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On the Protection of Human Rights and Dignity in Biomedical Research in the Member States of the Commonwealth of Independent States

The Law identifies the system of state guaranties ensuring the protection of human rights, dignity, autonomy and wholeness for biomedical research participants. This Law relies on the statutory provisions of the State Constitution, and corresponds to the required principles stated in the Nuremberg Code, International Code of Medical Ethics of World Medical Association (WMA), The Declaration of Helsinki, EC Convention on Human Rights in Biomedicine, The CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, also in the WHO and ICH Guidelines for Good Clinical Practice, and in the WHO Operational Guidelines for Ethics Committees That Review Biomedical Research.

The order of conducting biomedical research is regulated separately by corresponding national legislative acts, and also by international agreements [treaties] signed by the State.

CHAPTER 1. GENERAL STATEMENTS

Article 1. National Legislation on Protection of Human Rights and Dignity of Biomedical Research Participants Involving

National legislation on protection of human rights and dignity of biomedical research participants comprises this law, other national laws and normative legislative acts.

Article 2. The Scope

This Law applies to the State citizens who participate in biomedical research and to all institutions and all individuals engaged in the conduct of biomedical research carried out within the territory of the State.

Foreign citizens, and persons with no citizenship, residing in the territory of the State and being participants of biomedical research, enjoy every right established by this Law equally with the State citizens.

This Law covers the whole range of biomedical research involving human subjects that imply any intervention, including research carried out on embryos *in vivo*, but excluding research carried out on embryos *in vitro*.

Article 3. Definitions

The definitions provided within this Article apply to terms as they are used in this Law.

- **Biomedical research** (henceforth -- research) -- A research involving human subjects and conducted with the purpose of studying new diagnostic, therapeutic and/or prophylactic products, devices and methods, gaining new knowledge on human morphology, physiology and psychology in conditions of the norm and pathology and in extreme situations. Biomedical research may provide for the benefit of a particular individual involved in research, or it may not necessarily result in the direct benefit for the individual participant.
- **Research participant (human subject involved in a research)** An individual who participates in biomedical research either as the direct recipient of an intervention (eg, study product or invasive procedure) with the purposes of achieving research goals, or as a member of comparison group (control group). The participant may be a healthy volunteer, or a patient with a condition unrelated to the research carried out, or a patient whose condition is relevant to the use of the study product or problems being investigated.
- **Ethics committee (EC) –** An independent body operating on the level of a medical institution (local), country region (regional), state (national) or a group of states (international). EC is composed of both professionals (medical specialists and researchers) and community representatives, whose responsibility is to guarantee, by means of ethical review, the protection of human rights, safety and well-being of human subjects involved in a research;
- **Informed consent** -- Confirmation by a research participant of his/her voluntary decision to participate in a specific research made on the basis of information about the research.
- **Confidentiality –** Nondisclosure of information allowing identify the personality of a research participant, and of any research data of a confidential nature.
- **Benefit –** Valuable or desired effect, or advantage resulting from participation in a research.
- **Risk –** The probability of harm or damage (be it physical, psychological, morphological, social or economic) resulting from participation in a research. Both, probability and the degree of harm or damage may vary from minimal to extensive.
- **Minimal risk –** The probability of health damage that is no greater than that ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests.
- **Placebo – I**ndifferent substance that differs neither in form nor in taste from a tested product [device].

- **In vitro –** “in test-tube” refers to tests or observations that are not involving a living organism.
- **In vivo – “**in living being” refers to tests or observations that are conducted on a living

Article 4. State policy on protection of human rights and dignity of biomedical research participants

State police regarding the protection of human rights and dignity of a biomedical research participant is directed towards providing conditions for safeguarding participant’s health, receiving medical care adequate to contemporary scientific and practical achievements, and preventing any discrimination in the course of the research. State policy on protection of human rights and dignity of a biomedical research participant is carried out in accordance to the following principles:

- the scientific progress in medicine and biology that would serve to improve the quality of life, is impossible without biomedical research involving human subjects;
- in biomedical research involving human subjects participant’s interests and well-being should be prior to scientific or community interests;
- research involving human subjects must conform to the legislation safeguarding human rights in biomedical research involving human subjects, as well as to generally accepted principles and norms of international law; it also has to ensures compliance to all professional requirements, norms and standards established with regard of this kind of activity; it also ensures special measures for protection human rights and dignity of vulnerable groups of population in accordance with the requirements of this law and other normative legislation acts;
- research involving human subjects is motivated by the perspective of gaining new scientific knowledge that is essential for the improvement of biomedical practice, and cannot be obtained otherwise;
- research that does not imply a direct benefit for the individual participant, and aims at obtaining results and new knowledge that can be used for the improvement of other people’s health or for the progress in science, may only be permitted in exceptional, statutory cases, provided that a potential risk for the research participant does not exceed the minimal risk;
- research involving human subjects should be preceded by pre-clinical research, confirming expediency and safety of the research for the research participant, as well as by an independent ethical review of a research project conducted by an independent Ethics Committee;
- participation in a research involving human subjects must be voluntary and conscious; potential participants must not be pressed, forced or deceived into the research;
- research involving human subjects must conform to principles of autonomy, respect, mercifulness and justice;
- contemporary biomedical research requires united interdisciplinary and international efforts both in the professional sphere and in the sphere of the protection of research participants’ rights and dignity.

Article 5. Rights of Research Participants

Research participants are guarantied the following:

- the right to have available a full range of medical care, adequate in terms of his/her health condition and the contemporary level of medical science and good clinical practice;
- the right to receive comprehensive and honest information about the nature of a research; the information must be offered in the form and language that would be understood by a potential research participant;
- the right to personal freedom and inviolability, including protection of his/her physical, genetic and mental integrity;
- the right to be free in making decision about participation in a research, as well as the right to abstain from participation, or to withdraw his /her consent to participation at any time;
- the right to be sure that information about his/her health and other private information and personal data should be treated as confidential;
- the right to participate in a biomedical research only after an independent ethical review has been conducted;
- the right to act in accordance with his/her religious and other beliefs and convictions including traditions, moral and cultural values of the society;
- the right to protection of human rights and freedoms ensured by law and generally accepted principles and norms of international law.

CHAPTER 2. RESEARCH SAFETY

Article 6. General requirements on ensuring safety of biomedical research

Safety of a biomedical research with respect to a research participants' health must be ensured with every consideration of all professional standards and requirements, and also in accordance with the latest data and achievements of biomedical sciences. Biomedical research involving human subjects should be conducted only by highly qualified specialists able to adequately examine the health of each potential participant, and decide, if potential participants correspond to the research nature. Scientific, medical and ethical responsibility must always rest with qualified professionals.

Research should be conducted in the environment corresponding to the research nature. All necessary facilities, devices and methods should be available in case of emergent and unexpected clinical situations.

Article 7. Termination of biomedical research

In case of any additional information about the risk related to the research, the research must be suspended or terminated. Any available additional information

must be brought to the notice of research participants, Ethical Committee and other authorized persons and bodies.

The research can be reopened only if the data of additional risks are still negligible in comparison to foreseeable benefit for the research participant. To reopen the research, Ethics Committee may require to introduce corresponding amendments to the research protocols and to repeat the procedure of obtaining informed consent.

Article 8. Participant's Right to Medical Care

Research participants have all rights to be provided with adequate treatment he or she needs including diagnostic, prophylactic and therapeutic procedures.

Article 9. Safety of Participants in the Control Group

Participants in the control group must be guaranteed the use of well-tested methods of diagnostics, prophylactics and therapy. The use of placebo is acceptable only if the participant needs no active treatment, or if there are no products, devices or methods with a tested and proved effect.

CHAPTER 3. THE SYSTEM OF ETHICAL REVIEW

Article 10. The necessity of Independent Ethical Review

All projects of biomedical research involving human subjects must undergo an independent ethical review in Ethics Committee. Independence of the ethical review should base on established scientific and methodical standards of Ethics Committee's performance and guarantee the protection of individuals and communities in the course of a biomedical research. State legislation on the protection of human rights and dignity of a person involved into a biomedical research, other state norms and regulations covering this particular field of activity, as well as the nature of a biomedical research, define the level of the ethical review (local, regional or national), and also the distribution of authority within the system of ethical review accepted in the State.

Article 11. The Role of Ethics Committee (EC)

EC is providing ethical review necessary for making a decision on the adequacy of a proposed research project regarding the protection of human subjects participating in the research. EC is also providing an independent review regarding the value and significance of purposes pursued by the research.

Article 12. Principles of Constituting an EC and its Operation

Constituting an EC and its operation regarding ethical review should satisfy the principles of independence, competence, pluralism and openness [var.: transparency]. EC operation should rely on competent and multidisciplinary expertise and experience adequately representing opinions of both professionals and laypersons.

Article 13. Establishing an EC and its Operation

The order of establishing an EC and its operation including standard requirements on the structure, membership, education and rotation of EC members, also standards of the procedure of submitting review application, conducting the review, decision-making and communicating a decision, follow-up review of a biomedical research, the order of maintaining documentation and archiving are defined and stated by the State legislation. Standards, quality and independence of EC are achieved by developing and following standard operation procedures.

Article 14. EC Tasks

EC is conducting ethical review of each project of biomedical research, involving human subject, prior to the beginning of the research, and also providing a regular follow-up review to ensure ethical norms in the course of a research and after it has been completed.

Article 15. Decisions of EC

EC decisions regarding projects of biomedical research should contain clearly expressed arguments about the essence of the decision. In the process of decision-making EC should be independent and avoid any inappropriate influences due to a possible conflict of interests of EC members or invited experts. Variants of EC decisions include:

- approval of a biomedical research;
- approval with non-essential corrections that do not require a re-examination at the EC meeting;
- approval with recommendations to introduce specific changes into research procedures and/or materials that would require the ethical re-examination;
- approval refused;
- withdrawal of a previously given approval and stating the reasons for that.

Article 16. Surveying and Evaluating Ethical Review Practices

The purpose of surveying and evaluating ethical review practices is to ensure the quality of ethical review, and to assist EC in improving its structure, administrative and functional operation, and also to ensure the compliance of ethical review of a research to established standards.

Surveying provides the basis for independent evaluation of EC activity in accordance to international norms and State legislation. Information about results of surveying is open to all interested persons as stated by law.

Article 17. Rules of Surveying and Evaluating EC Practices

The development of the system of surveying and evaluating the ethical review quality rests with the national health authorities or regulatory bodies or authorized regulatory bodies, and also can be realized in the course of international cooperation.

The procedures of surveying and evaluating the quality of the ethical review should base on national norms and regulations and meet international standards developed by WHO.

Provisions, organization and principles of surveying and evaluating the ethical review quality should be characterized by free and open communication, both on the part of an independent surveyor and EC, to ensure the atmosphere of mutual trust and support.

Independent surveyors carrying out survey and evaluation of the quality of the ethical review must be adequately trained and certified by authorized bodies; they should have no conflict of interests in terms of financial, scientific, professional, juridical, moral and/or and other form of dependence, and must ensure confidentiality with regard to information received in the survey.

CHAPTER 4. INFORMED CONSENT

Article 18. Informed Consent

Obtaining informed consent (IC) prior to a biomedical research is a compulsory procedure necessary to safeguard human rights of research participants. IC should be voluntary and competent. If the person is incompetent and unable to give his/her consent, then informed consent should be obtained from his/her legal representative in accordance to provisions stated in this Law and other State normative acts.

Article 19. Information

Research participants should be adequately informed about the nature of research. Information should be given in a clear form and in language that would be understood by potential participants.

Information should convey:

- the fact that he/she participates in a research;
- the purpose and methods of the research;
- expected duration of the research;
- anticipated benefit from participation or refusal to participate;
- potential risks or discomfort;
- alternative therapy;
- guaranties of confidentiality
- guaranties of providing medical care;

- financial provisions, particularly, provisions for total compensation in the case of injury or death of a research participant attributable to the participation in the research, and also insurance arrangements;
- information about the right to withdraw from the research project at any stage without loosing the right to receive adequate and appropriate medical care;
- providing information about all changes in the process of the research that may affect the previous decision about participation in the research.

Article 20. Requirements on the procedure of obtaining information on biomedical research

Information for research participants must be conveyed in a clear form, and in the language that is national in the country, where the research is carried out, or, if required by the research participant, in his/her native language. Information presented should be adequately documented, clearly formulated; it must not contain any attempts to influence the free choice of the research participant in any form. Information must not contain details that might frighten the research participant, neither must it contain details of financial or some other kind of stimulating that would induce the research participant to making an inadequate decision.

Article 21. Procedure of Obtaining Informed Consent

The procedure of IC should ensure that the research participant has enough time to consider the information thoroughly, and that he receives answers to all questions that may arise at the stage of decision-making, as well as during the course of the research. The fact that the decision has been made is documented by signing the IC form according to guidelines for good clinical practice (GSP) and national legislation. IC to participate in the research can be withdrawn at any stage of the research, in which case the participant retains all guarantees for necessary medical care.

Article 22. The Right of the Research Participant to Receiving Information about His/Her Health Condition

Information about research participant’s health condition should be available for the participant regardless of

CHAPTER 5. CONFIDENTIALITY

Article 22. Confidential Information

Entire information received in the course of biomedical research is confidential and is to be identified as information relating to the protection of privacy and personal data. The access to this information is regulated by GCP rules and norms of State legislation.

Article 23. Research Participant's Right to Obtain Information on His/Her Health Condition

Information about the research participant's health condition should be available to the participant regardless of the stage of the research or his/her voluntary withdrawal from the research. If research participant does not want to receive any information, his or her wish should be respected.

CHAPTER 6. SPECIAL SITUATIONS

Article 24. Biomedical Research Involving Human Subjects from Vulnerable Groups

Vulnerable communities include minors (age limits are determined by national laws), pregnant and breast-feeding women, individuals with psychic and mental disorders, individuals who are in penitentiary institutions, servicemen, migrants, and also individuals and communities in different conditions of financial, administrative, national, religious, racial and other forms of dependency.

In conducting a biomedical research involving human subjects from vulnerable groups special procedures considering factors of age, intellectual, mental or social immaturity of the personality of research participant.

Article 25. Principles of Conducting Biomedical Research Involving Human Subjects from Vulnerable Groups

Biomedical research involving human subjects from a vulnerable group must ensure that the research is carried out exclusively in their best interests, and in the case if the research can only be carried out involving subjects from vulnerable groups. The purpose of the research should be to gain a direct or potential benefit provided that minimal risks and discomfort would be outweighed by the direct benefit.

It is essential to create conditions and environment for informing individuals from a vulnerable group about their rights and measures safeguarding the protection of their free will, respect and the right to withdraw from participation in the research. The possibility and the general order of conducting a biomedical research involving human subjects from vulnerable groups are stated by the law, defining special conditions for the protection of persons, who, for different reasons, are unable to give their conscious consent.

Article 26. The safeguarding human rights of the research participants, who are unable to give the conscious informed consent (children, people with mental disorders)

Participation of persons, who are unable to give the conscious informed consent, in a research is allowable only in the following cases:

- a direct beneficial effect for the research participant's health is expected;
- a similar research with other categories (or age groups) cannot be carried out, while the research is directed to gaining new knowledge and results that could be beneficial both for the health condition of the particular research participant, and for

other persons belonging to the same age category or having the same disease or disorder;

- participation in the research involves minimal risk or discomfort;
- informed consent has been obtained from parents or a legal representative, or a body authorized hereto by national legislation on the basis of information about the research presented as defined by Article 19 of this Law;
- all possible measures have been taken to inform a potential research participant adequately to his/her age and the level of psychic and mental maturity; research participant's opinion regarding consent (dissent) to participate in a research should be taken into consideration.

Article 26. Epidemiological Research

Epidemiological research entailing minimal risks or no risks expected may be carried out without direct informing and obtaining IC from potential participants. Nevertheless, the research should be submitted for an independent ethical review and coordination with authorized state bodies must be ensured. The principle of confidentiality should be observed, and provisions for responsibility insurance must conform to national legislation.

Article 27. Biomedical Research in Emergent Clinical Situations.

Special measures should be provided for the research conducted in emergency situations, when the very nature of the research implies involving individuals who, due to their condition (coma, the effect of psychotropic drugs, et al.), are unable to express their free will. Adequate conditions of obtaining a delayed IC should be defined and approved by ECs.

Article 28. Biomedical Research that Imply Obtaining Information about Research Participant's genetic Data

In the case of any research with the purpose of obtaining information about research participant's genetic code, it is necessary

- to present reliable and convincing data on the expediency of these investigations, their advantages and potential benefit of scientific data for research participants or other persons;
- to obtain an additional informed consent to participate in the research;
- to provide all possible measures for safeguarding confidentiality;
- to guarantee the compliance with requirements stated for this procedure by law and generally accepted norms and principles of international law.

CHAPTER 7. RESPONSIBILITY FOR VIOLATING REGULATIONS STATED IN THIS LAW

Article 29. Responsibility for Violating Regulations Stated in this Law

Persons guilty of violating regulations stated by this Law bear responsibility in accordance with national law.