REPUBLIC OF LITHUANIA

LAW
ON ETHICS OF BIOMEDICAL RESEARCH

11 May 2000 No VIII-1679

(As last amended on 26 June 2014 – No XII-981)

Vilnius

CHAPTER ONE
GENERAL PROVISIONS

Article 1. Scope of this Law

1. This Law shall set forth requirements for and principles of the ethics of biomedical research, a procedure for issuing approvals to conduct biomedical research, a procedure for controlling the conducting of biomedical research and liability for violation of requirements of this Law. Requirements for clinical trials on a medicinal product shall be set forth, in addition to this Law, by the Law of the Republic of Lithuania on Pharmacy and other legal acts.

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

Article 2. Definitions

1. **Biomedical research** means verification of hypotheses of biomedical sciences by means of methods of scientific research and development of knowledge about peculiarities of human health.

2. **Sponsor of biomedical research** means a natural or a legal person or a branch of an enterprise established in a Member State of the European Union or another state of the European Economic Area which is registered in the Republic of Lithuania and which initiates, finances, supervises biomedical research and takes responsibility for its conduct, consequences and publication of the research findings.

3. **Ethics of biomedical research** means adherence to the ethical requirements and principles as provided for in this Law when conducting biomedical research.

4. **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 a woman's pregnancy.

5. **Ethical supervision** means the activities carried out by the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee and having the purpose of controlling compliance of natural or legal persons with requirements and principles of ethics of biomedical research in conducting biomedical research.

6. **Confidentiality of information** means preservation of information about the state of health of the research subject, diagnosis, prognosis, medical treatment and other personal data relating to the subject's health.

7. **Informed consent** (hereinafter: '**consent**') means an explicit and knowing written consent by the subject to participate in a biomedical research.

8. **Clinical research** means biomedical research in human subjects.

9. **Clinical trial on a medicinal product** means any biomedical research in human subjects intended to discover, verify and confirm the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product/products, and/or to identify any adverse reactions to one or more investigational medicinal product/products and/or to study resorption, distribution, metabolism and excretion of one or more investigational medicinal product/products with the object of ascertaining the safety and/or efficacy of an investigational medicinal product.

10. (Repealed on 1 January 2008)

11. **Non-clinical research** means the research not involving human subjects.

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

13. **Representative of the subject** means a legal representative or an appointed representative. The authorisation of the appointed representative must be executed in accordance with the procedure laid down by laws of the Republic of Lithuania.

14. **Investigator** means a doctor or a person who may conduct a biomedical research because of an appropriate education and the experience in patient care. The investigator shall be responsible for the conduct of a biomedical research at a research site. Where the investigator himself conducts a biomedical research or leads a team of individuals conducting a research at the research site and is responsible for the activities of this team, he may be called the principal investigator. Qualification requirements for the principal investigator shall be set forth by the Ministry of Health.

15. **Foetus** means the stage of development of a human organism from the ninth week of a woman's pregnancy until birth.

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

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

18. **Human stem cells** means the unspecialised cells present during the period of development of an embryo and 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.

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

Article 3. Objectives, Objects and Peculiarities of Conducting Biomedical Research

1. Biomedical research may be undertaken on human subjects or their groups, a foetus, tissues, organs, cells and genetic material, cadavers and medical documents. Human subjects or their groups and a foetus may undergo biomedical research only where comprehensive data about relevant non-clinical trials are available. Non-clinical trials must be conducted in conformity with the Guidelines for Good Laboratory Practice approved by the Ministry of Health. Clinical trials must be conducted in accordance with the Guidelines for Good Clinical Practice approved by the Ministry of Health.

2. Human embryos may be subjects only of clinical observations (non-invasive trials). Other biomedical research involving human embryos, also their creation for the purposes of biomedical research shall be prohibited. A foetus may be subject only of such biomedical research where the potential benefit to the foetus under investigation exceeds medical risks.

3. Import into the territory of the Republic of Lithuania and export therefrom of tissues of a human embryo, stem cells of an embryo 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 2 of this Article. Transit through the territory of the Republic of Lithuania of tissues of a human embryo, stem cells of an embryo and lines thereof or tissues of a foetus and the stem cells taken therefrom and lines thereof shall be possible only subject to authorisation by the Ministry of Health. A Description of the Procedure for Authorising the Transit Through the Territory of the Republic of Lithuania of Tissues of Human Embryos, Stem Cells of an Embryo and Lines Thereof or Tissues of a Foetus and the Stem Cells Taken Therefrom and Lines Thereof as well as a Description of the Procedure for Importing into the Territory of the Republic of Lithuania and Exporting Therefrom of the Stem

Cells Taken from the Umbilical Cord or Placenta after the Birth of a Child and the Samples Taken for Genetic Research shall be specified by the Minister of Health.

4. Cloning of a human being shall be prohibited.

5. The peculiarities of the biomedical research undertaken on cadavers and medical documents shall be specified by laws and by the Lithuanian Bioethics Committee.

CHAPTER TWO
REQUIREMENTS FOR ETHICS OF BIOMEDICAL RESEARCH

Article 4. Requirements for Ethics of Biomedical Research

Biomedical research may only be conducted if the following requirements are met:

1) biomedical research has scientific and practical merit;

2) protection of interests of the subject and confidentiality of information about the subject has been ensured;

3) free consent of the subject has been obtained;

4) the investigator and the sponsor of biomedical research are covered by the third-party insurance against possible damage to the subject;

Version after 1 January 2015:

4) the third-party insurance against possible damage to the subject is provided in the cases specified in Article 11(2) and (3) of this Law;

5) the documents of the institutions indicated in Article 12 of this Law granting the right to conduct a biomedical research have been obtained;

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

Article 5. Vulnerable Subjects

1. Vulnerable subjects shall be the persons whose consent to participate in biomedical research may be influenced by external circumstances. The following subjects shall be regarded as vulnerable:

1) persons with mental disorders, but capable of giving their consent to participate in biomedical research;

2) minors;

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

4) persons in 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.

2. Biomedical research may not be undertaken on persons kept in prisons or other imprisonment institutions.

3. Other groups of persons may be recognised as (attributed to) vulnerable subjects by a reasoned decision of the Lithuanian Bioethics Committee.

4. Vulnerable subjects shall be applied additional measures for the protection of their interests specified in Article 7 of this Law.

Article 6. Protection of Interests of the Subject

With a view to protecting the interests of the subject, biomedical research shall be undertaken only where:

1) biomedical research may not be replaced by any another research without the involvement of human subjects;

2) free consent of the person has been obtained;

3) the person who does not give his consent to participate in biomedical research or who withdraws his consent shall not be deprived of his right to be provided with an appropriate health care;

4) the risks that may be incurred by the research subject must not be disproportionate to the potential benefits he derives from participation in the research. As a rule, the expected treatment may not be administered to the subject only when its efficacy has not been proved or when its non-administration does not pose a risk to the health of the subject;

5) the principal investigator and the sponsor of biomedical research are covered by the third-party insurance for compensation of the damage caused to the subject's health and the fatal damage incurred by biomedical research.

Version after 1 January 2015:

5) the principal investigator and the sponsor of biomedical research or a health care establishment are covered, in the cases specified by Article 11(2) and (3) of this Law, by the third-party insurance for compensation to the subject of the possible damage caused in the course of biomedical research.

Article 7. Protection of Interests of Vulnerable Subjects

1. Biomedical research involving vulnerable subjects shall be permitted only where:

1) such biomedical research may be undertaken only on vulnerable subjects;

2) the results of the biomedical research may be of direct and real benefit to the health of these subjects;

3) the biomedical research will not pose a risk to the health or life of the subject.

2. If the subject is a minor, consent to undertake a biomedical research shall be given by both parents or legal representatives of the minor and the children's rights protection agency of a district or a city. Where the parents of a minor are separated, consent of one of the parents or of the legal representative and of the children's rights protection agency of the district or the city must be obtained.

3. The consent of a psychiatric patient capable of giving knowing consent to take part in a biomedical research must be attested by two witnesses and the head of a health care establishment where the biomedical research is being conducted. Approval of the Medical Ethics Commission must also be obtained. The procedure for forming the Medical Ethics Commission and conducting its activities shall be laid down in the Model Regulations of the Medical Ethics Commission of a Health Care Establishment approved by the Ministry of Health.

Article 8. Consent

1. Biomedical research shall be undertaken after the subject has given his written consent. Before giving his consent, the subject shall be provided, against signature, with information understandable to him about the goal, plan of the research and the methods applied, decisions of the Lithuanian Bioethics Committee or an appropriate regional biomedical research ethics committee as well as about the following:

1) foreseeable benefits of the biomedical research to the subject;

2) the rights, foreseeable risks and inconveniences which the biomedical research may cause to the subject as well as the compensation available to the subject in the event of the damage incurred by the biomedical research;

3) the right of the subject to revoke his consent to participate in the biomedical research in writing at any time, providing to him information about the consequences of such discontinuation of the biomedical research;

4) guarantees of confidentiality of the information.

2. A decision on whether the consent is necessary for conducting biomedical research on tissues, organs, a foetus, cell or genetic material which had been obtained from a person for other purposes during medical interventions before applying for undertaking research on this person, also when biomedical research is undertaken on medical documents shall be taken by the Lithuanian Bioethics Committee or a regional biomedical research ethics committee issuing an approval to conduct biomedical research.

Article 9. Confidentiality of Information

1. Information obtained in the course of a biomedical research about the subject's state of health, diagnosis, prognosis, medical treatment and other health-related personal information shall be confidential and may be provided only in accordance with the procedure laid down by the Law on the Rights of Patients and Compensation of the Damage to Their Health.

2. The information obtained in the course of biomedical research about the subject's state of health, diagnosis, prognosis, medical treatment and other health-related personal information shall not be regarded as confidential and may be made public without the subject's consent if the subject's identity remains undisclosed after such information is made public.

Article 10. Compensation for Costs

Subjects shall be entitled to reimbursement of expenses for participating in a biomedical research. The procedure for calculating and paying these expenses shall be laid down by the Government or an institution authorised by it.

Article 11. Third-Party Liability of the Sponsor of Biomedical Research and the Principal Investigator and Its Insurance

1. The sponsor and the investigator of biomedical research shall be liable for the damage resulting from injury to the health of the subject or the death of the subject as well as for the non-pecuniary damage incurred by the biomedical research where they fail to prove that the damage has resulted from causes unrelated to the biomedical research or from deliberate acts of the subject. The damage done to health by the sponsor of biomedical research and the investigator, the damage incurred by reason of death and the non-pecuniary damage resulting therefrom shall be redressed in the cases specified in the Law on the Rights of Patients and Compensation of the Damage to Their Health and in accordance with the procedure laid down by the Civil Code.

2. The sponsor and the principal investigator of biomedical research must be covered by the third-party insurance against the damage which could be caused to the subject in the course of biomedical research under compulsory third-party insurance contracts of the principal investigator and the sponsor of biomedical research concluded with the insurers authorised, in accordance with the procedure laid down by legal acts, to provide the compulsory third-party insurance to principal investigators and sponsors of biomedical research. This requirement shall apply only where biomedical research is undertaken on human subjects.

Version after 1 January 2015:

2. The sponsor and the principal investigator of biomedical research must be covered by the third-party insurance against the damage which could be caused to the subject in the course of biomedical research under compulsory third-party insurance contracts of the principal investigator and the sponsor of biomedical research concluded with the insurers authorised, in accordance with the procedure laid down by legal acts, to provide the compulsory third-party insurance to principal investigators and sponsors of biomedical research. This requirement shall apply only in the cases of conducting of a clinical trial on a medicinal product, a clinical trial of a medical device or any other biomedical research in which the participant is, for research purposes, made subject to interventional research methods posing a risk to the subject's health, with the exception of the cases referred to in paragraph 3 of this Article. The risk posed to the subject's health by the interventional research methods applied for the purposes of biomedical research shall be assessed 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 Rules of Compulsory Third-Party Insurance of Principal Investigators and Sponsors of Biomedical Research laying down the procedure for calculating the extent of damage to the subject’s health and compensating for it shall be approved by the Government or an institution authorised by it.

The Article shall be supplemented with paragraph 3; paragraph 3 shall be renumbered as paragraph 4 as of 1 January 2015:

3. The conduct of a clinical trial on a medicinal product, a clinical trial of a medical device or any other biomedical research in which the participant is, for research purposes, made subject to interventional research methods having only a slightly detrimental and temporary impact on the subject’s health shall also be permitted if a contract on 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. The slightly detrimental and temporary impact on the subject’s health by the interventional research methods applied for the purposes of biomedical research shall be assessed 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 Rules of Compulsory Third-Party Insurance of Principal Investigators and Sponsors of Medical Research laying down the procedure for calculating the extent of damage to the subject's health and compensating for it shall be approved by the Government or an institution authorised by it.

CHAPTER THREE
PROCEDURE FOR CONTROLLING THE CONDUCT OF BIOMEDICAL RESEARCH

Article 12. Institutions Authorising to Conduct Biomedical Research

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

2. An approval 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 the approval to conduct biomedical research where the biomedical research is planned to be conducted at the research centres located solely within the territory attributed to activities of an appropriate regional biomedical research ethics committee. The approval to conduct the 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 regional biomedical research ethics committees.

3. Clinical trials on a medicinal product may be conducted only being in possession of a favourable opinion of the Lithuanian Bioethics Committee to conduct a clinical trial of the 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 centres located within the territory attributed to activities of an appropriate regional biomedical research ethics committee.

Article 13. Establishment of the Lithuanian Bioethics Committee and Remit Thereof

1. The Lithuanian Bioethics Committee shall be established and its composition and regulations shall be approved by the Ministry of Health. The Lithuanian Bioethics Committee shall be a legal person. Its activities shall be financed from the state budget.

2. The Lithuanian Bioethics Committee shall:

1) analyse problems of bioethics and consult state and local government 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 centres located within the territory attributed to activities of more than one regional biomedical research ethics committee, and undertake ethical supervision of this research;

3) issue a favourable opinion to conduct clinical trials on a medicinal product and undertake ethical supervision of these trials;

4) control the activities of regional biomedical research ethics committees;

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

6) control whether individual and public health care is in conformity with the requirements of bioethics and monitor compliance of legal persons with the requirements of bioethics;

7) provide methodological assistance and consult medical ethics commissions of health care establishments and other institutions on the issues relating to their activities;

8) represent Lithuania at international organisations within its remit;

9) perform other functions specified in its regulations.

3. The Lithuanian Bioethics Committee shall, in accordance with the procedure laid down by the Ministry of Health, keep a record of biomedical research, accumulate, store and provide information about the research ensuring protection of confidential information, also prepare and approve sample forms of documents.

4. With a view to solving specific problems of bioethics, ad hoc commissions may be formed by the Government.

As of 1 January 2015, Article 3 shall be supplemented with paragraphs 3 and 4; paragraphs 3 and 4 shall be renumerated as paragraphs 5 and 6 respectively:

3. An approval to conduct biomedical research and a favourable opinion to conduct clinical trials 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. 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 Experts of the Lithuanian Bioethics Committee by associations of health care professionals, whereas professionals of social sciences or humanities shall be nominated by the universities teaching bioethics or health law subjects. 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 the Group and work of the experts shall be laid down by the Minister of Health.

4. 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. 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 the Group shall be approved in accordance with the procedure established by law.

5. The Lithuanian Bioethics Committee shall, in accordance with the procedure laid down by the Ministry of Health, keep a record of biomedical research, accumulate, store and provide information about the research ensuring protection of confidential information, also prepare and approve sample forms of documents.

6. With a view to solving specific problems of bioethics, ad hoc commissions may be formed by the Government.

Article 14. Formation of Regional Biomedical Research Ethics Committees and Remit Thereof

1. Regional biomedical research ethics committees shall be formed 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 committees, carrying out activities thereof and addressing the issues falling within their remit shall be laid down by regulations of regional biomedical research committees which, subject to coordination with the Ministry of Health, shall be approved by the rector of a university. The territorial jurisdiction of the regional biomedical research ethics committees shall be specified by the Ministry of Health.

3. Regional biomedical research ethics committees shall be formed 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;

2) three health care professionals from the health care establishments operating in the area and a professional of social sciences or humanities shall be appointed by the Ministry 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 subject to coordination with the Ministry 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.

5. A regional biomedical research ethics committee shall:

1) issue an approval 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 centres located solely within the territory attributed to activities of the appropriate 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 centres 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 clinical trials on a medicinal product are planned to be conducted within the territory attributed to activities thereof;

4) undertake ethical review of biomedical research which it has authorised and clinical trials on medicinal products on which it has provided conclusions;

5) keep accounts of issued approvals;

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

Article 15. Procedure for Receiving and Considering Documents and Issuing Approvals

1. The sponsor, an authorised representative thereof and/or the principal investigator of biomedical research wishing to obtain an approval 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 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.

2. 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 the approval.

3. The procedure for issuing an approval to conduct biomedical research shall be laid down by the Minister of Health.

4. The Lithuanian Bioethics Committee or a regional biomedical research ethics committee shall have the right to take a decision not to issue an approval to conduct biomedical research, where the data provided in documents are in conflict with the requirements of ethics of biomedical research provided for in this Law, where the documents filed have been improperly executed, where incomplete or misleading information has been provided and the requirement to eliminate such shortcomings has not been complied with.

Article 16. Suspension or Revocation of an Approval to Conduct Biomedical Research

1. The Lithuanian Bioethics Committee or a regional biomedical research ethics committee shall have the right to revoke an approval to conduct biomedical research in the event

of proving violation of the requirements of ethics of biomedical research provided for in this Law or where so requested by the sponsor, an authorised representative thereof and/or the principal investigator of biomedical research. Evidence of the violation shall be provided by the Lithuanian Bioethics Committee or the regional biomedical research ethics committee within its remit.

2. The Lithuanian Bioethics Committee or a regional biomedical research ethics committee shall, upon taking a decision on the revocation of an approval to conduct biomedical research, not later than within five calendar days from the taking of the decision, give a written notice to the sponsor, an authorised representative thereof and/or the principal investigator of biomedical research as well as to heads of the health care establishments where the biomedical research is being conducted, who much ensure that the biomedical research is terminated without delay.

3. The Lithuanian Bioethics Committee or a regional biomedical research ethics committee shall have the right to suspend an approval if there are reasonable grounds to suspect violation of the requirements of ethics of biomedical research provided for in this Law or where so requested by the sponsor, an authorised representative thereof and/or the principal investigator of biomedical research. The procedure for suspending approvals shall be laid down by the Minister of Health.

4. The Lithuanian Bioethics Committee or a regional biomedical research ethics Committee shall, upon taking a decision on the suspension of an approval, not later than within three calendar days from the taking of the decision, give a written notice to the sponsor, an authorised representative thereof and/or the principal investigator of a biomedical research as well as to heads of the health care establishments where the biomedical research is being conducted. The sponsor and/or the principal investigator of biomedical research and heads of the health care establishments where the biomedical research is being conducted must ensure that the biomedical research is discontinued without delay.

Article 17. Procedure for Investigating Complaints

1. The sponsor of a biomedical research and/or the principal investigator shall have the right to appeal against a regional biomedical research ethics committee’s decision 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 investigate this appeal within 30 calendar days from its receipt.

2. Filing of a complaint shall not suspend the enforcement of a decision on the revocation or suspension of an approval.

3. Upon examining an appeal by the sponsor of a biomedical research and/or the principal investigator against a regional biomedical research ethics committee's decision to refuse the issuance of an approval or to revoke or suspend the approval, the Lithuanian Bioethics Committee shall have the right:

1) to uphold the decision of the regional biomedical research ethics committee and to dismiss the appeal of the sponsor of the biomedical research and/or the principal investigator;

2) to uphold the appeal of the sponsor and/or the principal investigator of the biomedical research and to issue the approval or to take a decision to overrule the decision on the revocation or suspension of the approval.

4. Where a decision to refuse the issuance of an approval or to revoke or suspend the approval is taken by the Lithuanian Bioethics Committee within its remit, the sponsor of a biomedical research and/or the principal investigator shall have the right to appeal against such a decision to court within 30 calendar days from the receipt of such a decision in accordance with the procedure laid down by law.

5. The subjects or their representatives shall have the right to appeal against actions of the sponsor of research, the principal investigator and other persons involved in the conduct of biomedical research to an institution which has issued an approval and to court in accordance with a procedure laid down by laws and other legal acts.

CHAPTER FOUR
FINAL PROVISIONS

Article 18. Liability for Violation of Requirements of Ethics of 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 approval or not in compliance with the requirements set forth by this Law and other legal acts, provided the research has not incurred damage to the subject's health, shall be held equivalent to an act of malpractice.

Article 19. Entry into Force of the Law

This Law shall enter into force as of 1 January 2001.

Article 20. *Repealed as of 1 January 2012.*

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

PRESIDENT OF THE REPUBLIC VALDAS ADAMKUS

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

LEGAL ACTS OF THE EUROPEAN UNION IMPLEMENTED BY THIS LAW

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).