgment of 17 July 2008), *Armonas v. Lithuania and Biriuk v. Lithuania* (Judgment of 25 November 2008), *K.H. and Others v. Slovakia* (Judgment of 28 April 2009), *Avilkina and Others v. Russia* (Judgment of 6 June 2013), *L.H. v. Latvia* (Judgment 29 April 2014), or Mockutė v. Lithuania (Judgment of 27 February 2018).

30. European Court of Human Rights: 'Health-related issues in the case-law of the European Court of Human Rights', 2015.

"sufficient safeguards to prevent disclosure inconsistent with the respect for [...] private life guaranteed under Article 8 of the ECHR" are provided.[31] The national law must also be "formulated with sufficient precision and afforded adequate legal protection against arbitrariness".[32] [33]

### ► 2.1.3. Medical confidentiality within the Oviedo Convention

As noted above, there is no detailed regulation in the Oviedo Convention on medical confidentiality. In a very generic way, Article 10(1) states, "everyone has the right to respect for private life in relation to information about his or her health". In this sense, it can be seen how the Oviedo Convention bases the protection of confidentiality on the same right (right to respect for private life) used within the ECtHR case-law.

However, certain restrictions to the respect of privacy are possible for one of the reasons and under the conditions provided for in under Article 26.1 (those such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others). Consequently, the Oviedo Convention covers the possibility that the exercise of the right to respect for confidentiality of health information may be limited. In the following sections, we will study what these conditions are.

In relation to medical secret, there is no specific provision within the Oviedo Convention. However, since it is considered as a professional obligation, we should consider Article 4, which prescribes that "any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards". As explained by The Explanatory Report, the content of professional standards, obligations and rules of conduct is not identical in all countries. The same medical duties may vary slightly from one society to another. However, the fundamental principles of the practice of medicine apply in all countries. Doctors and, in general, all professionals who participate in a medical act are subject to legal and ethical imperatives.[34] Medical secret is among these imperatives.

Information concerning health includes information concerning the past, present and future, physical or mental health of an individual, and which may refer to a person who is sick or healthy as well as genetic data, biometric data and health-related data which are considered as special categories of data[35].

31. ECtHR, *Avilkina and Others v. Russia*, No. 1585/09, 6 June 2013, para. 53.

32. ECtHR, L.H. v. Latvia, No. 52019/07, 29 April 2014, para. 59.

33. To illustrate the ECtHR doctrine, it is significant the most recent ECtHR ruling regarding medical confidentiality – Frâncu v. Romania (2020) –. Concerning the disclosure of confidential medical data of the applicant the Court recalled that medical data fall within the scope of the right to respect of private and family life of the patient, as protected by Article 8 of the ECHR. In this context, the Court also highlighted that respect for the confidential character of information related to health forms an essential principle of the legal system of every Contracting Party of the Convention. This principle must be respected not only for protecting private life of ill persons, but for maintaining the trust in the healthcare services as well. The Court further emphasised that the national legislation also needs to provide appropriate conditions in order to prevent every communication or disclosure of health data, which may not be covered by the protection of Article 8 of the Convention. Every communication or disclosure of health data without the consent of the person concerned, calls for a more severe examination by the Court.

34. Explanatory Report to the Oviedo Convention, paragraph 31. Oviedo, 4 April1997

35. Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data adopted in Strasbourg on 28 January 1981 (ETS No. 108).

## 2.2. Compliance of the RA Law on Medical Confidentiality and Medical Secret with the general human rights principles enshrined in the Oviedo Convention and its Additional Protocols

*General framework on private life and personal data protection*

From the constitutional point of view, our analysis should start Article 31 of the RA Constitution stipulates:

1. Everyone shall have the right to inviolability of his or her private and family life, honor and good reputation.
2. The right to inviolability of private and family life may be restricted only by law, for the purpose of state security, economic welfare of the country, preventing or disclosing crimes, protecting public order, health and morals or the basic rights and freedoms of others".

Moreover, Article 34 of the RA Constitution lays down that:

1. "Everyone shall have the right to protection of data concerning him or her.
2. The processing of personal data shall be carried out in good faith, for the purpose prescribed by law, with the consent of the person concerned or without such consent in case there exists another legitimate ground prescribed by law.
3. Everyone shall have the right to get familiar with the data concerning him or her collected at state and local self-government bodies and the right to request correction of any inaccurate data concerning him or her, as well as elimination of data obtained illegally or no longer having legal grounds.
4. The right to get familiar with personal data may be restricted only by law, for the purpose of state security, economic welfare of the country, preventing or disclosing crimes, protecting public order, health and morals or the basic rights and freedoms of others.
5. Details related to the protection of personal data shall be prescribed by law".

In accordance with Article 6 of the RA Law on Freedom of Information:

1. Each person has the right to address an inquiry to information holder to get acquainted with and/or get the information sought by him as defined by the law.
2. Foreign citizens can enjoy the rights and freedoms envisaged by the following law as defined by the Law of the Republic of Armenia and/or in cases defined by international treaties.
3. Freedom of information can be limited in cases envisaged by the Constitution and the Law of the Republic of Armenia".

In this regard, Article 8 of the same law stipulates the limitations of that right, inter alia, the information that infringes the privacy of the person's private and family life, or discloses data (medical, notarial and advocacy confidentiality) that requires accessibility limitation, conditioned by professional activity, shall not be provided.

In accordance with Article 3(1) of the RA Law on Protection of Personal Data, some legal definitions can be provided such as "personal data, "processing of personal data", "data on personal life", "biometric personal data", "special category personal data", "publicly available personal data".

Decision of the RA Government No 1849-N of 19 December 2019 approved the procedure of transferring personal data by means of electronic information system whereby the procedures and requirements of transferring personal data shall be regulated.

In accordance with Article 205 of the RA Criminal Code illegal dissemination of medical data shall cause criminal liability.

According to Article 189(17) of the RA Law on Administrative Offences the violation of the requirements prescribed by the RA Law on Protection of Personal Data shall cause administrative liability in the form of a fine.

It is worth noting that Article 9.1 of the RA Law on Legal Regime of the State of Emergency prescribes the case and procedure of restriction of the right to medical confidentiality in case of declaring state of emergency due to the epidemic. Particularly, in that case the bodies, organisations and the providers of medical care and services of the state administration system of healthcare sector shall be obliged to provide data processing state bodies with data, including data containing medical confidentiality, on the persons who were examined (tested) for the disease due to pandemic, who were carriers of infection, had disease symptoms, got infected, received treatment, as well as on the persons that had contact therewith.

Data processors may require and receive the data mentioned in this part by the bodies, organizations as well as providers of medical care and services of the state administration system of healthcare sector.

*Special framework on medical confidentiality*

Legal regulations on medical confidentiality are prescribed by different legal acts containing the RA healthcare sector; however, the basic regulations are included in the RA Law on Medical Care and Services to the Population. In the meantime, it should be established that the RA Legislation does not differentiate the concepts of medical confidential information and medical confidentiality.

In accordance with Article 2 (1(14)) of the RA Law on Medical Care and Service to the Population, medical confidentiality is the information on a patient's health condition or application for or receipt of medical care and services, as well as information revealed during the provision of medical care and services.

In accordance with Article 11(3) "Data deemed a medical confidentiality may be shared with the consent of the patient or his/her lawful representative, except for cases directly prescribed by law. The Authorized Body shall prescribe the form of the patient's or his/her lawful representative's consent on sharing of data that is deemed a medical confidentiality".

Part 2 of the same article stipulates that sharing of data deemed medical confidentiality is any action (inaction) aimed at the sharing of such data with or granting access to such data to a certain or uncertain group of persons, including the publication in the mass media of, posting in information and communication networks of, or otherwise granting other persons any access to, data that is deemed confidentiality.

Part 5 of the same article lays down that data that is deemed a medical confidentiality may, without the consent of the patient or his/her lawful representative, and in accordance with the procedure defined by the Government (the procedure is not adopted yet) can be shared only in specific circumstances established in the law: [36]

36 1) with providers of medical care and services for the purpose of providing medical care and services to the patient, when such medical care and services cannot be provided to the patient without such data;

Article 7 of the law stipulates health care sector databases; the purposes of compiling them, according to specific requirements [37]

2) with an Authorised Body: This includes State organisations carrying out activities in the field of population sanitary-epidemiological security and public health—in case of morbidity caused by infectious, as well as chemical, radiological, and biological factors, and in cases of certain non-infectious diseases or mass poisonings, or threat thereof prescribed by the Authorised Body. to the Authorised Body, when checking the progress and quality of works under contracts concluded for state-guaranteed provision of medical care and services free of charge or on concessional terms in accordance with the Civil Code of the Republic of Armenia;

3) by a judicial act that has become final;

4) for the purpose of performing a military medical examination when inquired by military conscription offices or medical or military medical commissions;

5) to the competent state authority performing medical social examination, for the purpose of performing a medical social examination and repeat examination;

6) to an unconscious patient's contact person or adult family members. For purposes of this sub-paragraph, "family members" include the father, mother, lawful representative, spouse, spouse's parents, adoptive parent, grandparent, sibling, and children, including adopted children;

7) to those performing scientific and scientific-technical activities in the cases defined by this Law;

8) to the police—regarding a patient taken to a medical institution (including deceased persons), about whom there is doubt that health deterioration or death was caused by violent, including unlawful actions;

9) to the inquest authority (the authority performing criminal intelligence activities), the investigator, the prosecutor, the court—in the performance of their respective obligations in the frameworks of proceedings, as well as to the Defender of Human Rights, based on a reasoned decision.

10) to a penitentiary institution of the Ministry of Justice, and to the penitentiary and probation services of the Ministry of Justice in cases provided by law;

11) to the Authorised Body (including state organisations carrying out activities in the field of population sanitary-epidemiological security and public health) and to providers of medical care and services, for purposes of maintaining health care sector databases defined by this Law;

12) to the inspection authority authorised by the Government to oversee the health care sector—in the performance of state oversight of compliance with health care and employee health protection rules.

37 1. Personal data of patients, including personal data of special categories protected by the Law on Personal Data Protection, shall be processed without the patient's consent in cases defined by this Law.

2. Health care sector databases shall be processed for the achievement of the following goals:

1) health care sector databases compiled by the Authorised Body (including by state organisations carrying out activities in the field of population sanitary-epidemiological security and public health) for:

(a) collection of the necessary information in a standard form concerning the patient's health, for the purpose of providing medical care and services (including prescription and dispensing of medication);

(b) medical care and organisation based on direct payments by persons and allocations from the state budget of the Republic of Armenia;

(c) planning, management, and evaluation of the activities of the health system;

(d) monitoring and evaluation of the public health situation, as well as identification of risks and threats and combatting them;

(e) evaluation of the quality, safety, and efficacy of health care services;

(f) implementation of activities necessary for and reporting on the comprehensive surveillance of diseases, epidemiological surveillance, disease prevention, treatment, and management, and ensuring the sanitary-epidemiological security of the population;

2) Health care sector databases compiled by providers of medical care and services for:

(a) collection of the necessary information in a standard form concerning the patient's health, for the purpose of providing medical care and services (including prescription and dispensing of medication);

(b) Medical care and organisation based on direct payments by persons and allocations from the state budget of the Republic of Armenia;

(c) oversight of documents issued by providers of medical care and services;

(d) implementation of activities necessary for and reporting on the comprehensive

(e) surveillance of diseases, epidemiological surveillance, disease prevention, treatment, and management, and ensuring the sanitary-epidemiological security of the population;

3) Depending on the purposes of the processing, health care sector databases may contain the following personal data, including data of special categories:

(a) the person's name, surname, and patronymic;

(b) sex;

(c) birth date, month, and year (if birth date and month are unknown, 01 July and the year shall be specified);

(d) the registration address and actual residence address, telephone number, and e-mail address, if any;

(e) the public services number or, in case of not having one, the number of the statement confirming that the person does not have a public services number, or the passport or ID number and series, or the military conscription booklet or birth certificate number or residence certificate number, and in case of foreign citizens, also the personal identification document number;

(f) citizenship;

(g) nationality;

(h) information on family status and children, and information on the relationship with the contact person and the person's lawful rep-

Also article 8 of the law stipulates the electronic health system and principles, to be organised under specific provisions:[38]

The procedure of an e-health system data processing, acceptance, expert evaluation, and publication of subscriber data is not adopted yet. In accordance with Parts 2,3,5 of Article 12 of the same law:

2. "Medical documents (including electronic documents) that contain personal data shall be kept in medical institutions in such a way as to preclude persons not having the relevant power under the

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resentatives (including adoptive ones), guardians, and trustees;

(i) information on education and employment;

(j) information on being a member of a socially-vulnerable or specific group;

(k) date of applying to the doctor (medical worker), the complaints, the symptoms, and if necessary, the disease history, and membership in an outpatient group;

(l) date, month, and year of falling ill;

(m) In case of hospitalisation—the date, month, year, and place of hospitalisation;

(n) the diagnosis and the volume, outcomes, and timeframe of medical care and services provided;

(o) medications prescribed and dispensed;

(p) information and data on health;

(q) in case of getting diseases posing a danger to the surroundings, publicly-accessible personal data on persons that had contact with the patient;

(r) information on the patient being a blood donor or an organ and/or tissue donor after death, or refusal thereof;

(s) information on consent to or refusal of pathological-anatomical dissection; and

(t) name, surname, and specialisation of the treating doctor.

4) Personal data incorporated in health care sector databases shall be protected in accordance with the procedure defined by the Law on Personal Data Protection.

5) The technical specifications of health care sector databases shall conform to the Government-approved security, interoperability, and general technical requirements and rules for e-systems used for delivery of e-services or performance of activities by state government bodies and local self-government bodies.

6) State bodies holding personal data prescribed by law may, without the person's consent, and in accordance with the procedure defined by the Government, exchange such data for purposes of organising and implementing preventive activities (including medical care and services) in emergency situations. For documenting diseases posing a general threat to animals and humans or a threat to the surroundings, personal data may be shared only with the person's consent.

38 1. The Republic of Armenia shall be deemed the owner of the anonymised information contained in the database within the electronic health (e-health) system, and such information shall be managed in accordance with the procedure defined by the Government.

2. In the e-health system, activities shall be organised in accordance with the following principles:

(a) information contained in the e-health system shall be personalised, except for cases provided by law;

(b) the database shall be common for all participants of the e-health system;

(c) the information shall at all times be accessible for persons that have the right to use the e-health system in accordance with the procedure defined by law, subject to the limits of their authority; and

(d) the information shall be confidential and protected.

3. The technical maintenance and operation of the e-health system shall be secured through the common operator of the e-health system (hereinafter, "the Operator"), which shall be selected through a competition. The competition procedure, the main requirements on the common operator, and the operator selection criteria shall be prescribed by the Government.

4. Entities licensed in the health care sector of the Republic of Armenia and state bodies and organisations that have access to health care sector data for the purposes specified in Paragraph 2 of Article 7 of this Law shall be deemed subscribers of the e-health system.

5. All subscribers of the e-health system shall have computers having sufficient technical features and connected to the system. The Authorised Body shall define the minimum conditions on technical features for connecting to the e-health system.

6. It the e-health system, a window for accessing e-information shall be assigned to the patient, and the Authorised Body shall prescribe the rules of browsing patient data contained therein; the persons that may have access thereto with the consent of the patient (or the patient's lawful representative), and the powers of such persons; the procedure of entering the window for accessing e-information on the patient and browsing patient personal data, including special-category data; and the patient consent form for accessing the window for accessing e-information on the patient.

7. In compliance with the provisions of the Law on Personal Data Protection, the licensed entity shall ensure updating of data in the e-health system, and shall secure the entry into the e-health system of data on patient visits, services provided, medical interventions, diagnoses, prescriptions, health of the person, and the medical data provided by Paragraph 3 of Article 7 of this Law at the time when they are actually performed, and in accordance with the procedure approved by the Authorised Body.

8. Electronic information collected through the e-health system may be used for obtaining detailed medical health care information on the person and providing the relevant medical services, as well as when making reimbursements for medical services, and in case of anonymised data, also for purposes of research, analysis, and monitoring.

9. The Authorised Body shall define the procedure of e-health system data processing, acceptance, expert evaluation, and publication of subscriber data.

law from accessing or photocopying them or taking excerpts from them or taking any information from them in any other way.

3. Scientists and researchers may, for purposes of performing scientific and scientific-technical activities in the health care sector, study (process) medical documents only after applying means that preclude the person's identification through them (applying concealment layers or providing certain segments that do not include the personal data contained in medical (including electronic) documents, or otherwise anonymizing them). The provider of the medical care and services and the medical worker compiling the relevant medical (including electronic) document shall be responsible for using means to preclude the person's identification through medical documents, except for archived medical documents, which are not handled by the medical worker.

If the use of means to preclude the person's identification through medical (including electronic) documents does not allow achieving the goals of the respective scientific and scientific-technical activities, or the use of such means is impossible due to technical reasons, then scientific and scientific-technical activities that research (process) medical documents containing special-category data may be performed without the person's consent, subject to the procedure prescribed by Article 23 of the Law on Personal Data Protection. Personal data, including special-category data that is researched without the person's consent under the procedure prescribed by this Paragraph may be disclosed only with the patient consent given in accordance with Paragraph 4 of Article 9 of this Law.

5. Medical (including electronic) documents of patients currently undergoing treatment may not be researched for the purpose of performing scientific and scientific-technical activities".

By Decision of the RA Government No 397-N of 4 April 2019, the sample list of the archive documents with the note of preservation period, wherein preservation period of 5-50 years shall be prescribed for the preservation of different documents containing medical confidentiality, according whereto the disease histories of the patients, receiving inpatient and outpatient treatment that have significance of scientific research shall be preserved permanently.

Article 14 of the law stipulates that every person (patient) shall have the right to get familiar with his/her medical (including electronic) documents or to receive their copies in accordance with the procedure defined by the Law on the Freedom of Information. In accordance with Article 9 of the Law on Freedom of Information, the inquiry on that data may be carried out through written or verbal procedures according to the purpose of the inquiry. The article prescribes the procedure, terms and conditions of responding to the inquiry. Article 14 of the same law stipulates, except for the cases provided for by law, that refusing to provide information or providing untrustworthy information, as well as other violations of the procedure prescribed by this law shall cause liability defined by law. In accordance with Article 189.7 of the RA Code of Administrative Offences, administrative liability (in the form of a fine) is defined for the violations of the Law on Freedom of Information.

Article 14 of the Law of the Republic of Armenia on Prevention of Disease Caused by Human Immunodeficiency Virus stipulates that the person infected with HIV has the right to require preservation of medical confidentiality except for cases prescribed by the Legislation of the Republic of Armenia. Specific exception, for instance in regard to providing such information to the partner, is not defined.

In accordance with Article 13 of the RA Law on Transplantation of Human Organs and (or) Tissues,

information on the donor and the recipient shall be medical confidentiality.

The publication of information on the donor and (or) recipient against their will by physicians, other employees of the medical institution shall be prohibited. The person(s) who publish (disseminate) that information shall be held liable in the manner prescribed by the Legislation of the Republic of Armenia.

At the request of the inquest authorities, information, statements and documents on the donor and recipient shall be issued to the court, Prosecutor's General Office and investigation bodies only with regard to the criminal and civil cases within the scope of their proceedings.

In accordance with Article 2.1 of the same law, the information registered in the Registry of Donors and Recipients of Organs and Tissues shall be deemed medical confidentiality and, in the manner prescribed by this law, may be provided to the licensed medical institutions taking transplantation organs and tissues, examinating and transplanting them.

In accordance with Article 2 (1(10)) of the RA Law on Donation of Human Blood and Its Components and Transfusion Services, the Blood Registry is an electronic information system of blood donation, transfusion medical services and blood components storage, complications of transfusion. Article 11 provides specific conditions for its organization [39]

The procedure of the activity of the Blood Registry, as well as registration, use and and transfer of the information are defined by RA Government Decision No 523-N of April 8, 2021:

In what concerns Psychiatric Care, article 16 of the RA Law on Psychiatric Care provides several provisions regarding the patient's information.[40]

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39 2. The information registered in the Blood Registry on the donors shall be deemed medical confidentiality and may be provided to the licensed medical institutions carrying out donation and transplantation without the donor's consent in cases and manner prescribed by the legislation.

3. In cases of detecting dangerous disease or infection-carrying that can pose a danger to the surroundings among the donors registered in the Blood Registry, the inspection body authorised by the Republic of Armenia to conduct supervision for the implementation of anti-epidemic measures shall be informed.

4. The information deemed medical confidentiality registered in the Blood Registry might be provided to other persons in cases provided for by law".

40 1. The information on the fact of person's applying to physician-psychiatrist or psychiatric organisation, his/her health, as well as information revealed during examination, diagnosis and treatment shall be medical confidentiality. Such information shall be provided to the person with mental health problems, whereas in case of the legal representative, if available, shall be provided to the legal representative at their request. Information deemed medical confidentiality without the person's or the legal representative's (if available) consent may be transferred to other persons or bodies only in cases provided for by law.

2. Data deemed medical confidentiality may be transferred in the manner prescribed by the Law on Protection of Personal Data only-

(a) to other persons or organisations providing medical care and services (in case of a life-threatening condition of the person having mental health problems or disease posing a danger to the surroundings or a suspicion thereof, or when the person having mental health problems lacks the ability to understand and give consent to the transfer of personal data and does not have legal representative) for the purposes of diagnosis, examination or treatment in case of professional necessity, namely it shall be impossible to make the person's accurate diagnosis or carry out his/her examination or treatment.

(b) to the Authorised Body, when checking the progress and quality of works under contracts concluded for state-guaranteed provision of medical care and services.

(c) to the inquest authority (the authority performing criminal intelligence activities), the investigator, the prosecutor, the court—in the performance of their respective obligations in the frameworks of proceedings,

(d) to a penitentiary institution of the Ministry of Justice, and to the penitentiary and probation services of the Ministry of Justice in cases provided by law;

(e) for the purpose of performing a military medical examination when inquired by military conscription offices or medical or military medical commissions;

(f) when inquired by the inspection authority overseeing the health care sector-in the performance of state oversight of compliance with work safety provision and employee health protection rules prescribed by the Law on Healthcare, Law on Sanitary-epidemiological Safety, Labor Code.

(g) to the Police-for the purposes of issuing (exchanging) driving license, overseeing arms in circulation, protecting public order and public security.

(h) In other cases, provided for by law.

3. Data deemed medical confidentiality in psychiatric institutions shall be preserved with the Government's sample list of archive documents with the note of preservation period and for periods prescribed for the preservation of health care sector documents.

In accordance with Article 18 of the RA Law on Human Reproductive Health and Rights to Reproduction

1. Information on the assisted reproductive technology, namely on use of artificial insemination or fecundation and surrogacy shall be deemed medical confidentiality and shall not be subject to publication.

2. Information provided for by Part 1 of this article shall be provided only with regard to criminal or civil cases initiated by the court (judge), Prosecutor General's Office, preliminary investigation, inquest authorities, as well as at the request of competent authorities in cases and manner provided for by law".

In accordance with Point 137 Approved by Decision of the RA Government No 825-N of 26 May 2006 envisaging the procedure of organising medical and sanitary, as well as medical and preventive care for the detainees and convicted, using the services of medical institutions of health care authorities and involving the medical staff thereof for that purpose, the information on the detainee or convicted registered in medical documents who applied for medical care, as well as information revealed during examination, diagnosis and treatment shall be confidential and may be provided to other persons in cases prescribed by law.

Those medical documents shall be provided in the form of an extract or copy to the detainee or convicted or the person authorized by them upon written request.

In accordance with Point 85 of the same procedure "Information on the detainees and convicted registered and (or) removed from registration, having addiction to drugs and psychotropic (psychoactive) substances shall be monthly provided to the Police of the Republic of Armenia. When transferring the mentioned information, the confidentiality thereof shall be ensured".

*Obligations and liability regarding medical confidentiality*

In accordance with Article 28 of the RA Law on Medical Care and Services to the Population, providers (medical institutions) of medical care and services shall be obliged to maintain medical confidentiality except for cases prescribed by law.

The same law stipulates that ethics rules shall be rules of professional conduct of medical workers that shall be approved by the Government (Government decision 182-N of 17 Of February 2022 ). In the meantime, to examine the cases of violating ethics rules, Ethics Commission shall be established (which has not been established yet). Decisions of Ethics Commission shall be of confidential nature.

The Ethics Commission shall examine violations of rules of professional ethics of medical workers, for which no criminal or administrative liability is prescribed. After examining a case, the Ethics Commission shall adopt a decision.[41]

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4. Processors of data deemed medical confidentiality shall be obliged to preserve the information deemed medical confidentiality revealed during the performance of employment or official duties. Violation of the requirements envisaged by the Law on Protection of Personal Data shall cause liability provided for by law.

41 1) In case of discovering acts that are prime facie subject to criminal or administrative liability, or in case the professional ethics rules have not been violated:

(a) a decision to reject the application, or

(b) a decision to terminate case examination, in case of initiating such examination at its own initiative.

2) In case of confirming a violation of professional ethics rules for which the law does not prescribe criminal or administrative liability:

(a) to propose to the Authorised Body to reprimand the medical worker who has committed the violation for the first time;

(b) in case the medical worker violates the professional ethics rule again within a year, to propose to the Authorised Body to severely reprimand the medical worker;

(c) in case the medical worker violates the professional ethics rule for a third time within a year, to propose to the Authorised Body to

In the Republic of Armenia, the violation of the law requirements along with medical confidentiality shall cause administrative or criminal liability based on the nature and the graveness of the crime. Moreover, the subject of liability shall not be only the medical worker, but also every person who is ex officio engaged in the process of personal (special) data processing within the scope of his/her liabilities.

In accordance with Article 205 (Illegal dissemination of medical data) of the RA Criminal Code,

- Revealing of data containing medical confidentiality by the processor of personal data provided by law without the written consent of the person or his/her legal representative in cases not provided for by law, or
- Disclosure of data containing medical confidentiality through mass media in cases not provided for by law or publication thereof on the information and communication networks by the processor of personal data provided for by law without the written consent of the person or his/her legal representative, shall be punished with a fine or a with the public work or by deprivation of the right to hold certain posts or practice certain activities or with limitation of liberty or with arrest or shall be punished with imprisonment.

## ► Analysis

However, based on the analysis carried out, several comments can be made:

Although not being mandatory it is possible that RA legislation may, in exceptional cases place restrictions on the right to know or not to know in the interests of the patient's health, such as withholding part of the information; disclosing it with circumspection; or disclosing to third parties under restricted circumstances[42]

The RA Law on Medical Care and Services to the Population envisages the patient's right not to be informed of his/her medical confidential information his right is absolute and there are no exceptions prescribed. Whereas, based on the interests of the patient and sometimes also his/her family, it is necessary to provide that information to the patient in certain cases.

## ► Conclusions

- The RA legislation is generally in line with the provisions of the Oviedo Convention relevant to confidentiality and medical secrecy.
- The base of a medical confidentiality and medical secrecy are present in the Armenian law, either in the Armenian Constitution or in the RA Law on Protection of Personal Data, Criminal Code and others.
- It seems that there are no general contradictions between the Armenian legal framework on this section and the principles of the Oviedo Convention.

suspend the license of the provider of medical care and services in respect only of the specific medical worker for a one-month term, based upon sub-paragraph 12 of Paragraph 1 of Article 36 of the Law on Licensing.

42. Vd. Articles 4, 10 and 26 Oviedo Convention and Explanatory Report to the Oviedo Convention. Such exceptions are not required by the Convention. Article 26 only makes them possible under specific conditions.

### Recommendations

Even though there is neither an incompatibility nor a gap with the Oviedo Convention and its additional protocols, RA legal framework would beneficiate if better structured or condensed in a sole legislation or having some provisions of the applicable legislation reviewed in order to provide a more complete framework on medical confidentiality and medical secret.

# 3. Expert examination of the legislation on medically assisted procreation and embryo protection of the Republic of Armenia

## ► 3.1. Council of Europe standards

### ► Introduction

It is important to stress that the Oviedo Convention does not directly regulate reproductive rights in a detailed way, even though there are provisions relevant to them such as equitable access to health care of appropriate quality (Article 3) and informed consent (Art. 5). Only one mention appears in Article 14 when it establishes that "the use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided".

As the Explanatory Report of the Convention clarifies, when meaning "*medically-assisted procreation*", this provision is including artificial insemination, *in vitro* fertilization and any technique having the same effect, which permits procreation beyond the natural process. According to this Article, as an exception to the general prohibition, it is allowed to use a technique of medically assisted procreation in order to choose a future child's sex only when "serious hereditary sex related disease is to be avoided".

It is for internal law to determine, according to the procedures applied in each state, the seriousness of a hereditary sex-related disease. In some countries, guidelines are laid down by political or administrative authorities or by national ethics committees, ad hoc committees, professional bodies, etc. In every case, appropriate genetic counselling of the persons concerned is necessary[43].

It is recognized that, apart from the present provision it does not exist a general consensus regarding the regulation of assisted reproduction.

### ► 3.1.1 Protection of human embryo

Although not mentioning directly the medically assisted procreation, it is a fact that the approach to embryo protection in Article 18º of the Oviedo Convention exists in view of the existence of embryos derived from such technique (it refers to embryos in vitro that may be created with medically assisted procreation techniques) when the country's legislation allows research on embryos.

In relation to the protection of embryos, Article 18 of the Oviedo Convention establishes two principles. First, where the law allows research on embryos in vitro, it shall ensure adequate protection of the

43. Explanatory report, paragraph 94.

embryo. Therefore, this provision shows two different consequences: i) it is neither contrary to the Oviedo Convention to prohibit research on embryos in vitro nor to allow it; ii) in the event that domestic law permits it, "adequate" protection must be provided. The second provision prohibits the creation of human embryos for research purposes.

### 3.2. Compliance of the RA law on medically assisted procreation and embryo protection with the general human rights principles enshrined in the Oviedo Convention

## ► Analysis

*Medically Assisted Procreation*

In the Republic of Armenia (RA) reproductive health relations are regulated by RA Constitution[44], RA Law on Reproductive Health and Reproductive Health Rights[45].

According to the article 85 of RA Constitution everyone shall, in accordance with law, have the right to health care. The law prescribes the list of free of charge basic medical services and the procedure for the provision thereof.

RA Law on Reproductive Health and Reproductive Health Rights lists the sexual-reproductive rights and, among them reference is made to the use of new reproductive technologies, including safe and effective means and (or) methods of fertility control, as well as assisted reproductive technologies used to treat infertility.

It is also worth mentioning that according to RA Civil Code[46] the "passive legal capacity" of a citizen (the capacity of holding civil rights and bearing obligations) shall arise from the moment of his or her birth and shall terminate by death.

RA Law on Reproductive Health and Reproductive Health Rights stipulates (article 4) the right to use new reproductive technologies, including safe and effective means and (or) methods of fertility control, as well as Assisted Reproductive Technologies (ART) used to treat infertility.

In the Republic of Armenia, it is allowed to use the following assisted reproductive technologies:

- Artificial insemination with spouse's or donor's sperm;
- Artificial (extracorporeal / in vitro) fertilization with spouse's or donor's sperm and embryo implantation;
- Transplantation of a donor embryo in the uterus of a surrogate mother.

There is an age limit of using ARTs, only women and men aged less than 53 can use ARTs.

Before the recent changes in the Law on Reproductive Health and Reproductive Health Rights, legislation stipulated that the man and woman applying for ARTs (in vitro fertilization and surrogacy), or at least one of them must be biological parent of the future child. The amendments eliminated this restriction.

It is not our purpose to analyze AR legislation on assisted reproduction except regarding the provisions that refer to the selection of sex or embryos.

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44. The Constitution of the Republic of Armenia, 2015 // https://www.president.am/en/constitution-2015/

45. RA Law on Reproductive Health and Reproductive Health Rights, 2003

46. Civil Code of the Republic of Armenia, 1998// http://www.translation-centre.am/pdf/Translat/HH_Codes/CIVIL_CODE_en.pdf

According to the article 14 of Oviedo Convention the use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.

Before the latest amendments, in case of use of assisted reproductive technologies, the legislation was not allowing to plan the sex of the future child, except in cases when there is a possibility of inheriting sex-related disease. This provision was perfectly complying with the requirements of the Oviedo Convention.

However, the recent amendments changed this provision too. As an exception to the rule it is added the fact of having 3 or more children of the same sex. Thus, according to the new regulation, planning the sex of the future child while using ARTs will be allowed, if:

- there is a possibility of inheriting sex-related disease;
- there are three or more children of the same sex in the family.

New regulation is a clear contradiction to the Article 14 of the Oviedo Convention since at least in the second case it does not concern any avoidance of an hereditary sex-related disease.

In this regard, it is worth noting that Article 26 (2) does not provide for any possible domestic restriction to be placed on this provision.

## ► Protection of embryo

According to the article 18 of the Oviedo Convention, where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo. RA legislation neither allows nor prohibits the research on the embryos and does not envisage any relevant regulations.

The same article of the Oviedo Convention stipulates that the creation of human embryos for research purposes is prohibited.

The RA legislation neither allows nor prohibits the creation of human embryos for research purposes.

As a result of Assisted Reproductive Technologies (ART), there is excess of embryos obtained for procreation. The number of embryos created for procreation is often much higher than what is reasonably necessary for pregnancy. Until recently, it was not clear what to do with unused embryos. In this case, usually, the unused embryos are frozen and finally destroyed with the mutual written consent of the parents and the medical center.

Just to note, RA Government Decree N 907-N[47] regulates the procedure and terms of the preservation of germ cells and embryos and determines under what conditions and how the embryo should be stored. However, only recent legislative changes specified in which case the embryo can be stored.

The latest amendments to RA Law on Reproductive Health and Reproductive Health Rights[48] made on 28.06.2021, define a new article in the Law related to embryo preservation, destruction and gratuitous provision.

According to the recent amendments, after the completion of the treatment provided with assisted reproductive technologies, the biological parents/couple or the man or woman who is not in a marriage registered in the manner prescribed by RA legislation, give written consent to the unused embryos

47. RA Government Decree N 907-N, 2013.

48. RA law on making amendments in RA law on Reproductive Health and Reproductive Health Rights N264-N, 28.06.2021.

created by in vitro fertilization:

a) to give to the institution providing a care with assisted reproductive technologies in order them to provide it to an infertile couple or unmarried woman free of charge;

b) to destroy them;

c) to save them for monetary "compensation".

Within one month after the expiration of the term of embryo preservation stipulated by the agreement on embryo provision or free of charge donation or destruction, if the biological parent fails to reaffirm their wish by an agreement on embryo preservation or destruction, the embryo-preserving medical organization may dispose of the embryo at its discretion.

This means that the medical organization can:

a) destroy the embryo

b) provide it gratuitously to another infertile couple or unmarried woman, except for foreigners residing in the Republic of Armenia who are not in a marriage registered (recognized as valid) in accordance with RA legislation.

It is also clear that the creation of embryos for the sole purpose of research is not envisaged in the AR legislation, thus, in compliance with Article 18 of the Oviedo Convention.

Mentioned modifications in the legislation bring some clarity about the preservation of the embryo, however a number of questions still remain unanswered, such as:

- Can research be carried out on embryos or can the embryos be donated for the research purposes, if yes, how the embryos shall be protected?
- The concept of "saving embryos for monetary compensation" is not clear.

These are the questions that need to be answered while drafting legislation to ensure adequate protection of the embryo and in order to avoid any contradiction with Oviedo Convention.

On the other hand, it is not clear what is meant with the provision c) *to save them for monetary compensation*. The meaning of "compensation" in this context should be clearly explained in order to evaluate if it does or not conflict with art. 18 of the Oviedo Convention and the concept of "adequate protection".

## ► Cloning of Human Beings

The Additional Protocol to the Oviedo Convention on the Prohibition of Cloning Human Beings on 12 January 1998.

According to the Additional Protocol, any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited (Article 1). For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set. It is important to stress that no domestic derogation from the provisions of this Additional Protocol are allowed to Member States under Article 26 (1), paragraph 1, of the Convention.

Article 25 of RA Constitution defines the right to physical and mental integrity. Thus, everyone shall have the right to physical and mental integrity.

Paragraph 3 of this article expressly prohibits reproductive cloning of a human being: *In the fields of*

*medicine and biology, eugenic practices, making the human organs and tissues a source of financial gain, and the reproductive cloning of a human being shall be particularly prohibited.*

The above-mentioned provision complies with the provisions of the Additional Protocol to the Oviedo Convention with regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings, and holistically prohibits the cloning of human being.

At the same time, the RA Criminal Code condemns reproductive cloning of a human being - any action aimed at artificially creating a genetically similar to a dead or living person.

Considering the abovementioned legislation, there is no contradiction with the Oviedo Convention.

## ► Conclusion

Having regard to the principles and provisions of the Oviedo Convention and its Protocols, it is concluded that:

- in what regards assisted reproduction there is a contradiction between the RA legislation and the Oviedo Convention regarding the provision giving the right to plan the sex of the future child while using ARTs when there are three or more children of the same sex in the family (RA legislation) and Article 14 of the Oviedo Convention which prohibits the use of techniques of medically assisted procreation for the purpose of choosing a future child's sex ( except where serious hereditary sex-related disease is to be avoided).

In what concerns embryo protection, there is no contradiction between RA legislation and Oviedo Convention, although it is recommended to provide clearer provisions on embryo research.

It is also not clear what is the meaning of "saving embryos for monetary compensation" provided on the RA Law on Reproductive Health and Reproductive Health Rights made on 28.06.2021.

There is no contradiction between RA legislation and the prohibition of human cloning as referred in the Oviedo Convention and its Additional Protocols.

## ► Recommendations

Based on the analysis carried out, four recommendations are made:

- Research on embryos in vitro needs to be addressed either to not allow such research or, if allowed, in order to define a scope of clear provisions regulating the research on embryos in vitro, including the conditions and terms, where the research can be done and the means of embryo protection.
- To add a provision clearly prohibiting the sole creation of human embryos for research purposes.
- The meaning of "saving embryos for monetary compensation" should be clearly explained in order to evaluate if it does or not conflict with art. 18 of the Oviedo Convention and the concept of "adequate protection".
- Concerning the RA Law on Reproductive Health and Reproductive Health Rights, the provision that allows to plan the sex of the future child while using ARTs when there are three or more children of the same sex in the family should be changed to a provision in line with Article 14 of the Oviedo Convention.

# 4. Expert examination of the legislation on Transplantation of Organs and (or) Tissue of human origin, Blood Donation, Genetic Testing and Biomedical Research of the Republic of Armenia

## ► 4.1. Council of Europe standards

### ► Introduction

The Oviedo Convention is considered as a standard framework in evaluation of essential human rights principles to protect the dignity and identity of everyone and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms[49]. Focusing on the highest value of human being, Article 2 of the Convention is affirming the primacy of the human being over the sole interest of society or science. Given this, the following general human rights principles set out in the Oviedo Convention and its Additional Protocols shall be considered:

- in the field of organ and tissue transplantation (Oviedo Convention and its additional Protocol concerning transplantation of organs and tissues of human origin):
  1. protect the dignity and identity, respect of integrity and other rights and fundamental freedoms that must be guaranteed without discrimination with regard to transplantation of organs and tissues of human origin, as enshrined in Article 1 of the Oviedo Convention and in Article 1 of its Additional Protocol[50];
  2. equitable access to transplantation services for patients, as enshrined in Article 3 of the Oviedo Convention and in Article 3 of its Additional Protocol;[51]
  3. respect for autonomy (right to self-determination), as enshrined in Articles 5 and 19 of the Oviedo Convention and in Articles 12, 13 and 17 of its Additional Protocol;
  4. protection of persons unable to consent, as enshrined in Articles 6 and 20 of the Oviedo Convention and in Article 14 of its Additional Protocol;
  5. minimisation of risks and maximisation of benefits, as enshrined in Articles 4 and 19 of the Oviedo Convention and in Articles 3, 4, 6, 7, 9 ad 11 of its Additional Protocol;
  6. dignified treatment of the deceased, as enshrined in Articles 16, 17 and 18 of the Additional Protocol;
  7. confidentiality of personal data (right to privacy), as enshrined in Article 10 of the Oviedo Convention and in Article 23 of its Additional Protocol;
  8. prohibition of financial gain, as enshrined in Article 21 of the Oviedo Convention and in Article 21;

49. See Article 1 of the Conventions and its Additional Protocols.

50. Oficially 'Additional Protocol to the Oviedo Convention concerning Transplantation of Organs and Tissues of Human Origin', 24 January 2002, ETS No. 186. Signed by 22 European countries and ratified by 15 of them (Bulgaria, Croatia, Estonia, Finland, Georgia, Hungary, Iceland, Montenegro, North Macedonia, Portugal, Republic of Moldava, Romania, Slovenia, Spain and Switzlerland). It entered into force on 1 May 2006.

9. prohibition of organ and tissue trafficking, as enshrined in Article 22 of its Additional Protocol;

- in the field of genetic testing (Oviedo Convention and its additional Protocol concerning genetic testing for health purposes):

1. protect the dignity and identity, respect of integrity and other rights and fundamental freedoms that must be guaranteed without discrimination on the grounds of genetic heritage, as enshrined in Articles 1 and 11 of the Oviedo Convention and in Articles 1 and 4 of its Additional Protocol;
2. the primacy of human being over the sole interest of society or science, as enshrined in Article 2 of the Oviedo Convention and in Article 3 of its Additional Protocol;
3. equitable access to genetic services of appropriate quality and to the genetic screening programmes, as enshrined in Article 3 of the Oviedo Convention and in Articles 5 and 19 of its Additional Protocol;
4. respect for autonomy, as enshrined in Articles 5 of the Oviedo Convention and in Article 8 and 9 of its Additional Protocol;
5. protection of persons unable to consent, as enshrined in Article 6 of the Oviedo Convention and in Articles 14 of its Additional Protocol;
6. minimisation of risks and maximisation of benefits, in Articles 5, 6 and 7 of its Additional Protocol;
7. confidentiality of personal data (right to privacy), as enshrined in Article 10 of the Oviedo Convention and in Article 16, 17 and 18 of its Additional Protocol;

- in the field of biomedical research (Oviedo Convention and its additional Protocol concerning biomedical research):

1. protect the dignity and identity, respect of integrity and other rights and fundamental freedoms that must be guaranteed without discrimination with regard to any research involving interventions on human beings in the field of biomedicine, as enshrined in Article 1 of the Oviedo Convention and in Article 1 of its Additional Protocol;
2. the primacy of human being over the sole interest of society or science , as enshrined in Article 2 of the Oviedo Convention and in Article 3 of its Additional Protocol;
3. protection of persons not able to consent to research, as enshrined in Article 17 of the Oviedo Convention and in Articles 15 of its Additional Protocol;
4. where the law allowed for research on the embryo, adequate protection of the embryo as enshrined in Article 18 of the Oviedo Convention;
5. prohibition of creation of human embryos for research purposes, as enshrined in Article 18 of the Oviedo Convention;
6. protection during pregnancy or breastfeeding, as enshrined in Article 18 of its Additional Protocol;
7. respect for autonomy, as enshrined in Articles 5, and 15 of the Oviedo Convention and in Article 13 and 14 of its Additional Protocol;

8. minimisation of risks and maximisation of benefits, as enshrined in Articles 16 and 17 of the Oviedo Convention and in Articles 5, 6, 15, 17, 21, 22 and 23 of its Additional Protocol;
9. confidentiality of personal data (right to privacy) and right to information, as enshrined in Article 10 of the Oviedo Convention and in Article 25, 26, 27 and 28 of its Additional Protocol;

- in the field of donation and transfusion of blood and its components

1. the primacy of the human being over the sole interest of society or science, as enshrined in Article 2 of the Oviedo Convention;
2. equitable access to healthcare of appropriate quality of the Oviedo Convention;
3. respect for autonomy, as enshrined in Articles 5 of the Oviedo Convention;
4. protection of persons unable to consent, as enshrined in Articles 6 of the Oviedo Convention;
5. right to any medically necessary intervention during the emergency situation, as enshrined in Articles 8 of the Oviedo Convention;
6. minimisation of risks and maximisation of benefits, as enshrined in Article 8 of the Oviedo Convention;
7. confidentiality of personal data (right to privacy) and right to information, as enshrined in Article 10 of the Oviedo Convention;
8. prohibition of financial gain, as enshrined in Article 21 of the Oviedo Convention.

## 4.2. Compliance of the RA law on Transplantation of Organs and (or) Tissue of human origin, RA law on the Human Blood and its Components Donation and Transfusion, RA law on Medical Care and Services to the Population with the general human rights principles enshrined in the Oviedo Convention and its Additional Protocols

The general principles governing the RA legislation on organ and (or) tissue transplantation, genetic testing, biomedical research, donation and transfusion of blood and its components are partially in conformity with the human rights standards stipulated by the Oviedo Convention and its Additional Protocols.

**First,** the RA regulates transplantation of organs and tissues of human origin in the RA Constitution, the RA Law on Transplantation of Organs and/or Tissues of Human Origin, as well as by a number of RA Government decrees[52] and RA Minister of Health orders. The law on organ and (or) tissue

52. RA Decree N 1465-Ա on terms of use of the register for donors and recipients of organs and/or tissues of human origin that defines the procedure for the activity, registration and use of information in the register of organs, tissue donors and recipients.

RA Government Decree N 1450-Ա on the Conditions for taking bodies and (or) tissues for transplantation from a person in the detention place, as well as on the approval of conditions for medical assistance and care after taking the body and (or) tissue from a person in the detention place. The GoA decree regulates conditions for taking bodies and (or) tissues for transplantation purposes from a person in the detention place who is eligible for being a recipient for a close relative (parent, child, spouse, brother, sister).

RA Government Decree N 131-Ա on establishing a medical conclusion on the need for transplantation which defines the procedure for issuing a medical report on the need for transplantation.

RA Government Decree N 335-Ա on import and export order of human donor organs and (or) tissues, blood and its components, drugs, psychotropic substances and their precursors.

transplantation defines legal basis for human organ and (or) tissue transplantation, balancing the rights and obligations of the donors[53], the recipients, and medical institutions as well as the relations connected to transplantation. The provisions set out in the law do not apply to the organs, their parts and tissues/cells concerning the process of human reproduction (e.g., eggs, ovaries, testicles, semen, embryos), blood and its components. The law sets out the conditions[54] for organs and tissue removal from both living and deceased donor as well as limitations on the selection of living donors. These provisions include inter alia (i) (written) consent of the living donor, and recipient (including written consent of the parents or legal representative in case if the recipient is minor or with restricted active capacity), consent from a deceased person, if latter has clearly expressed his/her wishes during lifetime or in the absence of a decision, the transplantation can be performed with the consent of relatives; (ii) prohibition of financial gain or other source of profit, (iii) confidentiality regarding donors and recipients data; (iv) prohibition of export donors' organs and (or) tissue for transplantation purposes; (v) state control over the transplantation procedures. Armenian legal framework does not ensure that the recipient and, where appropriate, the person or body providing authorisation for the implantation is beforehand given appropriate information as to the purpose and nature of the implantation, its consequences and risks, as well as on the alternatives to the intervention. Moreover, it does not explicitly define that the person concerned may freely withdraw consent at any time., although these requirements are in the law on Medical Care and Assistance and can be applied to these relations as well.

**Second,** the Republic of Armenia (hereinafter RA) regulates donation and transfusion of human blood and its components in the RA Constitution, in the law on donation and transfusion of human blood and its components, and in a variety of RA Government Decrees and RA Minister Orders. The law on donation and transfusion of human blood and its components defines basic principles (i) for the organisation and provision of donation and transfusion of human blood and its components, (ii) rights, obligations and liabilities of donors, recipients, medical and other organisations included in the field, and (iii) procedures required to ensure the quality and safety of human blood and its components. The law includes provisions stipulating governance and state control over voluntary process of donation (allowed are only the reimbursement of food and travel expenses before and after blood donation), ensuring access to medical care for blood transfusion, defining national blood program and service[55] and maintaining the blood register. The provisions stipulating the processing of information registered in the blood register include (i) information regarding donor; (ii) information on side effects of blood donation and complications during transfusion while medical care was provided; (iii) information on organisation responsible for human blood donation and transfusion as well as availability of human blood in these organisations, and (iv) information regarding the defects of human blood and its components including expiration dates, safety standards. Special attention shall be paid on provision of confidential information regarding blood donors. In special cases prescribed by law, information regarding donation and transfusion of human blood can be provided without donor's consent. Additionally, the law sets out the main concepts (definitions), conditions for donation

53. E.g., Right to request full information from the medical institution regarding the expected surgical intervention and possible complications arising from the removal of an organ and (or) tissue.

54. E.g., transplantation of organs and/or tissue are allowed only in appropriate licensed medical facilities. Medical institution is liable if health condition of the donor or recipient is damaged by organ and/or tissue donation/transplantation procedure or due to violation of the terms and conditions of the transplant. Further analysis is provided in the section 3.

55. See also Art. 2 (1) p. 5, Art. 32 of the law of 2011 on donation and transfusion of human blood and its components.

and transfusion of human blood and its components, including procedures for donor blood testing, prohibitions and selection criteria for blood donors (i.e., eligibility criteria)[56] as well as requirements for obtaining consent[57]. Advertising the donation of blood or blood components and/or medical care for blood transfusion are prohibited, only if advertisement has commercial aspects.

**Third,** the Republic of Armenia regulates genetic testing for health purposes fragmentally in the provisions laid down in Law on Medical Care and Services to the Population, Law on the Human Reproductive Health and Rights to Reproduction and a variety of Decisions of the Government of Republic of Armenia[58] and Order(s) of the Ministry of Health of Republic of Armenia[59]. The Republic of Armenia does not have an exact framework of predictive genetic testing for medical purposes and medical research purposes aimed at detecting genetic predisposition or susceptibility, exceptions therefrom, as well as any specific legislation on the necessity to receive special genetic counselling therefor (the issues related to awareness are regulated in a general manner). As such, terms related to genetic testing (e.g., genetic laboratory diagnosis and licensing) are considered as a type of medical care and services. It should be also noted that a precondition for the implementation of professional and licensing requirements related to the interventions on the human genome have been eliminated in the Armenian legislation since 2017. Further, a precondition for assigning genetic testing the effectiveness and clinical utility thereof over other methods are not specifically prescribed. The Armenian Legislation has no specific provisions regarding the consent to genetic tests, however requirements to consent are stipulated in a general manner in the Law on medical Care and Services to the Population. Yet, patient management procedure (protocol) is not adopted.

Fourth, in the Republic of Armenia biomedical research is partially regulated in the provisions laid down in the Constitution, Law on Medicines, Law on Medical Care and Services to the Population and Government Decree No 168-N. Legal gaps are present throughout most of the provisions laid down in the Oviedo Convention and Additional Protocol concerning Biomedical Research.

The general principles that govern the RA legislation on organ and (or) tissue transplantation, genetic testing, donation and transfusion of blood and its components are mostly in conformity with the general human rights principles established by the Council of Europe in the Oviedo Convention and its Additional Protocols. Despite this, legal gaps are present and identified. **In Armenia, no separate laws governing genetic testing and biomedical research are available yet.**

### ► 4.2.1 Examination of potential incompatibilities

The expert examination found several incompatibilities between the provisions contained in the Armenian legislation regarding (i) organ and tissue transplantation, (ii) donation and transfusion of human blood and its components, (iii) genetic testing, (iv) biomedical research and the provisions of

56. E.g., according to the law of 2011 on donation and transfusion of human blood and its components, blood donor is considered a person who has reached the age of 18 years old, with active legal capacity and who has undergone medical examination and does not have contra-indication to donation on the basis of the well-reasoned conclusion/decision of the physician.

57. E.g., according to Art. 27 (5) of the law of 2011 on donation and transfusion of human blood and its components, transfusion is allowed only with the informed consent of the recipient. Obtaining consent from the donor is stipulated in the Art. 17. According to Art. 17, donor must give written consent and fill in the declaration on his/her health condition after receiving information in an understandable language on the purpose and process of the donation of blood and its components and related biological changes in the organism, safety measures, possible risks, rights and obligations.

58. See also No 1936-N of 5 December 2002 on licensing terms of genetic laboratories
No 1051-N of 25 June 2020 on procedures for recording DNA characteristics

59. See also No 87-N of 24 December 2013 on forensic genetic examinations

the Oviedo Convention and its Additional Protocols.

To fill in the gaps and ensure the conformity of Armenian legislation with the Oviedo Convention and its Additional Protocols, experts have formulated a list of recommendations provided below.

1. *Incompatibilities found in the field of organ and tissue transplantation*
   a. *Consent of the recipient for transplantation purposes*

## ► Analysis

The RA Law on Transplantation of Organs and (or) Tissues of Human Origin (Art. 6) stipulates that transplantation of organs and (or) tissues can be performed on a basis of written consent of the prospective recipient. In cases, where recipient is minor (i.e., has not reached 18 years of age) or is recognized as not able to consent according to the law, the transplantation procedure can be performed with the written consent of the recipient parents or legal representative.

The transplantation of organs and (or) tissue can be performed inter alia without written consent of the recipient, his/her parents or legal representative only in exceptional cases, e.g., if: (i) a delay of transplant may cause a threat to the recipient life and (ii) it is impossible to obtain consent in accordance with the existing law.

According to the Article 6 of the Law on Transplantation of Organs and (or) Tissues of Human Origin, the recipient must be given a written warning about possible complications associated with surgery in 15 days prior to the procedure.

Although, provisions on consent of the recipient are in general in conformity with the provisions laid down in the Convention (e.g., Art. 8) and its Additional Protocol, some clarifications and additional provisions are relevant. More specifically, Article 5 of the Convention as well as of its Additional Protocol stipulate that a prospective recipient and, where appropriate, the person or body providing authorization for the implantation (Article 6 of the Oviedo Convention) should receive beforehand appropriate information as to the purpose and nature of the implantation/intervention, its consequences and risks, as well as on the alternatives to the intervention. In addition, Article 5 of the Convention regulates that the person may freely withdraw consent at any time.

   b. *Selection and evaluation of a living donor*

## ► Analysis

The Armenian Law on Transplantation of Organs and (or) Tissues of Human Origin (Art. 11) stipulates the limitations on the selection of a living donors. According to Article 11, a living donor cannot be (1) minor, except for the case of bone marrow transplantation; (ii) person not able to consent in prescribed manner, (iii) pregnant, (iv) individuals who are serving a sentence in the place of imprisonment, unless the recipient is imprisoned and in case if recipient is a close relative (i.e., parent, child, husband, sister or brother); (v) a hostage and (vi) a person who has reached 65 years of age. It is also forbidden to remove organs for donation from a person who suffers a serious disease that might endanger the life and/or health of the recipient.

Though these limitations are in a good manner to evaluate potential organ living donors and are in conformity with Article 11 of the Additional Protocol, it is important to emphasise that a person is not

eligible for donation, if the removal may cause a serious risk to the life or health of the donor. In addition, a comprehensive medical examination before donation (as stipulated in the Armenian Law on Organ and (or) Tissue Transplantation of Human Origin, Article 10 – see below) shall encompass not only evaluation and reduction of possible physical risks to the health of the donor but also psychological risks.

*c. Information and consent from a living donor*

## ► Analysis

The RA Law on Transplantation of Organs and (or) Tissues of Human Origin (Art. 10) stipulates that prior to the donation, in 15 days, donor must receive in a written format information about possible consequences associated with the removal of the organs and (or) tissues. More specifically, a living donor consent shall be given voluntarily and consciously (knowingly) regarding the removal of the organs and (or) tissues. Further, Article 12 of the law stipulates that a living donor has right to (i) request full information on possible complications that might be caused after the removal of organs and (or) tissues from the medical institution where the donation is expected to be performed; (ii) receive free treatment (medical care) in case of complications in the same medical institution where donation has been performed.

Article 12 of the Additional Protocol stipulates that a donor shall be beforehand given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks. A living donor shall also be informed of the right to have access to independent advice about risks by a health professional having appropriate experience and who is not involved in the organ or tissue removal or subsequent transplantation procedures. Article 13 of Additional Protocol stipulates that an organ or tissue may be removed from a living donor only after the person concerned has given free, informed and specific consent to it either in written form or before an official body. In addition, living donor may freely withdraw consent at any time.

*d. Medical follow-up after transplantation*

## ► Analysis

The Armenian Law on Transplantation of Organs and (or) Tissues of Human Origin (Art. 10) stipulates that organ and (or) tissue removal from a living donor for transplantation purposes is allowed if a donor has undergone a comprehensive medical examination. The Law does not further provide information on medical follow-up after transplantation either for donors and/or for the recipients.

Article 7 of the Additional Protocol stipulates that an appropriate medical follow-up must be offered to living donors and recipients after transplantation. At least, short term medical follow-up is necessary to ensure recovery from the procedure. Monitoring is necessary to avoid long term effects of the donation to be identified, the complications and serious side effects on the individual's health. According to the explanatory report, para 56, both donors and the recipients cannot be forced to accept long term medical follow-up.

*e. Traceability of organs and tissues*

## ► Analysis

The Armenian Law on Transplantation of Organs and (or) Tissues of Human Origin (Art. 2.1.) contains provisions regulating the collection of information on organ and tissue donors as well as recipients. According to the Article 2.1. information collected in the (centralized/unified) register of organs and tissue shall include (i) cases of organ and tissue transplantation; (ii) information on recipients; and (iii) information on persons who have rejected to act as organ and tissue donor during lifetime. This information is considered as medical secret and might be provided to licensed medial institutions engaged in transplantation processes in the manner provided by the law.

It should be noted that Article 3 of the Additional Protocol refers to the importance of ensuring traceability of organs and/or tissues through the collection and recording of the required information.

As explained in the paragraph 39 of the Explanatory report to the Protocol, traceability means being able to track all organs or tissues from donor to recipient and vice versa in order to eliminate the risks of transmission of disease from donor to recipient and contamination of preserve material. Traceability is important to inform for public health reasons as well as donors and recipients on possible complications.

Given this, the Armenian authorities could consider amending the Article 2.1. with the provisions regulating the collection and recording of the required information from donor to recipient and vice versa. Armenian authorities could consider collecting information (i) on persons who declared objection to post-mortem removal; (ii) on persons, from whom organs and tissues have been removed; (iii) living donation and the outcomes after donation; (iv) traceability of organs and tissues; and (v) serious adverse events and reactions, including during and after transplantation of organs and tissues from a deceased person.

*f. Prohibition of financial gain (including advertisement) and compensation for undue damage*

## ► Analysis

The Armenian Law on Transplantation of Organs and (or) Tissues of Human Origin (Art. 2) prohibits to make organs and (or) tissues a source of profit from a living or deceased donor. Article 2 clarifies that 'profit' is considered to be money for donor or through his/her intermediary, property or any other (comparable) advantage, a promise or an offer that might be accepted by donor.

Further, Article 11 stipulates that any person who is forced to give an organ donation to a living donor is subject to liability in the manner prescribed by the legislation of the Republic of Armenia. Important to note, that medical institutions are liable in case donor or recipient health is damaged due to organ and (or) tissue collection and/or due to the violation of the procedures for transplantation (Art. 14). Nonetheless, the law does not include provisions for compensation in case of undue damage as seen in Article 24 of the Convention and Article 25 of the Additional Protocol (vide infra).

Armenian legislation does not regulate advertising related to transplantation of organs and tissues of human origin, although the commercials of organ/tissue transplantation are prohibited according the law on Advertising (Article 15). However, there are not relevant norms for liability in the case of violation of article 15. In this regard Armenian legislation needs amendments. It should be noted that any attempt to advertise anything to do with organ or tissue transplantation with a view to financial or

equivalent gain for any party shall be prohibited according to Article 21 of the Additional Protocol (vide infra).

The prohibition of financial gain or comparable advantage of organs and tissues for the person from whom they have been removed or for a third party is established in Article 21 of the Convention and in Articles 21 and 22 of its Additional Protocol.[60]

As stipulated in Article 21 of the Additional Protocol, the prohibition of financial gain does not prevent: (i) compensation of living donors for loss of earnings and other justifiable expenses caused during or as a result of donation or other parts of the transplant process (e.g., during medical examination); (ii) reasonable remuneration, i.e., payment of a justifiable fee for legitimate medical or related technical services performed as part of the transplantation process (e.g., the cost of retrieval, transport, preparation, preservation and storage of organs or tissues); and (iii) compensation in case of undue damage resulting from the removal of organs and/or tissues from living persons (e.g., any harm that might occur after transplantation procedure that is not a normal consequence of transplantation). The latter refers to Article 25 of the Additional Protocol stipulating compensation for undue damage resulting from transplantation procedures.

Next to the principle of prohibition of financial gain is the principle of prohibition of advertisement – the prohibition to advertise the need for, or the availability of, organs or tissues, with a view to offering or seeking financial gain or comparable advantage. That principle is also laid down in Article 21 of the Additional Protocol.

The principles established in Articles 2 and 14 of the Armenian Law on Organ and (or) Tissue Transplantation of Human Origin are partially in compliance with the Oviedo Convention and its Additional Protocol. Concomitantly, few remarks can be considered. Articles 2 and 14 do not cover: (i) compensation of costs incurred by (potential) donors before donation (e.g., pre-operative screening costs); (ii) compensation of all of the costs incurred by donors' post-donation (e.g., expenses related to the medical follow-up); (iii) loss of income by (potential) donors linked to the donation; (iv) compensation in the event of complications resulting from the donation, and (v) prohibition of advertisement. These clarifications could be included.

*g. International cooperation and organ and (or) tissue exchange*

## ► Analysis

The Armenian Law on Transplantation of Organs and (or) Tissues of Human Origin (Art. 10) prohibits the export of organs and (or) tissues of human origin from the Republic of Armenia for transplantation purposes.

It should be noted that current legislation on organ and (or) tissue exchange at international level is incomplete due to insufficient measures and inappropriate safeguards regarding quality and safety of organs and tissues as well as unequitable distribution policy (the rate of total organ donation between 2011 and 2013 in Armenia was decreasing). Given this, Armenian legislation on organ and (or) tissue exchange does not fully comply with the provisions laid down in the Art. 3 and 27 of the Additional Protocol.

60. See for more guidance, the Guide for the Implementation of the Principle of the Prohibition of Financial Gain with Respect to the Human Body and its Parts from Living or Deceased Donors, adopted by the Committee on Bioethics of the Council of Europe at its 12th meeting on 26-27 October 2017.

2. Incompatibilities found in the field of donation and transfusion of human blood and its components

*a. Informed consent and rights of the donor*

## ► Analysis

The Armenian Law on donation and transfusion of human blood and its components stipulates the definition of 'informed consent of the donor' (Art. 2). According to the definition an informed consent of the donor is voluntary given consent regarding the donation of blood and its components based on information provided to the donor in an understandable manner from medical staff about the purpose and process of donation, biological changes in the organism of the donor caused due to donation, safety measures and possible risks.

Further, Article 14 of the national law stipulates that the blood used for human medical purposes shall be taken only from a human.

Article 17 of the national law stipulate provisions regulating the provision of information to a donor in order to obtain his/her consent. According to the provisions in Article 17 of the national law, a blood donor shall receive information regarding the purpose and process of the donation of blood and its components, the biological changes in the organism of a donor by donation procedure, safety measures and possible risks, as well as rights and responsibilities in a language he/she can understand before giving a written consent.

Article 25 of the law stipulates rights, duties and responsibilities of the donor. According to the provisions in Article 25, donor has right to (i) receive complete information before blood donation about (a) the process of blood donation, (b) possible complications related to blood donation, (c) the procedure regarding examination of the blood donor, (d) rights and duties of the donor as well as privileges; (ii) receive information on results of the blood examination; (iii) receive compensation in case of damage to the health of the in a manner prescribed by law; (iv) refuse from the donation as well as declare the components of blood not suitable for use without explaining the reasons; (v) demand to ensure confidentiality of blood donation except in cases provided by the law of the RA.

In this regard, Art. 5 of the Oviedo Convention stipulates that a person shall be given appropriate information to the purpose and nature of the intervention as well as on its consequences and risks he/she is undergoing on. Explanatory report para 35 suggests that a person consent is considered as informed if it includes inter alia information on potential consequences of the planned intervention and is given in the absence of any pressure from anyone as well as risks related to the individual characteristics of a person. Further, Article 5 stipulates that person undergoing intervention may freely withdraw consent at any time, except in cases, as provided in the para 38 of the Explanatory report, where the refusal may endanger the life of the person undergoing the intervention.

*b. Informed consent and rights of the recipient*

The RA Law on donation and transfusion of human blood and its components stipulates the definition 'informed consent of the recipient' (Art. 2). According to the definition an informed consent of the recipient is a voluntary given consent regarding the transfusion of blood components based on information provided in an understandable manner by the medical staff about the purpose and the process of the transfusion, biological changes in the organism of the recipient caused due to

transfusion of blood components, safety measures and possible risks.

Article 27 of the national law specifies the principles of blood transfusion. According to the provisions in Article 27, blood transfusion is performed by a doctor or a nurse under their supervision only for the treatment purposes as well as to save the life and to ensure the health recovery of the recipient. Further, transfusion of blood components is allowed only with the informed consent of the recipient, except in cases of emergency where recipient's life is in danger and (i) his/her physical and mental condition does not allow to provide informed consent; (ii) the consent cannot be obtained from the legal representative.

Article 29 of the national law stipulates provisions regulating the rights of the recipient. According to the provisions in Article 29, before transfusion of blood components a recipient or his/her legal representative has right to (i) receive complete and reliable information on the process of transfusion, (ii) complications related with the transfusion as well (iii) withdraw consent to transfusion except in case of imminent danger to life. Where recipient or his/her legal representative refuse the transfusion of blood components, the recipient or his/her legal representative shall be informed about the degree of deterioration of the health condition of the person concerned. Finally, recipient has right to receive compensation for health damage caused during the transfusion as well as demand confidentiality regarding the services he/she has received and his/her health condition except in cases provided in the law.

Similarly, as in the sub-section a) Informed consent and rights of the donor, Art. 5 of the Oviedo Convention stipulates that a person shall be given appropriate information on the purpose and nature of the intervention as well as on its consequences and risks. As provided in the para 35 of the Explanatory report, a person consent is considered free and informed if it includes inter alia information on potential consequences of the planned intervention or of its alternatives as well as risks related to the individual characteristics of a person, and in the absence of any pressure from anyone. Further, Article 5 stipulates that person undergoing intervention may freely withdraw consent at any time. However, there may be circumstances where the withdrawal of a consent may not be followed for example during an operation. In such situation the doctor may have to continue the operation so as to avoid seriously endangering the health of the person undergoing the intervention. Additionally, provisions laid down in Article 10 para 2 of the Convention stipulate respect individuals' wishes not to be informed regarding the intervention under which they are concerned. Para 40 of the Explanatory report suggests that patients wish not to be informed shall be respected, but the consent itself shall be proposed to the patient. In this regard, if recipient does not wish to be informed on the procedure, risks and complications related with the transfusion of blood and its components, his/her consent for transfusion can be not so informed as it is seen to be in the context of Article 5.

*c. Principles of voluntary donation without financial gain*

## ► Analysis

The Armenian Law on donation and transfusion of human blood and its components stipulates that donating human blood is a voluntary act (Art. 14). However, according to Article 5 of the Law, wording 'gradual transition' (in Armenian 'աստիճանական անցումը') is included in the main principle of state policy to provide free voluntary donation of blood and its components. In this regard, wording 'gradual

transition' included in the Art. 5 causes uncertainty whether donation and transfusion of blood and its components in the RA is fully voluntary or there is an undergoing shift toward voluntary donation without financial gain.

*d. Prohibition of financial gain of the blood and its components*

The Armenian Law on donation and transfusion of human blood and its components stipulates that advertising for the donation of blood or blood components for commercial purposes of transfusion and treatment is prohibited (Art. 9). Nevertheless, wording 'reimbursable donor' (in Armenian 'փոխհատուցվող դոնոր') is included in the provisions regulating the procedure for taking blood and its components (Art. 18) and 'monetary compensation' (in Armenian 'դրամական փոխհատուցում') is included in the provisions regulating the privileges granted to blood donors (Art. 26) in addition to other compensations such as food and travel costs.

Further, Article 23 of the RA Constitution envisages that eugenic practices, making the human organs and tissues a source of financial profit, the reproductive cloning of a human being in the fields of medicine and biology shall be particularly prohibited. Article 183 of the RA Criminal Code envisages criminal liability for illegal turnover of human organs (and) or tissues, embryo,ֆետուս, biological materials and liquids In this regard, Article 21 of the Convention prohibits that the human body and its parts give as such rise to financial gain. According to para 132 of the Explanatory report, blood and its components must not be bought or sold or give rise to financial gain for the person from whom they have been removed or for a third party, i.e., an individual or a hospital.

3. Incompatibilities found in the field of genetic testing

*a. Interventions on the human genome or so called 'genetic engineering' or 'gene therapy'*

## ► Analysis

Since 2017 in the Armenian legislation, a precondition for the implementation of professional and licensing requirements related to the interventions on the human genome have been eliminated. As such, the Armenian legislation does not define professional, ethical and logistic conditions. According to the information received from RA Ministry of Health, licenses or permissions for performing interventions on the human genome have never been issued in the Republic of Armenia.

RA Constitution in Article 29 provides a general principle of non-discrimination. According to such provision, discrimination based on sex, race, skin colour, ethnic or social origin, genetic features, language, religion, world view, political or other views, belonging to a national minority, property status, birth, disability, age, or other personal or social circumstances shall be prohibited.

Article 11 of the Oviedo Convention provides the general principle of non-discrimination with a prohibition of any form of discrimination against a person on the grounds of his or her genetic heritage.

As indicated in Article 13 of the Oviedo Convention, "an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes , and only if its aim is not to introduce any modification in the genome of any descendants". Further, as indicated in the Explanatory report para 73, the aim of the gene therapy is to correct changes to the human genetic heritage which may result in hereditary diseases, e.g., to correct the genetic defects in the somatic cells. In this regard, para 90 of the explanatory report clearly states that interventions on human

genome to be performed for purposes not related to a disease or to an ailment shall be prohibited.

As such, gene therapy shall be provided in accordance with Article 4 of the Convention by persons with appropriate qualifications, professionals obligations and standards. As explained in the para 29 and 30 of the Explanatory report of the Convention, the term 'intervention' covers all medical activities for the purpose of preventative care, diagnosis, treatment or rehabilitation or research and shall be in compliance with the law in general, supplemented and developed by professional rules.

*b. Predictive genetic testing*

## ► Analysis

The Republic of Armenia does not have an exact framework of predictive genetic testing for medical purposes and medical research purposes aimed at detecting genetic predisposition or susceptibility, exceptions therefrom, as well as any specific legislation on the necessity to receive special genetic counselling therefor (the issues related to awareness are regulated in a general manner). As such, terms related to genetic testing (e.g., genetic laboratory diagnosis and licensing) are considered as a type of medical care and services defined in the Decision No 276-N of 27th March 2008 and Decision of the RA Government No 196-N of 5th December 2002 respectively.

Nevertheless, genetic testing is used to proceed with reproductive health services. According to the Article 12 of the RA Law on the Human Reproductive Health and Rights to Reproduction, individuals who wish to become a gametes and/or embryo donor, or a surrogate mother shall undergo medical genetic testing. Further, Article 15 of the same Law stipulates that the surrogate-born baby shall be given to the person in case test confirms using assisted reproductive technology that (i) at least one of the spouses or an unmarried person is the biological parent of the child; (ii) the surrogate mother is not the biological parent of the child.

As indicated in the para 29 of the Explanatory report of the Additional Protocol concerning Genetic Testing for Health Purposes 'genetic test' is based on (i) methods used and (ii) purpose of the test. In this regard, Article 12 of the Convention stipulates that predictive genetic test are aimed to identify a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease followed by an appropriate genetic counselling.

*c. Quality of genetic services*

## ► Analysis

The RA Law on Medical Care and Services to the Population (Art. 6) stipulates that a quality control system shall be implemented in the organisations performing laboratory activities. The quality control system and its implementation procedure as well as the procedure of designating reference laboratories in the health care sector shall be defined by the Government (Government decision No 1413-N of September 2, 2021 and No 1206-N of 22th of July 2021). Next, in-vitro products are subject to quality control which shall be defined by the Authorized Body. However, the relationships related to the use, storage or transmission of the biological samples required for genetic testing for health purposes are not regulated.

Further, Decision of the Government No 1936-N of 5 December 2002 stipulates those persons with

relevant specialization are performing genetic tests and defines the criteria for continuous professional development (e.g., necessary essential training credits).

In this regard, Article 5 of the Additional Protocol on Genetic Testing for Health Purposes stipulates that genetic services must be of appropriate quality. This means, that (i) genetic test shall be of widely recognized criteria of scientific and clinical validities at international level; (ii) a general quality control system (e.g., quality assurance requirements) is implemented in each laboratory regarding laboratory procedures and laboratories are subject to regular monitoring preferably by an external audit to guarantee the confidentiality of data, security of the biological samples, the quality of the procedures and the specific scientific and technical skills of the staff involved; (iii) persons providing genetic services have appropriate qualifications (i.e., at national level and in-service trainings) in accordance with professional obligations and standards.

*d. Clinical utility*

The Armenian Law on Medical Care and Services to the Population defines that medical care and healthcare services, including decisions made for the purposes of preventive, diagnostic and treatment care are based on evidence of available treatment efficacy and safety (evidence-based medicine). However, as a precondition for assigning genetic testing the effectiveness and clinical utility thereof over other methods are not specifically prescribed in the current legislation. Also, in the context of genetic testing, patient management procedure (protocol) is not adopted yet.

In this regard, Article 6 of the Additional Protocol on Genetic Testing for Health Purposes stipulates that clinical utility of a genetic test (i.e., clinical value of the test results to be addressed to person concerned to make his/her decision in terms of prevention and treatment) shall be an important criterion to decide whether it is appropriate to offer a genetic test to a person or a group of persons (e.g., family members). Further, para 59 of the Explanatory report of the Protocol indicates that providing clinical utility of genetic testing to an individual might be beneficial (e.g., information on the risks of developing the disease) and lead toward achieving good medical practice.

*e. Information and genetic counselling*

## ► Analysis

The Armenian Law on Medical Care and Services to the Population (Art. 15) regulates provisions related to the provision of information in a general manner. As such, every person has 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 in an accessible manner.

4. Incompatibilities found in the field of biomedical research

There is no AR legislation on Biomedical Research. In fact, there is one general provision on Article 38 of the AR Law on Medical Care and Assistance to the Population, that needs to be regulated.

## ► 4.3 Conclusions

- ✚ The expert examination has identified that several provisions of the Oviedo Convention and of its Additional Protocols are not properly addressed in the Armenian legislation on (i) organ and (or) tissue transplantation of human origin, (ii) donation and transfusion of human blood and

its components, (iii) genetic testing and (iv) biomedical research. The experts suggest revising some aspects of the Armenian legislation related to the above-mentioned fields to ensure its compliance with the Oviedo Convention and its Additional Protocols. The identified legal gaps are examined and followed by the recommendations.

## ► Recommendations

**In what concerns organ transplantation and tissues of human origin legislation:**

- To ensure compliance with Article 19 of the Convention and its Additional Protocol, the Armenian authorities should consider amending Article 6 of the Law on Transplantation of Organs and (or) Tissues of Human Origin to make explicit that the prospective recipients shall beforehand also be given appropriate information about: (i) the purpose and nature of the implantation and (ii) the alternatives to the intervention. Besides that, it is important to mention that recipients should have freedom of consent (except in cases if there is a threat to the life or to the health of the recipient).
- To ensure compliance with Article 11 of the Additional Protocol, the Armenian authorities should consider amending Article 10 and 11 of the Law on Transplantation of Organs and (or) Tissues of Human Origin as follows: (i) organ and (or) tissue removal cannot be carried out if there is a serious risk to the life or health of the donor; (ii) a comprehensive medical examination shall include evaluation and reduction of (physical and) psychological risks before organ and (or) tissue removal.
- It is also recommended the addition to the requirements for organ removal from a living donor that the recipient must have a close personal relationship with the donor as defined by law, or, in the absence of such relationship, only under the conditions defined by law and with the approval of an appropriate independent body, as referred in art. 10 of the Additional Protocol.
- To ensure compliance with Articles 12 and 13 of the Additional Protocol, the Armenian authorities should consider amending Article 10 and 12 of the Law on Transplantation of Organs and (or) Tissues of Human Origin to make explicit that (i) a living donor shall have an independent consultation with medical professional who is not involved in donation/ transplantation procedures; and (ii) a living donor consent shall receive appropriate information on the purpose and nature of the removal and not limited to the consequences and risks only.
- It also must be clear stressed that the necessary consent of the living donor must have been given expressly and specifically, either in written form or before an official body, in accordance with Article 19 of the Oviedo Convention. Consent must always be in writing or before an official body.
- To ensure compliance with Article 7 of the Additional Protocol, the Armenian authorities should consider amending Article 10 of the Law on Transplantation of Organs and (or) Tissues of Human Origin to make explicit that the prospective recipients and living donors are given access to medical follow-up after transportation. Though living donors and recipients can refuse to accept long term medical follow-up, the state should ensure that appropriate medical follow-up is offered to living donors and recipients after transplantation to avoid possible consequences and risks associated with donation and transplantation.

- In order to improve the quality and safety of the donation and transplantation process, the Armenian authorities might consider establishing (i) a real-time national living organ donor registry; and (ii) a central reporting and management system for serious adverse events and reactions.

- To ensure compliance with art. 24 of the Oviedo Convention it is recommended to add a provision regarding the compensation for damages for the person who has suffered undue damage resulting from an intervention.
- To ensure compliance with Article 25 of the Oviedo Convention and Article 26 of the Additional Protocol, the Armenian authorities should consider attaching clear sanctions to the infringements of the prohibitions of financial gain and advertisement, to the extent that this has not yet been properly addressed by other national legislation (e.g., the prohibition for advertising blood and its components is stipulated in the Armenian Law on Donation and Transfusion of Blood and its Components).
- It is recommended to Armenian authorities to consider. adopting legislation to ensure that there is efficient international co-operation on organ and tissue transplantation.
- It has been noticed that RA legislation on organ transplantation has no provision about the existence of an official/competent body)in the field of transplantation. In order to comply with the Oviedo Convention, it is necessary to establish such a body provided by law that certificates the conditions of the transplantation as referred in Articles 19 and 20 of the Oviedo Convention.
- It is recommended to Armenian authorities to consider adopting legislation to ensure that there is efficient international co-operation on organ and tissue transplantation.

**In what concerns blood transfusion**

- To ensure compliance with Article 5 of the Convention, the Armenian authorities may consider amending Article 2 and Article 27 to include provisions stipulating potential consequences related with transfusion in the scope of the informed consent as well as information to be provided to a recipient regarding the alternatives, such as artificial blood components (e.g., PFCs) used in case of emergency. Further, it is recommended to make explicit in Article 2, 27 and 29 that recipient gives his/her consent in the absence of any pressure from anyone (where recipient is considered not able to consent, the authorisation of legal representative or a decision of medical board shall be addressed for the vital benefits and best interests of patient). In addition, where necessary, Armenian authorities should consider wishes of recipients regarding the depth of information they wish to receive before giving their consent.
- However, few recommendations can be considered to ensure compliance with provisions laid down in the Oviedo Convention. As such, to ensure the compliance with Article 5 of the Convention, the Armenian authorities may consider amending Article 2 and Article 17 to include provisions stipulating potential consequences of the intervention considered related with donation in the scope of the informed consent. Further, it is recommended to make explicit in Article 2, 17 and 25 that a donor gives his/her consent in the absence of any pressure from anyone. In addition, where necessary, Armenian authorities should consider the possibility for donors to have access to information they wish to have before giving their consent.
- The provisions laid down in the national law are in conformity with the recommendations laid down in the Resolution CM/RES(2008)5 of the Committee of Ministers to member States on donor responsibility and on limitation to donation of blood and blood components according to which blood components shall be produced solely from blood collected from safe blood donors.
- The Armenian authorities may consider removing wordings 'gradual transition' to be in conformity with the main principles and provisions laid down in Articles 5 of the Convention of Human Rights and Biomedicine regarding free and voluntary intervention in the health field.
- To ensure compliance with Article 21 of the Convention, it is recommended that Armenian authorities consider amending Article 26 of the RA law on donation and transfusion of human blood and its components to make explicit that law includes the prohibition of financial gain of the blood and its components, as such, in particular that blood donors shall not receive money or other advantages not compatible with the principle of prohibition of financial gain (see Guide on prohibition of financial gain).

**In what concerns genetic testing and interventions to the human genome**

- RA legislation has already a general non-discrimination provision that includes the prohibition of genetic discrimination.
- Since there are no specific provision regarding interventions on the human genome or genetic testing, it is recommended that, before introducing such practices a robust legislation must be built in line with the Oviedo convention and its Additional Protocols.
- Further, it is recommended that healthcare professionals providing genetic testing shall receive appropriate in-service and national trainings to comply with the specific scientific and technical standards and not limit professional development to a number of required credits.
- To ensure compliance with Article 6 of the Additional Protocol on Genetic Testing for Health Purposes, the Armenian authorities should amend the relevant legislative acts as follows: (i) include criteria to assign a genetic test to a person or a group of persons (in accordance with para 57 of the Explanatory report of the Protocol); (ii) to ensure that a person has right to be informed on the genetic tests results including possible risks of developing diseases even in case where no preventive no treatment are available.
- Since there is no RA specific legislation on genetic testing it is recommended that genetic counselling should be legislated following the principles of Oviedo Convention and its Protocols when such legislation takes place.

**In what concerns Biomedical research Biomedical research is regulated in Articles 15º to 17º of the Oviedo Convention as well as on the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research.**

- It has been noticed that there is no RA legislation on Biomedical Research. In fact, there is one general provision on Article 38 of the AR Law on Medical Care and Assistance to the Population, that needs to be regulated.
- Consequently, it is recommended, and also strongly encouraged to regulate biomedical research (including clinical trials) in accordance with Oviedo Convention and its Additional Protocols.

| Field of examination | Compatibility/incompatibility with the Oviedo Convention and recommendations | Compatibility/incompatibility only with the Additional Protocols of the Oviedo Convention and recommendations |
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| *Informed consent:*<br><br>1) **Consent** for an intervention in the health field (as referred to in the general rule of Art. 5);<br><br>2) **Right to information** regarding the patient´s health (as referred to in art. 10). | **Compatibility with the Oviedo Convention:**<br>***1) Consent***<br>• Expressed consent is required for research (art. 25, 4 of the Armenian Constitution);<br>• General rule of consent (art. 14, 1 p. 8; 16, 1 Law on Medical Care and Services to the Population);<br>• Exceptions to the informed consent rule (art. 24, 1; art. 16, 5 Law on Medical Care and Services to the Population);<br>• Withdrawal of consent (art. 25, 1; art. 14, 1 p.3 Law on Medical Care and Services to the Population).<br>• Protection of persons not able to consent (art. 16, 3 and 4; art. 15, 2 Law on Medical Care and Services to the Population);<br>***2) Right to information:***<br>• Right to know (art. 14, 13; art. 15, 1 Law on Medical Care and Services to the Population);<br>• Right not to know (art. 14, 1 p. 11 Law on Medical Care and Services to the Population);<br>• Recommendations for full compliance with the Oviedo Convention:<br>• Undertake a clearer and more understandable free informed consent framework, including a better elaboration for the protection of persons not able to provide consent, and the inclusion of provisions related to emergencies when there is a previously expressed wish.<br>• Proceed with a review of the legislation regarding free informed consent towards its implementation by the standards provided by the convention. | |
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| Field of examination | Compatibility/incompatibility with the Oviedo Convention and recommendations | Compatibility/incompatibility only with the Additional Protocols of the Oviedo Convention and recommendations |
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| **Reproductive health rights** | **INCOMPATIBILITY WITH THE OVIEDO CONVENTION**<br>• The RA legislation is not compatible with the Oviedo Convention regarding sex selection, i.e giving the right to plan the sex of the future child while using ARTs when there are three or more children of the same sex in the family (RA legislation), and Article 14 of the Oviedo Convention which prohibits the use of techniques of medically assisted procreation for the purpose of choosing a future child's sex (except where serious hereditary sex-related disease is to be avoided).<br>**Recommendations for full compliance with the Oviedo Convention:**<br>• Concerning the RA Law on Reproductive Health and Reproductive Health Rights, the provision that allows to plan the sex of the future child while using ARTs, when there are three or more children of the same sex in the family should be reconsidered to reflect the prohibition laid down in Art. 14 of the Oviedo Convention.<br>• Research on embryos in vitro would need to be addressed, in order to define the scope of clear provisions regulating the research on embryos in vitro, including the conditions and terms, where the research can be done and the means of embryo protection (artº 18.1 of the Oviedo Convention).<br>• To add a provision prohibiting the sole creation of human embryos for research purposes (artº 18.2 of the Oviedo Convention)<br>• The meaning of "saving embryos for monetary compensation" should be clearly explained in order to evaluate if it conflicts or not with art. 18 of the Oviedo Convention and the concept of "adequate protection". | |

| Field of examination | Compatibility/incompatibility with the Oviedo Convention and recommendations | Compatibility/incompatibility only with the Additional Protocols of the Oviedo Convention and recommendations |
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| **Transplantation of Organs and Tissues** | **Compatibility with the Oviedo Convention:**<br>• There is no incompatibility but several provisions contained in the Armenian legislation regarding organ and tissue transplantation, can be improved to fully comply with the provisions of the Oviedo Convention and its Additional Protocols.<br>• Regarding articles 5 and 6 of the RA Law on Transplantation of Organs Tissues, the provisions on consent of the recipient are in general in conformity with the provisions laid down in the Convention (e.g., Art. 8) and its Additional Protocol, but some clarifications and additional provisions are needed; more specifically, Article 5 of the Convention as well as the Additional Protocol, both stipulate that a prospective recipient and, where appropriate, the person or body providing authorization for the implantation (Article 6 of the Oviedo Convention) should receive beforehand appropriate information as to the purpose and nature of the implantation/intervention, its consequences and risks, as well as on the alternatives to the intervention.<br>**Recommendations for full compliance with the Oviedo Convention:**<br>• The living donor must give the necessary consent in an express and specific way, either in written form or before an official body, in accordance with Article 19 of the Oviedo Convention. Consent must always be in writing or before an official body.<br>• It should be added a provision regarding the compensation for damages for the person who has suffered undue damage resulting from an intervention, in order to ensure compliance with artº 24 of the Oviedo Convention<br>• The Armenian authorities should consider attaching clear sanctions to the infringements of the prohibitions of financial gain and advertisement, to the extent that this has not yet been properly addressed by other national legislation in a way to ensure compliance with Article 25 of the Oviedo Convention and Article 26 of the Additional Protocol.<br>• Armenian authorities should consider adopting legislation to ensure that there is efficient international co-operation on organ and tissue transplantation.<br>• Armenian authorities might consider establishing (i) a real-time national living organ donor registry; and (ii) a central reporting and management system for serious adverse events and reactions, in order to improve the quality and safety of the donation and transplantation process. This body should be provided by law and certificates the conditions of the transplantation, as referred in Articles 19 and 20 of the Oviedo Convention. | **Compatibility only with the Additional Protocol of the Oviedo Convention:**<br>• The Armenian Law on Transplantation of Organs and (or) Tissues of Human Origin (Art. 11) stipulates the limitations on the selection of living donors are in conformity with Article 11 of the Additional Protocol.<br>**Recommendations for full compliance with the Additional Protocol:**<br>• Armenian authorities should consider amending Article 10 and 11 of the Law on Transplantation of Organs and (or) Tissues of Human Origin as follows: (i) organ and (or) tissue removal cannot be carried out if there is a serious risk to the life or health of the donor; (ii) a comprehensive medical examination shall include evaluation and reduction of (physical and) psychological risks before organ and (or) tissue removal. This way it is ensured compliance with Article 11 of the Additional Protocol.<br>• Concerning the organ removal from a living donor, the recipient must have a close personal relationship with the donor as defined by law, or, in the absence of such relationship, only under the conditions defined by law and with the approval of an appropriate independent body, as referred in art. 10 of the Additional Protocol. |

| Field of examination | Compatibility/incompatibility with the Oviedo Convention and recommendations | Compatibility/incompatibility only with the Additional Protocols of the Oviedo Convention and recommendations |
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| **Transplantation of Organs and Tissues** | | • Armenian authorities should consider amending Article 10 and 12 of the Law on Transplantation of Organs and (or) Tissues of Human Origin to make explicit that (i) a living donor shall have an independent consultation with medical professional who is not involved in donation / transplantation procedures; and (ii) a living donor consent shall receive appropriate information on the purpose and nature of the removal and not limited to the consequences and risks only. This way it is ensured compliance with Articles 12 and 13 of the Additional Protocol, the<br>• Armenian authorities should consider amending Article 10 of the Law on Transplantation of Organs and (or) Tissues of Human Origin to make explicit that the prospective recipients and living donors are given access to medical follow-up after transportation, to ensure compliance with Article 7 of the Additional Protocol.<br>• Armenian authorities should consider amending the Article 2.1 of the Law on Transplantation of Organs and (or) Tissues of Human Origin with the provisions regulating the collection and recording of the required information from donor to recipient and vice versa, ensuring this way compliance with article 3 of the Additional Protocol.<br>• Armenian authorities should consider collecting information (i) on persons who declared objection to post-mortem removal; (ii) on persons, from whom organs and tissues have been removed; (iii) living donation and the outcomes after donation; (iv) traceability of organs and tissues; and (v) serious adverse events and reactions, including during and after transplantation of organs and tissues from a deceased person. |

| Field of examination | Compatibility/incompatibility with the Oviedo Convention and recommendations | Compatibility/incompatibility only with the Additional Protocols of the Oviedo Convention and recommendations |
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| **Genetic testing** | **Compatibility with the Oviedo Convention:**<br>Compatible but there is no specific provision regarding interventions on the human genome or genetic testing.<br>**Recommendations: for full compliance with the Oviedo Convention:**<br>• In order to ensure compliance with Article 6 of the Additional Protocol on Genetic Testing for Health Purposes, the Armenian authorities should:<br>• Include criteria to assign a genetic test to a person or a group of persons (in accordance with para 57 of the Explanatory report of the Protocol);<br>• Ensure that a person has right to be informed on the genetic tests results including possible risks of developing diseases even in case where no preventive no treatment are available.<br>• Build a robust legislation in line with the Oviedo Convention and its Additional Protocols regarding interventions on the human genome or genetic testing, taking into consideration the existing gap on specific provisions in this matter.<br>• Provide appropriate in-service and national trainings to healthcare professionals that are performing genetic testing, in order to comply with the specific scientific and technical standards and not limit professional development to a number of required credits.<br>• Legislate on genetic counselling following the principles of Oviedo Convention and its Protocols when such legislation takes place. | **Compatibility with the Oviedo Convention:**<br>• Compatible but there is no RA legislation on Biomedical Research although there is one general provision on Article 38 of the AR Law on Medical Care and Assistance to the Population, that needs to be regulated.<br>**Recommendations for full compliance with the Oviedo Convention:**<br>• To regulate biomedical research in accordance with the Oviedo Convention and its Additional Protocols. |
| **Biomedical research** | **Compatibility with the Oviedo Convention:**<br>• Compatible but there is no RA legislation on Biomedical Research although there is one general provision on Article 38 of the AR Law on Medical Care and Assistance to the Population, that needs to be regulated.<br>**Recommendations for full compliance with the Oviedo Convention:**<br>• To regulate biomedical research in accordance with the Oviedo Convention and its Additional Protocols. | |