REPUBLIC OF LITHUANIA

LAW AMENDING

LAW NO VIII-1679

ON

ETHICS OF BIOMEDICAL RESEARCH

17 September 2015 No XII-1938

Vilnius

Article 1. New version of Republic of Lithuania Law No VIII-1679 on Ethics of Biomedical Research

Republic of Lithuania Law No VIII-1679 on Ethics of Biomedical Research shall be amended and set forth to read as follows:

"**REPUBLIC OF LITHUANIA**

ON ETHICS OF BIOMEDICAL RESEARCH

LAW

CHAPTER I
GENERAL PROVISIONS

Article 1. Purpose of the Law

1. This Law shall set forth ethical requirements for biomedical research, terms and conditions of processing of human biological samples and managing personal health information for the purposes of biomedical research and activities of biobanks, terms and conditions of issuance of approvals to conduct biomedical research, supervision of conducting of biomedical research and liability of sponsors of biomedical research and investigators for damage resulting from the subject's health impairment or death.

2. The provisions of this Law have been harmonised with the legal acts of the European Union listed in the Annex to this Law.

Article 2. Definitions

1. **Personal health information** (hereinafter: 'health information') means data on a person's health, diseases and health disorders, causes thereof, external factors, diagnosis,

course, prognosis, medical treatment, outcome, death, heritability or any other information related to the person's health.

2. **Provision of personal health information** (hereinafter: 'provision of health information') means disclosure of personal health information by transmitting it or making it otherwise available, except for publication thereof in the media.

3. **Processing of personal health information** (hereinafter: 'processing of health information') shall mean any operation which is performed with personal health information such as collection, recording, accumulation, storage, classification, grouping, combining, alteration (supplementation or correction), biomedical research, disclosure, making available, use, logical and/or arithmetic operations, retrieval, dissemination, destruction or any other operation or operations.

4. **Person who for health reasons cannot be considered to be capable of reasonably assessing his interests** means a person of legal age adjudged as being incapacitated or of limited capacity, or a person of legal age or a minor adjudged as being of full capacity (emancipated) whose health condition does not allow him to assess his interests or hinders reasonable assessment thereof.

5. **Biobank** means a public legal person acting in the capacity of a budgetary or public establishment and holding a licence for personal health care services, including the right to process human biological samples and health information for the purposes specified in this Law and conducting of biomedical research (hereinafter: a 'licence for biobanking').

6. **Bioethical requirements** means the ethical requirements stipulated in legal acts of the Republic of Lithuania and international legal acts and codes of ethics and applicable to the provision of health care services and conducting of biomedical research.

7. **Biomedical research** means verification of hypotheses of biomedical sciences by means of methods of scientific research pursuing the aim of developing scientific knowledge about human health, diseases, diagnosis, medical treatment or prevention thereof.

8. **Biomedical research site** (hereinafter: a '**research site**') means a legal person whereat biomedical research is conducted.

9. **Sponsor of biomedical research** means a natural or a legal person or another organisation or a branch thereof which initiates, manages biomedical research and ensures funding thereof.

10. **Ethical requirements for biomedical research** means bioethical requirements as stipulated by this Law and applicable to the conducting of biomedical research.

11. **Ethical supervision of biomedical research** means the activities carried out by the Lithuanian Bioethics Committee and/or a regional biomedical research ethics committee and having the purpose of controlling compliance of sponsors of biomedical research and investigators with ethical requirements for biomedical research.

12. **Informed consent to biobanking** (hereinafter: a 'person's consent to biobanking') means a voluntary, explicit and knowing written consent by a person or, in the cases and in accordance with the procedure provided for by this Law, by another person entitled to give a person's consent to biobanking, by the surviving spouse or, where the person was not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately - by a close relative, to process a human biological sample and health information for the purposes specified in this Law.

13. Informed consent to participate in biomedical research (hereinafter: a 'person's consent to participate in research') means a voluntary, explicit and knowing written consent by a person or, in the cases and in accordance with the procedure provided for by this Law, by another person entitled to give a person's consent to participate in biomedical research, by the surviving spouse or, where the person was not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately – by a close relative, to participate in biomedical research.

14. **Clinical research** means biomedical research on living human subjects.

15. **Investigator** means a natural person conducting biomedical research and meeting the requirements set forth by this Law.

16. **Subject** means a person who participates in a biomedical research.

17. **Human biological sample** means biological material taken from a living or dead human organism.

18. **Provision of human biological samples** means transfer of human biological samples or otherwise making them available.

19. **Processing of human biological samples** means any action performed with human biological samples: procurement, treatment, conservation, collection, storage, identification, assessment, biomedical research, classification, grouping, combining, alteration (supplementation or correction), provision, search, destruction or any other action or actions.

20. **Human embryo** means the stage of development of a human organism from the moment of impregnation (formation of a zygote) until the end of the eighth week of pregnancy.

21. **Human embryonic stem cells** means the cells of a human embryo which can divide *in vitro* and/or can develop into specialised types of cells.

22. **Human embryonic stem cell line** means the stem cells of a human embryo which can be grown *in vitro* and divide without differentiating into other types of cells for a long period of time.

23. **Human stem cells** means the unspecialised cells present during the period of development of a human embryo and a human foetus as well as in tissues of an adult person which are capable to differentiating into specialised cells of different tissue types and renew at the same time.

24. **Human stem cell line** means the human stem cells which are grown in vitro ensuring their long-term division without differentiation.

25. **Human foetus** means the stage of development of a human organism from the ninth week of pregnancy until birth.

26. Other definitions used in this Law shall be interpreted as they are defined in the Civil Code of the Republic of Lithuania (hereinafter: the 'Civil Code'), the Law of the Republic of Lithuania on Insurance (hereinafter: the 'Law on Insurance'), the Law of the Republic of Lithuania on Pharmacy, the Law of the Republic of Lithuania on Equal Treatment, the Law of the Republic of Lithuania on the Rights of Patients and Compensation for the Damage to Their Health (hereinafter: the 'Law on the Rights of Patients and Compensation for the Damage to Their Rights'), the Law of the Republic of Lithuania on Health Care Institutions (hereinafter: the 'Law on Health Care Institutions'), the Law of the Republic of Lithuania on the Health System, the Law of the Republic of Lithuania on Fundamentals of Protection of the Rights of the Child, the Law of the Republic of Lithuania on Donation and Transplantation of Human Tissues, Cells and Organs, the Law of the Republic of Lithuania on the Establishment of Death of a Human Being and on Critical Conditions and the Law of the Republic of Lithuania on Legal Protection of Personal Data (hereinafter: the 'Law on Legal Protection of Personal Data').

Article 3. Objects of biomedical research

1. Biomedical research may be undertaken on living or deceased human subjects or their groups, a human embryo, a human foetus, a human biological sample and health information.

2. The creation of human embryos for the purposes of biomedical research shall be prohibited.

3. A human embryo and a human foetus may be subject only of such biomedical research where the potential benefit to the human embryo and human foetus under investigation exceeds risks.

4. It shall be prohibited to undertake biomedical research on a human embryo and a human foetus who died after an abortion at a woman's request, in the absence of medical indications.

5. Cloning of a human being shall be prohibited.

6. Biomedical research on human embryos or human foetuses during which or after which a human embryo or a human foetus is destroyed or a human embryo is not placed into a woman's uterus shall be prohibited.

7. Biomedical research involving modifications of the human genome may only be carried out for preventive, diagnostic or therapeutic purposes and only in the cases when it is not intended to modify the genome of descendants.

8. Import into the territory of the Republic of Lithuania and export therefrom of tissues of a human embryo, embryonic stem cells and lines thereof or tissues of a foetus and the stem cells taken therefrom and lines thereof shall be prohibited. This prohibition shall not apply to the import into the territory of the Republic of Lithuania and export therefrom of the stem cells taken from umbilical cord or placenta after the birth of a child and the samples taken for genetic research in accordance with requirements of paragraph 3 of this Article. Transit through the territory of the Republic of Lithuania of tissues of a human embryo, embryonic stem cells and lines thereof or tissues of a human foetus and the stem cells taken therefrom and lines thereof shall be possible only subject to an authorisation by the Minister of Health. The Description of the Procedure for Issuing Authorisations for the Transit Through the Territory of the Republic of Lithuania of Tissues of Human Embryos, Embryonic Stem Cells and Lines Thereof or Tissues of a Human Foetus and the Stem Cells Taken Therefrom and Lines Thereof as well as the Description of the Procedure for Importing into the Territory of the Republic of Lithuania and Exporting Therefrom of the Human Stem Cells Taken from the Umbilical Cord or Placenta after the Birth of a Child and the Human Biological Samples Taken for Genetic Research shall be approved by the Minister of Health.

Article 4. Prohibition of discrimination

It shall be prohibited to discriminate against a person, restrict his rights or legitimate interests:

1) by virtue of processing or non-processing of human biological samples and health information by a biobank;

2) on grounds of human biological samples and health information processed by a biobank;

3) by virtue of the person's participation or non-participation in biomedical research;

4) on grounds of biomedical research results.

CHAPTER II
ETHICAL REQUIREMENTS FOR BIOMEDICAL RESEARCH

Article 5. Ethical requirements for biomedical research

1. Biomedical research must be conducted according to the principle that the interests of the human being prevail over the interests of society and science.

2. Biomedical research may be conducted only if all of the following requirements are met:

1) biomedical research has scientific and practical merit;

2) biomedical research may not be substituted by another research without the involvement of human subjects;

3) protection of interests of the subject and confidentiality of his health information are ensured;

4) a person's consent to participate in research (with the exception of the cases referred to in Article 7(5) and (11) of this Law) has been obtained or, when biomedical research is conducted on the human biological samples and health information processed in a biobank – a person's consent to biobanking has been obtained;

5) having refused to give his consent to participate in research or his consent to biobanking or having withdrawn it, the person will retain the right to adequate personal health care;

6) comprehensive data of relevant pre-clinical tests are available (applies only to clinical research);

7) benefits of biomedical research outweighs the risks and inconveniences for the subject concerned. In the case of clinical research, it shall be permissible not to provide the subject with personal health care applicable according to usual clinical practice only in a situation where the effectiveness of personal health care applicable according to usual clinical practice has not been proven and the benefits of biomedical research outweighs the risks and

inconveniences for the subject concerned, or where non-provision of such personal health care does not pose a threat to the health of the subject;

8) the principal investigator and the sponsor of biomedical research or a health care institution are covered, in the cases specified by Article 12(2) and (3) of this Law, by the third-party insurance for compensation to the subject of the possible pecuniary and non-pecuniary damage caused in the course of biomedical research;

9) the documents of the institutions indicated in Article 20 of this Law granting the right to conduct biomedical research have been obtained;

10) there are no prohibitions against it in other laws.

Article 6. Vulnerable subjects and protection of their interests

1. The following subjects shall be regarded as vulnerable subjects whose consent to participate in biomedical research may be influenced by external factors or who are wholly or in part incapable of defending their interests:

1) persons who for health reasons cannot be considered as being capable of rationally assessing their interests;

2) minors;

3) students, where their participation in biomedical research is related to their studies;

4) persons in social nursing homes;

5) soldiers in the active military service;

6) personnel of health care institutions where biomedical research is being conducted who are subordinate to the investigator;

7) persons in prisons or other places of detention.

2. Other groups of persons may be recognised as vulnerable subjects by a reasoned decision of the Lithuanian Bioethics Committee or a regional biomedical research ethics committee when considering documents for the issue of an approval to conduct biomedical research or by a reasoned decision of the Lithuanian Bioethics Committee when considering documents for the issue of a favourable opinion to conduct a clinical trial on a medicinal product.

3. Clinical research may be undertaken on vulnerable subjects only in the following cases:

1) when clinical research may be conducted exclusively on vulnerable subjects and there are scientific grounds for expecting that participation in the clinical research will

produce direct benefit to the subject, which will outweigh the risks and inconveniences posed by the clinical research;

2) when clinical research may be conducted exclusively on vulnerable subjects and the clinical research relates directly to the medical condition from which the subject suffers and there are scientific grounds for expecting that participation in the clinical research will produce some benefit for the group of persons not participating in the research whereto the subject belongs, and the invasive research methods applicable to the subject for the purposes of the clinical research have slightly detrimental and temporary impact on the health of the subject;

3) when clinical research relates directly to the life-threatening or debilitating medical condition from which the subject suffers subject, in the case whereof there is no adequate personal health care, and there are scientific grounds for expecting that participation in the clinical trial will produce direct benefit to the subject, which will be outweigh the risks and inconveniences posed by the clinical research.

Article 7. Person's consent to participate in research

1. Before involving a person in biomedical research, with the exception of biomedical research on the human biological samples and/or health information processed in a biobank with a person's consent to biobanking, a person's consent to participate in research must be obtained. The person's consent to participate in research must meet all of the following conditions:

1) the person's consent to participate in research has been given by a person capable of expressing his will;

2) the person's consent to participate in research has been given after having been duly informed in accordance with the procedure laid down in paragraph 8 of this Article;

3) the person's consent to participate in research has been given freely by the person (in the cases and in accordance with the procedure laid down by this Law – another person entitled to give a person's consent to participate in research, the surviving spouse or, where the person was not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately – a close relative referred to in paragraph 5 of this Article in the order of priority);

4) the person's consent to participate in research meets detailed requirements for the consent of a person's consent to participate in research as set forth by the Minister of Health.

2. If a person, due to a physical handicap, illness or for other reasons, is unable to sign a person's consent to participate in research, the person's consent to participate in research shall be signed in accordance with the procedure laid down by the Civil Code.

3. A minor must, having regard to his age and capacity to understand, be provided with the information referred to in paragraph 8 of this Article. A person's consent to participate in research in respect of a minor's participation in biomedical research shall be given by the minor's legal representatives, however if the minor who is capable of understanding the information provided to him expresses his wish not to participate in the biomedical research or, if the minor is already involved in such a biomedical research, to discontinue his participation therein, the minor's participation in the research shall not commence or shall be terminated, unless this is contrary to the interests of the minor. The issue of whether the minor's wish not to participate in the research is contrary to the minor's interests shall be decided by the minor's legal representatives having regard to the investigator's opinion. When biomedical research involves minors, a decision to issue a favourable opinion to conduct a clinical trial on a medicinal product, shall be taken at the meeting of the Lithuanian Bioethics Committee attended by a representative of the State Child Rights Protection and Adoption Service under the Ministry of Social Security and Labour. The procedure for a minor's participation in biomedical research shall be laid down by the Minister of Health and the Minister of Social Security and Labour of the Republic of Lithuania.

4. Consent of a person who for health reasons cannot be considered as being capable of rationally assessing his interests shall be given by the person's spouse or, if the person is not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately – by one of the person's parents/adoptive parents or by one of children/adopted children who are of legal age or, when a person is adjudged as incapacitated – by his guardian or, when the person's capacity is limited – by his caretaker (hereinafter: 'another person entitled to give a person's consent to participate in research'). The subject must, having regard to his capacity to understand, be provided with the information referred to in paragraph 8 of this Article. The investigator shall take into account the wish of the subject capable of understanding the information provided to him not to participate in biomedical research or, if the subject is already involved in such biomedical research, the wish to withdraw from it. Upon receiving objection of one of the mentioned persons in the order of priority, it shall be prohibited to undertake biomedical research on the person who for health reasons cannot be considered as capable of rationally assessing his interests.

5. Where prior to his death a person did not give a person's consent to participate in research or did not withdraw it, a person's consent to undertake biomedical research on the deceased person's human biological sample/samples and health information shall be given by the surviving spouse or, where the person was not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately – by one of his close relatives in the following order of priority: parents/adoptive parents, children/adopted children of legal age, brothers/sisters, grandparents, grandchildren. If the consent is given by one of the above-mentioned persons in the order of priority, the consent of other close relatives of the deceased shall not be asked for. If one of the above-mentioned persons expresses his objection in the order of priority, it shall be prohibited to undertake biomedical research on a human biological sample/samples and health information of the deceased.

6. A person and another person entitled to give a person's consent to participate in research may be informed, and the person's consent to participate in research may be obtained after the inclusion of the person in biomedical research, provided that all of the following conditions are fulfilled:

1) due to a critical condition or other medical condition which requires emergency aid, the person is unable to receive the prior information referred to in paragraph 8 of this Article and give prior consent to participate in research, and a person who for health reasons cannot be considered as capable of rationally assessing his interests or the minor is unable to receive the prior information referred to in paragraph 8 of this Article and cannot express his willingness or unwillingness to participate in biomedical research;

2) there are scientific grounds for expecting that the person's participation in biomedical research will produce direct and significant benefit to his health, that is, his suffering will be relieved and/or health will improve, or conditions will be provided to diagnose an illness or predict the course thereof;

3) the person must undergo a biomedical research diagnostic or medical procedure (hereinafter: a 'procedure') without delay, which precludes the provision of the prior information referred to in paragraph 8 of this Article and obtaining prior consent to participate in research from another person entitled to give the person's consent to participate in research;

4) the investigator certifies that he is not aware of any objections to participate in the biomedical research previously expressed by the person concerned;

5) biomedical research relates directly to the person's health condition which requires undertaking an urgent procedure, which precludes the provision of the prior

information referred to in paragraph 8 of this Article and to obtain prior consent to participate in research from the person or another person entitled to give a person's consent to participate in research, and biomedical research is of such a nature that it may be conducted exclusively in life-threatening or other serious medical conditions arising in emergency situations;

6) the biomedical research poses a minimal risk to, and imposes a minimal burden on, the person's health in comparison with usual clinical practice in the case of the subject's health condition.

7. A person involved in biomedical research under the conditions referred to in paragraph 6 of this Article may continue to participate in the biomedical research after he is provided the information referred to in paragraph 8 of this Article, also information about the right to object to further use of the health information obtained in the course of the biomedical research, when the person objects to continuing participation in the research, and the consent to participate in the research is obtained from the following persons:

1) a minor's legal representatives, when the subject is a minor, or another person entitled to give a person's consent to participate in research, when the subject is a person who for health reasons cannot be considered as being capable of rationally assessing their interests – without delay, as soon as it becomes possible to provide them with the information referred to in paragraph 8 of this Article and to obtain from them a person's consent to participate in research;

2) the subject – without delay, as soon as the subject becomes capable of rationally assessing his interests.

8. Before giving his consent to participate in research, a person or, in the cases provided for by this Law, another person entitled to give a person's consent to participate in research, the surviving spouse or, where the person was not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately – a close relative referred to in paragraph 5 of this Article in the order of priority, having regard to the age and health condition of the person giving the consent to participate in research, must be informed in a comprehensible manner, by explaining specific medical terms, about:

1) the purpose of biomedical research;

2) the design of biomedical research;

3) the methods applicable in the course of biomedical research;

4) an approval to conduct biomedical research issued by the Lithuanian Bioethics Committee or a regional biomedical research ethics committee or a favourable opinion to conduct a clinical trial on a medicinal product issued by the Lithuanian Bioethics Committee

and an authorisation of the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania, as referred to in Article 20 of this Law;

5) foreseeable benefits of biomedical research to the subject;

6) rights of the subject;

7) risks posed and burden imposed by biomedical research to the subject;

8) the procedure for compensating for the damage which could be caused in the course of biomedical research;

9) the right to withdraw his consent to participate in research at any time, providing to him information about the consequences of such withdrawal;

10) guarantees of confidentiality of health information.

9. The investigator shall provide a person or, in the cases provided for by this Law, another person entitled to give a person's consent to participate in research or the surviving spouse or, where the person was not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately – a close relative referred to in paragraph 5 of this Article in the order of priority with a clear, free-of-charge and practicable possibility of withdrawing, at a written request, the person's consent to participate in research. The results of biomedical research obtained through conducting biomedical research prior to the receipt of the person's request to withdraw the person's consent to participate in research shall not be destroyed.

10. Detailed requirements for the content of a person's consent to participate in biomedical research and information indicated in paragraph 8 of this Article as well as a procedure for giving and withdrawing the consent shall be stipulated by the Minister of Health.

11. A decision on whether a person's consent to participate in research is necessary for conducting biomedical research on a person's biological sample and/or health information which has been obtained for the purpose of provision of personal health care, statistical or other purposes before applying for undertaking research on this person shall be taken by the Lithuanian Bioethics Committee or a regional biomedical research ethics committee issuing an approval to conduct biomedical research.

Article 8. Person's consent to biobanking

1. Human biological samples and health information shall be processed for the purposes specified in Article 16(1) of this Law only subject to obtaining a person's consent to biobanking. The person's consent to biobanking must meet all of the following conditions:

1) the person's consent to biobanking has been given by a person capable of expressing his will;

2) the person's consent to biobanking has been given by a person after having been duly informed in accordance with the procedure laid down in paragraph 6 of this Article;

3) the person's consent to biobanking has been given freely by the person (in the cases and in accordance with the procedure laid down by this Law – another person entitled to give a person's consent to participate in research, the surviving spouse or, where the person was not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately – a close relative referred to in paragraph 5 of this Article in the order of priority);

4) the person's consent to biobanking meets detailed requirements for the consent of a person's consent to biobanking as set forth by the Minister of Health.

2. If a person, due to a physical handicap, illness or for other reasons, is unable to sign a person's consent to biobanking, the person's consent to biobanking shall be signed in accordance with the procedure laid down by the Civil Code.

3. A person's consent to biobanking in respect of the processing of a minor's biological sample and health information for the purposes specified in Article 16(1) of this Law shall be given by legal representatives of the minor.

4. A person's consent to biobanking in respect of the processing of a human biological sample and health information of a person who for health reasons cannot be considered as being capable of reasonably assessing his interests for the purposes specified in Article 16(1) of this Law shall be given by the person's spouse or, if the person is not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately – by one of the person's parents/adoptive parents or by one of children/adopted children who are of legal age or, when a person is adjudged as incapacitated – by his guardian or, when the person's capacity is limited – by his caretaker (hereinafter: 'another person entitled to give a person's consent to biobanking').

5. A person's consent to biobanking in respect of the processing of a human biological sample of a deceased person and his health information for the purposes specified in Article 16(1) of this Law shall be given by the surviving spouse or, where the person was not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately - by one of his close relatives in the following order of priority: parents/adoptive parents, children/adopted children of legal age, brothers/sisters, grandparents, grandchildren. If the consent is given by one of the above-mentioned persons in the order of priority, the

consent of other close relatives of the deceased shall not be asked for. If one of these persons objects in the order of priority, it shall be prohibited to use the deceased person's human biological sample and health information in the activities of the biobank.

6. Before giving his consent to biobanking, a person or, in the cases provided for by this Law, another person entitled to give a person's consent to biobanking, the surviving spouse or, where the person was not married – a close relative referred to in paragraph 5 of this Article in the order of priority, having regard to the age and health condition of the person giving the consent to biobanking, must be informed in a manner comprehensible to him, by explaining specific medical terms, about:

1) the meaning of the person's consent to biobanking, potential benefits, inconveniences and risks to the person;

2) the objectives and means of processing of a biological sample and health information, including obtaining of health information from health care institutions, registers and/or state information systems, and the fact that the objectives and means of specific biomedical research on the human biological sample and health information concerned at the moment of giving a person's consent to biobanking may be unknown due to the insufficient level of development of science or technology or for other objective reasons;

3) a possibility to access information contained in the biobank regarding the use of his (or deceased person's) human biological sample and health information and the objectives pursued by such a use;

4) guarantees of the confidentiality of health information and the statement that the biobank provides human biological samples and/or health information or the biomedical research findings obtained from the use thereof or a part thereof allowing for identification of the person only by a reasoned decision of the court, where it is necessary for the hearing of a case in court;

5) the right to withdraw the person's consent to biobanking.

7. A minor or a person who for health reasons cannot be considered as capable of rationally assessing his interests must, having regard to his capacity to understand, be provided with the information indicated in paragraph 6 of this Article, and his wish not to grant to a biobank a permission to process his biological sample and health information for the purposes specified in Article 16(1) of this Law and, where a person's consent to biobanking has already been given, to withdraw this consent must be respected.

8. A biobank may process health information and human biological samples remaining after surgery, invasive and/or interventional procedures whereof a person has not

given a person's consent to biobanking in accordance with the procedure laid down in this Article, but only to the extent necessary for the preservation of these human biological samples and, where the person would give a person's consent to biobanking within one month after a surgery, an invasive and/or interventional procedure, processing of the samples in the biobank, while health information – only to the extent necessary for the assessment of the suitability of such human biological samples for the purposes set out in Article 16(1) of this Law. Where the person or, in the cases specified by this Law, another person entitled to give a person's consent to biobanking does not give a person's consent to biobanking within the time limit laid down in this paragraph, the biobank must forthwith destroy a human biological sample and health information stored in the biobank. Information that human biological samples and health information may be processed in the biobank in accordance with the procedure laid down in this paragraph must be available to patients at personal health care institutions.

9. Any invasive and/or interventional procedure whose sole purpose is receipt and further processing of a human biological sample/samples in a biobank and undertaking of biomedical research on it/them rather than a person's medical treatment or diagnosis shall be permitted only if a person's consent to biobanking contains a consent to procure a human biological sample for this purpose.

10. A biobank shall provide a person or, in the cases provided for by this Law, another person entitled to give a person's consent to biobanking or the surviving spouse or a close relative with a clear, free-of-charge and practicable possibility of withdrawing, at a written request, the person's consent to biobanking. At the person's written request to withdraw the person's consent to biobanking, the human biological sample and health information stored in the biobank may not be processed, and the human biological sample and health information transferred to the persons indicated in Article 17 of this Law may not be used and must be destroyed in accordance with the procedure laid down by the Minister of Health, and the person must be notified thereof. The results of biomedical research obtained through biomedical research on human biological samples and health information prior to the receipt of the person's request to withdraw the person's consent to biobanking shall not be destroyed.

11. Detailed requirements for the content of a person's consent to biobanking and information indicated in paragraph 6 of this Article shall be set forth as well as a procedure for giving and withdrawing a person's consent to biobanking shall be laid down by the Minister of Health.

Article 9. Confidentiality of health information

1. The health information obtained in the course of biomedical research and enabling a person's identification of shall be confidential and may be provided solely in accordance with the procedure laid down by the Law on the Rights of Patients and Compensation for the Damage to Their Health.

2. The health information obtained in the course of biomedical research shall not be considered as confidential and may be published without the subject's consent, where the publication of such health information will not enable the person's identification.

Article 10. Compensation for Costs

Subjects shall be entitled to compensation for the expenses incurred due to participation in biomedical research and the time spent. The procedure for calculating and paying compensation shall be laid down by the Government of the Republic of Lithuania (hereinafter: the 'Government') or an institution authorised by it.

Article 11. Sponsor of biomedical research and investigator

1. The sponsor of biomedical research shall be responsible for the initiation, management and funding of the biomedical research.

2. The investigator shall be responsible for the conduct of a biomedical research at a research site. Where the investigator himself conducts the biomedical research or leads a team of individuals conducting the biomedical research at the research site and is responsible for the activities of this team, he shall be referred to as the principal investigator.

3. When conducting a biomedical research involving the interventional methods of biomedical research which pose a risk to the health of the subject (with the exception of the biomedical research referred to in paragraph 4 of this Article), the investigator must possess a higher education qualification conforming to the nature of such a biomedical research, a relevant medical practice or dentistry licence, have experience in patient care and be employed at a research site, and the principal investigator must have also experience in the area of the biomedical research involving the use of the interventional methods of biomedical research which pose a risk to the health of the subject. Specific requirements for the higher education qualification and experience of the investigator conducting a biomedical research indicated in this paragraph shall be set forth by the Minister of Health.

4. When conducting a clinical trial on a medicinal product, the investigator must possess a higher education qualification conforming to the nature of the clinical trial on the medicinal product, a relevant medical practice or dentistry licence, have experience in patient care, have completed a training course in Good Clinical Practice and be employed at a research site. When conducting the biomedical research indicated in this paragraph, the principal investigator must have also experience in the area of clinical trials on medicinal products. Specific requirements for the higher education qualification, training in Good Clinical Practice and experience of the investigator conducting a clinical trial on a medicinal product shall be set forth by the Minister of Health. A person may be employed as the principal investigator only at one site conducting the same research.

Article 12. Civil liability of the sponsor of biomedical research and the investigator and Its insurance

1. The sponsor of biomedical research and the investigator shall be liable for the pecuniary and non-pecuniary damage incurred to the subject, except for the pecuniary and non-pecuniary damage resulting from causes unrelated to biomedical research or from deliberate acts of the subject. The sponsor of biomedical research and the investigator shall assume solidary liability for the pecuniary and non-pecuniary damage indicated in this paragraph and incurred to the subject, unless the sponsor of biomedical research and the investigator agree otherwise in writing. The pecuniary and non-pecuniary damage incurred to health of the subject by the sponsor of biomedical research and the investigator shall be redressed in accordance with the procedure laid down by the Civil Code, the Law on Insurance and other legal acts.

2. The sponsor of medical research and the principal investigator must insure their civil liability against any pecuniary and non-pecuniary damage incurred as a result of impairment to the subject's health or the subject's death by entering with insurers into contracts of compulsory insurance against civil liability of the sponsor of biomedical research and the principal investigator. This requirement shall apply only in the cases of conducting of a clinical trial on a medicinal product or any other biomedical research in which the participant is, for the purposes of biomedical research, made subject to interventional research methods posing a risk to the subject's health. The risk posed to the subject's health by the interventional research methods applied for the purposes of biomedical research shall be established by the Lithuanian Bioethics Committee, which issues a favourable opinion to conduct a clinical trial on a medicinal product or an approval to conduct biomedical research,

or by a regional biomedical research ethics committee, which issues an approval to conduct biomedical research.

3. The conduct of a clinical trial on a medicinal product or any other biomedical research in which the participant is, for the purposes of biomedical research, made subject to interventional research methods having only a slightly detrimental and temporary impact on his health shall also be permitted if a contract of insurance of civil liability for damage caused to patients of a health care institution which itself or whose employee is the sponsor of such research or whose employee is an investigator in such research provides for compensation for the damage that may result from such research. Whether the interventional methods applied for the purposes of biomedical research cause slightly detrimental and temporary impact on the subject's health shall be established by the Lithuanian Bioethics Committee, which issues a favourable opinion to conduct a clinical trial on a medicinal product or an approval to conduct biomedical research, or by a regional biomedical research ethics committee, which issues an approval to conduct biomedical research, acting in compliance with the List of Interventional Methods of Biomedical Research Causing a Slightly Detrimental and Temporary Impact on the Subject's Health as approved by the Minister of Health. The Lithuanian Bioethics Committee or a regional biomedical research ethics committee may, by a reasoned decision, recognise as causing a slightly detrimental and temporary impact on the subject's health also other interventional methods of biomedical research not included in the List of Interventional Methods of Biomedical Research Causing a Slightly Detrimental and Temporary Impact on the Subject's Health.

4. The amount of compulsory insurance against civil liability of the sponsor of biomedical research and the principal investigator may not be less than EUR 29 000 for compensation of pecuniary and non-pecuniary damage incurred to a single subject. The compulsory insurance cover against civil liability of the sponsor of biomedical research and the principal investigator must be effective from the commencement of biomedical research until completion thereof and for not less than five years from the completion of biomedical research. Rules for compulsory insurance against civil liability of the sponsor of biomedical research and the principal investigator, which stipulate other terms of the contract of compulsory insurance of civil liability of the sponsor of biomedical research and the principal investigator and the procedure for calculating the amount of compensation and compensating for pecuniary and non-pecuniary damage incurred to the subject's health, shall be established by the Government or an institution authorised by it.

CHAPTER III
TERMS OF BIOBANKING ACTIVITY

Article 13. Biobanking activity

1. Biobanks shall carry out their activity in compliance with the requirements of this Law, the Law on Legal Protection of Personal Data and the Law on Health Care Institutions, while respecting the rights and freedoms of individuals and observing the principles of transparency, reliability, data security and openness.

2. Biobanks shall process human biological samples and health information for the purposes specified in Article 16(1) of this Law.

3. Biobanks shall be entitled:

1) to be sponsors of biomedical research and to conduct biomedical research;

2) to cooperate, in accordance with the procedure laid down by legal acts, with biobanks of the European Union Member States, other states of the European Economic Area and third countries and international organisations and to participate in activities thereof;

3) to obtain health information in accordance with the procedure laid down in Article 15 of this Law.

Article 14. Licensing of biobanks

1. A public legal person acting in the capacity of a budgetary or public establishment seeking to be issued and having been issued a licence for biobanking must meet the requirements for the issue of a licence for personal healthcare services set forth in the Law on Heath Care Institutions and the following requirements:

1) ensure that the requirements of traceability, security, quality and availability to investigators of human biological samples and health information set out in the Requirements for Biobanking Activity as approved by the Minister of Health are met by:

a) premises, equipment and material used for human biological samples and processing of health information;

b) the system of organisation, management and processing of human biological samples and health information;

2) appoint a member of staff responsible for compliance of the processing of human biological samples and health information to requirements of legal acts.

2. A licence for biobanking shall be issued, suspended, suspension thereof shall be lifted and the licence shall be revoked in accordance with the procedure laid down by the Law on Health Care Institutions.

Article 15. Right of a biobank to obtain health information

1. Upon the receipt of a person's consent to biobanking, a biobank shall have the right to obtain the health information of a person whose human biological sample and health information are processed in the biobank from health care institutions, registers and/or state information systems in accordance with the procedure laid down by law.

2. A biobank shall have the right to obtain health information from other legal persons indicated in a person's consent to biobanking, where such health information is not available in registers and/or state information systems and to health care institutions or its provision would require from health care institutions unreasonably high material costs and/or time.

3. A biobank shall exercise the rights indicated in this Article at its own discretion or at the request of the sponsor of biomedical research, his authorised representative or the principal investigator.

Article 16. Processing of human biological samples and health information

1. The processing of human biological samples and health information in a biobank shall pursue the following goals:

1) provision, in accordance with the procedure laid down by this Law, of human biological samples and health information to the persons referred to in Article 17 of this Law;

2) use, in accordance with the procedure laid down by this Law, of human biological samples and health information for the purposes of biomedical research;

3) improvement of the quality of stored biological samples or their suitability for future biomedical research, use of the biological samples which are unsuitable for biomedical research for the purposes of improvement of preparation of such samples for storage, storage technologies and quality control procedures and carrying out of other actions of improvement of the biobanking process.

2. Biobanks shall ensure the traceability, security, quality and availability to investigators of the processing of human biological samples and health information in accordance with the procedure laid down in the Requirements for Biobanking Activity.

3. The health information processed in a biobank shall be confidential and be processed in accordance with the procedure laid down by law. The confidentiality of the health information processed in the biobank shall be ensured by all natural and legal persons using such health information, also the entities referred to in Article 15(1) and (2) of this Law.

4. The health information processed by a biobank shall not be considered as confidential and may be published without the consent of a person who has given a person's consent to biobanking, where the publication of such health information will not enable the person's identification.

5. A biobank shall encode a human biological sample and/or health information received and shall separately process the personal data enabling identification of a person whose biological samples and/or health information is processed in the biobank, while providing a possibility to identify a specific person.

Article 17. Notification of human biological samples and/or health information and of information which is important for a person's health

1. The human biological samples and health information processed in a biobank may be provided for the sponsor of biomedical research, his authorised representative or the principal investigator upon receipt of an approval to conduct biomedical research by the institutions provided for in Article 20 of this Law.

2. The human biological samples and health information processed in a biobank may be provided to other biobanks of the Republic of Lithuania, the European Union Member States and other states of the European Economic Area and third countries, to the sponsor of biomedical research, his authorised representative or the principal investigator conducting biomedical research outside the Republic of Lithuania where the biobank providing the human biological samples and health information obtains an approval of the Lithuanian Bioethics Committee for the provision of the human biological samples and/or health information processed in the biobank.

3. An approval for the provision of the human biological samples and/or health information processed in a biobank shall be issued where the Lithuanian Bioethics Committee decides that:

1) objectives of the provision of the human biological samples and health information correspond to the scope of a person's consent to biobanking given by the person concerned;

2) the persons referred to in paragraph 2 of this Article are in possession of the authorisations issued by the ethics committee of their country of operation and/or other institutions and granting the right to process the human biological samples and/or health information for the purposes of biomedical research.

4. A procedure for issuing an approval for the provision of the human biological samples and/or health information processed in a biobank shall be laid down by the Minister of Health.

5. A biobank shall provide human biological samples and health information or the results of biomedical research obtained from their use or a part of such results, where they enable the person's identification, only by a reasoned decision of the court, where it is necessary for the hearing of a case in court.

6. The sponsor of biomedical research, his authorised representative or the principal investigator shall notify a biobank of information which emerged in the course of biomedical research on the person's biological sample and health information and which is important for the person's health. The biobank shall assess the notified information based on the criteria for the information which is important for a person's health and, upon establishing that such information must be notified, shall provide it to the person concerned, another person entitled to give a person's consent to biobanking or the person's treating physician. Criteria of the information which is important for a person's health to be notified in accordance with the procedure laid down in this Article and the procedure for providing it shall be laid down by the Minister of Health.

Article 18. State supervision of biobanking activity

The state supervision of biobanking activity shall be exercised by the Lithuanian Bioethics Committee and the State Health Care Accreditation Agency within their respective remit.

Article 19. Publicity of biobanking activity

Biobanks shall publish information on their activity in accordance with the procedure laid down by the Minister of Health.

CHAPTER IV
SUPERVISION OF CONDUCT OF BIOMEDICAL RESEARCH

Article 20. Institutions authorising the conduct of biomedical research

1. Biomedical research may be undertaken in the Republic of Lithuania only subject to obtaining of an authorisation of the institutions referred to in paragraphs 2 and 3 of this Article.

2. Approvals to conduct biomedical research, with the exception of a clinical trial on a medicinal product, shall be issued by the Lithuanian Bioethics Committee or a regional biomedical research ethics committee. The regional biomedical research ethics committee shall issue approvals to conduct biomedical research where the biomedical research is planned to be conducted at the research sites located solely within the territory attributed to activities of the respective regional biomedical research ethics committee. An approval to conduct biomedical research planned to be conducted within the territory attributed to activities of more than one regional biomedical research ethics committee shall be issued by the Lithuanian Bioethics Committee upon receipt of conclusions of the regional biomedical research ethics committees. The institutions referred to in this paragraph shall issue approvals to conduct biomedical research on medical devices only upon receipt of a conclusion of the State Health Care Accreditation Agency under the Ministry of Health regarding conformity to the requirements for medical devices intended to be used for clinical research as specified by the Minister of Health.

3. Clinical trials on medicinal products may be conducted only subject to the issuance of a favourable opinion of the Lithuanian Bioethics Committee to conduct a clinical trial on a medicinal product and an authorisation of the State Medicines Control Agency under the Ministry of Health. The Lithuanian Bioethics Committee shall issue a favourable opinion to conduct a clinical trial on a medicinal product upon receipt of conclusions of regional biomedical research ethics committees, where the clinical trial on the medicinal product is planned to be conducted at the research sites located within the territory attributed to activities of an respective regional biomedical research ethics committee.

Article 21. Lithuanian Bioethics Committee

1. The Lithuanian Bioethics Committee shall be a budgetary institution financed from the state budget and other state monetary funds. The rights and duties of the owner of the Lithuanian Bioethics Committee shall be exercised by the Ministry of Health of the Republic of Lithuania (hereinafter: the 'Ministry of Health').

2. The Lithuanian Bioethics Committee shall:

1) analyse problems of bioethics and consult state and municipal institutions, agencies and organisations on the issues of bioethics, submit conclusions and proposals relating to the draft laws and other legal acts regulating these issues;

2) issue approvals to conduct biomedical research, with the exception of clinical trials on medicinal products, where the biomedical research is planned to be conducted at the research sites located within the territory attributed to activities of more than one regional biomedical research ethics committee, and undertake ethical supervision of such research;

3) issue a favourable opinion to conduct a clinical trial on a medicinal product and undertake ethical supervision of such biomedical research;

4) issue authorisations to provide the human biological samples and/or health information and/or health information processed in biobanks to the persons referred to in Article 17(2) of this Law;

5) in accordance with the procedure laid down by the Minister of Health, to keep a registry of biomedical research, accumulate, store and provide information thereon while ensuring protection of confidential information;

6) prepare and approve sample forms of the documents issued by the Lithuanian Bioethics Committee and regional biomedical research ethics committees and submitted to the Lithuanian Bioethics Committee and the regional biomedical research ethics committees;

7) supervise the activities of regional biomedical research ethics committees;

8) annually report to the Ministry of Health about its own activities and make proposals regarding resolution of bioethical problems;

9) supervise compliance with bioethical requirements by health care institutions and the institutions providing personal and public healthcare services;

10) provide methodological assistance and consult medical ethics commissions of health care institutions and other institutions on the issues related to bioethics;

11) represent the Republic of Lithuania at international organisations within its remit;

12) perform other functions as prescribed in this Law, other laws and the regulations of the Lithuanian Bioethics Committee.

3. An approval to conduct biomedical research and a favourable opinion to conduct a clinical trial on a medicinal product shall be issued by the Lithuanian Bioethics Committee subject to a positive conclusion by the Group of Biomedical Research Experts of the Lithuanian Bioethics Committee.

4. The Group of Biomedical Research Experts of the Lithuanian Bioethics Committee shall consist of nine members, of whom five experts shall be professionals of biomedical sciences and four – professionals holding a degree in the area of social sciences or humanities. Professionals of biomedical sciences shall, within the time limit and in accordance with the procedure laid down by the Minister of Health, be nominated to the Group of Biomedical Research Experts of the Lithuanian Bioethics Committee by associations of personal health care professionals, whereas professionals of social sciences or humanities shall be nominated by the universities where bioethics or health law is taught. The composition of the Group of Biomedical Research Experts of the Lithuanian Bioethics Committee shall be approved by the Minister of Health acting in compliance with the principles of impartiality and transparency and having regard to the professional qualifications and competence of candidates and their experience in the area of ethics of biomedical research. The procedure for remunerating for activities of this group and work of the experts shall be laid down by the Minister of Health.

5. The term of office of a member of the Group of Biomedical Research Experts of the Lithuanian Bioethics Committee shall be four years. A person may serve as a member of the Group of Biomedical Research Experts of the Lithuanian Bioethics Committee for no longer than two terms in succession.

6. The mandate of a member of the Group of Biomedical Research Experts of the Lithuanian Bioethics Committee shall expire with the expiry of his term of office, when he resigns or when he is recalled by the Minister of Health on the recommendation of an association or institution which nominated him in the cases when he no longer can perform the duties of a member of the Group of Biomedical Research Experts of the Lithuanian Bioethics Committee due to an illness or when he dies. In such cases, where the term of office of the Group of Biomedical Research Experts of the Lithuanian Bioethics Committee is not expired, a new candidate for a member of the Group of Biomedical Research Experts of the Lithuanian Bioethics Committee shall be nominated, and the new member of this Group shall be approved in accordance with the procedure established by this Law.

Article 22. Establishment of regional biomedical research ethics committees and remit thereof

1. Regional biomedical research ethics committees shall be established under universities offering three-cycle medical studies. Funds shall be provided for the activities of

the regional biomedical research ethics committees in the state budget appropriations allocated to the Ministry of Health.

2. The procedure for establishing regional biomedical research ethics committees, carrying out activities thereof and addressing the issues falling within their remit shall be laid down by the statute of regional biomedical research ethics committees which shall be approved by the rector of a university in agreement with the Minister of Health. The territorial jurisdiction of the regional biomedical research ethics committees shall be specified by the Minister of Health.

3. Regional biomedical research ethics committees shall be established in accordance with the procedure laid down by regulations of the regional biomedical research ethics committees and consist of nine members:

1) two representatives of biomedical sciences holding a scientific degree and two representatives of social sciences or humanities holding a scientific degree shall be appointed by a university under which a regional biomedical research ethics committee has been formed;

2) three health care professionals from the health care institutions operating in the area and a professional of social sciences or humanities shall be appointed by the Minister of Health;

3) one member shall be appointed by patients' organisations.

4. The composition of a regional biomedical research ethics committee shall be approved by a university rector in agreement with after getting agreement of the Minister of Health. The term of office of a member of the regional biomedical research ethics committee shall be four years. A person may serve as a member of the regional biomedical research ethics committee for no longer than two terms in succession.

5. A regional biomedical research ethics committee shall:

1) issue approvals to conduct biomedical research, with the exception of clinical trials on medicinal products, where the biomedical research is planned to be conducted at the research sites located solely within the territory attributed to activities of the respective regional biomedical research ethics committee;

2) submit conclusions to the Lithuanian Bioethics Committee, where the biomedical research is planned to be conducted at the research sites located within the territory attributed to activities of more than one regional biomedical research ethics committee;

3) submit conclusions to the Lithuanian Bioethics Committee, where a clinical trial on a medicinal product is planned to be conducted within the territory attributed to activities thereof;

4) undertake ethical supervision of biomedical research to conduct which it has issued an approval and clinical trials on medicinal products on which it has provided conclusions;

5) keep a registry of issued approvals;

6) report to the Lithuanian Bioethics Committee in accordance with the procedure laid down by it.

Article 23. Receipt and Consideration of Documents and Issuance of Approvals

1. In order to obtain an approval to conduct biomedical research, the sponsor, an authorised representative thereof and/or the principal investigator shall submit to the Lithuanian Bioethics Committee or to a regional biomedical research ethics committee the documents a list whereof shall be approved by the Minister of Health. The documents must be considered and the approval to conduct biomedical research must be issued or a reasoned refusal to issue it must be given not later than within 45 calendar days from the receipt of all duly executed documents. The documents must be considered and the approval to conduct biomedical research on a medical device must be issued or a reasoned refusal to issue it must be given not later than within 60 calendar days from the receipt of all properly filled-in documents.

2. The procedure for issuing approvals to conduct biomedical research shall be laid down by the Minister of Health.

3. The Lithuanian Bioethics Committee or a regional biomedical research ethics committee shall adopt a decision to refuse the issuance of an approval to conduct biomedical research where, based on submitted documents, it is established that the biomedical research contradicts the ethical requirements for biomedical research stipulated in Chapter II of this Law, incomplete and/or false documentation and/or information has been submitted, and the instruction to eliminate these shortcomings has not been complied with, and a decision to refuse the issuance of an approval to conduct biomedical research on a medical device - also in the case when the State Health Care Accreditation Agency provides a conclusion that the medical device does not conform to the requirements for medical devices intended to be used for clinical research as specified by the Minister of Health.

4. A state fee of the established amount shall be paid for expert examination of the documents submitted for the issuance of an approval to conduct biomedical research and for the issuance of approvals.

Article 24. Suspension of an approval to conduct biomedical research, lifting of the suspension and revocation of the approval to conduct biomedical research

1. An approval to conduct biomedical research shall be suspended in the following cases:

1) violations of the requirements for biomedical research ethics as set out in Chapter II of this Law have been established, which could significantly undermine subjects' rights, security, health and/or the quality and/or integrity of biomedical research data, or information on possible violations of this kind is available;

2) when requested by the sponsor of a biomedical research, his authorised representative or the principal investigator;

3) violations of the requirements for medical devices intended to be used for clinical research as approved by the Minister of Health have been established, which could significantly undermine subjects' rights, security, health and/or the quality and/or integrity of biomedical research data.

2. Upon adopting a decision on suspension of an approval to conduct biomedical research on the ground indicated in point 1 of paragraph 1 of this Article, a notice thereof shall be given not later than within three calendar days from the adoption of the decision to the sponsor of biomedical research, the principal investigator and the head of a research site and a time limit for eliminating the violations identified shall be laid down. This time limit may not exceed 30 calendar days, with the exception of the cases when, for objective reasons, elimination of the violations requires a longer period of time or when an approval to conduct biomedical research is suspended at the request of the sponsor of biomedical research or the principal investigator on grounds other than violations. The sponsor of biomedical research, the principal investigator and the head of the research site must ensure that biomedical research is immediately discontinued.

3. A decision on lifting the suspension of an approval shall be adopted where no violations are established or upon eliminating the violations or, where the approval to conduct biomedical research is suspended at the request of the sponsor of biomedical research, his authorised representative or the principal investigator on grounds other than violations, when the sponsor of biomedical research, his authorised representative or the principal investigator

file an application for annulling the decision on suspension of the approval to conduct biomedical research.

4. An approval to conduct biomedical research shall be revoked in the following cases:

1) violations of the requirements for biomedical research ethics as set out in Chapter II of this Law have been established, which could significantly undermine subjects' rights, security, health and/or the quality and integrity of biomedical research data and which may not be eliminated upon suspending the biomedical research;

2) violations of the requirements for biomedical research ethics as set out in Chapter II of this Law have been established, which could significantly undermine subjects' rights, security, health and/or the quality and integrity of biomedical research data, on the basis of which the approval to conduct biomedical research has been suspended and which have not been eliminated within the determined time limit;

3) when requested by the sponsor of a biomedical research, his authorised representative or the principal investigator;

4) where the sponsor of biomedical research, his authorised representative or the principal investigator fail to submit an application for lifting the suspension of the approval within two years from the adoption of a decision on suspension of the approval to conduct biomedical research on the ground indicated in point 2 of paragraph 1 of this Article;

5) violations of the requirements, as approved by the Minister of Health, for the medical devices intended to be used for clinical research have been established, which could significantly undermine subjects' rights, security, health and/or the quality and integrity of biomedical research data and which may not be eliminated upon suspending biomedical research or on the basis of which the approval to conduct biomedical research has been suspended and which have not been eliminated within the determined time limit.

5. Upon taking a decision to revoke an approval to conduct biomedical research, the sponsor of a biomedical research, his authorised representative or the principal investigator as well as the head of a research site shall be notified thereof in writing not later than within three calendar days from the taking of the decision and must ensure that biomedical research be immediately terminated.

6. Powers to suspend an approval to conduct biomedical research, to lift the suspension of the approval and to revoke the approval to conduct biomedical research shall be vested in an institution which has issued such an approval.

Article 25. Procedure for Examining Complaints

1. The sponsor of a biomedical research, his authorised representative and/or the principal investigator shall have the right to appeal against a decision of a regional biomedical research ethics committee to refuse the issuance of an approval or to revoke or suspend the approval to the Lithuanian Bioethics Committee within 15 calendar days from the receipt of such a decision. The Lithuanian Bioethics Committee must examine this appeal and take a decision within 30 calendar days from its receipt.

2. Filing of an appeal shall not suspend the execution of a decision on the revocation or suspension of an approval to conduct biomedical research.

3. Upon examining an appeal by the sponsor of a biomedical research, his authorised representative and/or the principal investigator against a decision of a regional biomedical research ethics committee decision to refuse the issuance of an approval to conduct biomedical research or to revoke or suspend the approval to conduct biomedical research, the Lithuanian Bioethics Committee shall take a decision:

1) to dismiss the appeal by the sponsor of a biomedical research, his authorised representative and/or the principal investigator and to uphold the decision of the regional biomedical research ethics committee or

2) to uphold the appeal of the sponsor of a biomedical research, his authorised representative and/or the principal investigator and to issue the approval or to take a decision to overrule the decision to revoke or suspend the approval to conduct biomedical research.

4. A decision of the Lithuanian Bioethics Committee shall, not later than within five working days from the taking thereof, be dispatched to a person who has filed an appeal and to a regional biomedical research ethics committee which has taken a decision appealed against.

5. The sponsor of a biomedical research, his authorised representative or the principal investigator shall have the right to appeal to court in accordance with the procedure laid down by laws against a decision of the Lithuanian Bioethics Committee to refuse to issue an approval to conduct biomedical research, to revoke or suspend the approval to conduct biomedical research, also a decision of the Lithuanian Bioethics Committee to dismiss an appeal by the sponsor of a biomedical research, his authorised representative and/or the principal investigator and to uphold a decision of a regional biomedical research ethics committee.

6. The subjects or other persons entitled to give a person's consent to participate in research in the cases specified in this Law shall have the right to appeal to an institution

which has issued an approval or to court in accordance with the procedure laid down by law and other legal acts against actions of the sponsor of a biomedical research, his authorised representative, the principal investigator and other persons conducting biomedical research.

7. The persons whose biological sample and/or health information is processed by a biobank shall have the right to appeal against actions of the biobank in accordance with the procedure laid down by laws and other legal acts.

CHAPTER V
FINAL PROVISIONS

Article 26. Liability for infringements of ethical requirements for biomedical research

1. Persons in breach of requirements of this Law shall be held liable under law.

2. The fact of conducting a biomedical research without an authorisation or not in compliance with the requirements set forth by this Law and other legal acts, provided the research has not incurred either pecuniary or non-pecuniary damage to the subject's health, shall be held equivalent to an act of malpractice.

Annex to
the Republic of Lithuania
Law on Ethics
of Biomedical Research

LEGAL ACTS OF THE EUROPEAN UNION IMPLEMENTED BY THIS LAW

1. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ 2004 special edition, Chapter 13, Volume 26, p. 299)."

Article 2. Entry into force, implementation and application of the Law

1. This Law, except for paragraph 2 of this Article, shall enter into force on 1 January 2016.

2. The Government of the Republic of Lithuania or an institution authorised by it, the Minister of Health of the Republic of Lithuania and the Minister of Social Security and Labour of the Republic of Lithuania shall, by 31 December 2015, adopt the legal acts implementing this Law.

3. The documents submitted before the entry into force of this Law for the issuance of an approval to conduct biomedical research or for a favourable opinion to conduct a clinical trial on a medicinal product and an authorisation to conduct a clinical trial on a medicinal product (hereinafter: an 'authorisation') shall be examined and biomedical research for which the approval was issued before the entry into force of this Law shall be conducted in accordance with the provisions of the Law of the Republic of Lithuania on Ethics of Biomedical Research in force before the entry into force of this Law, with the exception of the cases indicated in paragraphs 4 and 5 of this Article.

4. The documents for the issuance of an approval which were submitted and were not examined before the entry into force of this Law shall, upon the entry into force of this Law, be examined in compliance with the Law of the Republic of Lithuania on Ethics of Biomedical Research as set forth in Article 1 of this Law.

5. This Law shall apply to biomedical research for which an approval was issued before the entry into force of this Law after the lapse of three years from the entry into force of this Law. This Law may apply to biomedical research referred to in this paragraph also before the expiry of the time limit referred to in this paragraph where amendments conforming to provisions of the Law of the Republic of Lithuania on Ethics of Biomedical Research as set forth in Article 1 of this Law are made to the documents related to the respective research in accordance with the procedure laid down in the Procedure for the Issuance of Approvals to Conduct Biomedical Research or the Procedure for the Issuance of Favourable Opinions to Conduct a Clinical Trial on a Medicinal Product and Approvals to Conduct a Clinical Trial on a Medicinal Product, Conducting and Exercising Control of the Trials as approved by the Minister of Health of the Republic of Lithuania.

6. Where a legal person holding a licence for personal healthcare services issued before the entry into force of this Law becomes entitled to engage in biobanking activity in accordance with the procedure laid down by the Law of the Republic of Lithuania on Ethics of Biomedical Research as set forth in Article 1 of this Law, its licence for personal healthcare services shall be supplemented by making therein an entry on a new licensed activity.

7. A legal person holding a licence for personal healthcare services issued before the entry into force of this Law and having established a biobank before the entry into force of this Law must, without suspending biobanking activity within 90 calendar days from the entry into force of this Law and in accordance with the procedure laid down by the Law of the Republic of Lithuania on Ethics of Biomedical Research as set forth in Article 1 of this Law, obtain the right to engage in biobanking activity. In this case, the legal person's licence for personal healthcare services shall be supplemented by making therein an entry on a new licensed activity.

8. A biobank indicated in paragraph 7 of this Article must, within 90 calendar days from the entry into force of this Law, obtain consent to biobanking from a person whose biological samples and/or health information was/were processed in the biobank before the entry into force of this Law. Where the person's consent to biobanking is not obtained, the person's biological sample and health information may not be processed after the lapse of 90 calendar days from the entry into force of this Law.

9. A biobank indicated in paragraph 7 of this Article must, within 90 calendar days from the entry into force of this Law, register human biological samples processed before the entry into force of this Law and submit this registry to the Lithuanian Bioethics Committee and publish them in accordance with the procedure laid down in Article 19 of the Law of the Republic of Lithuania on Ethics of Biomedical Research as set forth in Article 1 of this Law.

I promulgate this Law passed by the Seimas of Republic of Lithuania.

PRESIDENT OF THE REPUBLIC DALIA GRYBAUSKAITĖ