VELFERÐARRÁÐUNEYTIÐ

*Ministry of Welfare*

# Act on Scientific Research in the Health Sector
# No. 44/2014.

## SECTION I
## Objective and scope.

Article 1

*Objective.*

The objective of this Act is to foster scientific research of a high standard in the health sector, and to safeguard the interests of participants.

Article 2

*Scope and oversight.*

This Act applies to scientific research in the health sector. It applies to scientific studies carried out, in whole or in part, in Iceland. The provisions of Sections IV and V apply only to research on human subjects, and the provisions of Section VI only to retrospective studies.

Clinical trials of medicinal products are in addition subject to the provisions of the Medicinal Products Act and of regulations issued on the basis of that Act. In addition, clinical trials of medical equipment are subject to the provisions of the Act on Medical Devices and of regulations issued on the basis of that Act.

The Data Protection Act applies in so far as other provisions are not made under this Act. Access to health registers kept by the Medical Director of Health is subject to the Medical Director of Health and Public Health Act. Access to biological samples stored in biobanks is subject to the Biobanks and Health Databanks Act. Access to data in health databanks is subject to the Biobanks and Health Databanks Act. The use of human gametes and embryos for stem-cell research is subject to the provisions of the Act on Artificial Fertilisation and use of Human Gametes and Embryos for Stem-Cell Research. Matters for which the above-mentioned legislation makes no provision are additionally subject to the provisions of this Act, as applicable.

The Minister is responsible for the implementation of this Act.

Article 3

*Definitions.*

In this Act the following terms have these meanings:

1. *Scientific research in the health sector:* Research on human subjects, biological samples and health data in which scientific methods are applied in order to enhance knowledge of health and diseases.
2. *Scientific research project on human subjects:* A study in which the individual takes an active part in scientific research, for instance by undergoing tests, or providing samples or information for the study.

3. *Intervention:* An intervention entails physical intervention, or an intervention which entails a risk to the psychological health of the individual in question.
4. *Health data:* Information in health records, information and data from biobanks and health databanks, and other information on medical history and health.
5. *Biological sample*: Organic material from a human being, alive or deceased, which may provide biological information about him/her.
6. *Health information materials:* Health data and biological samples.
7. *Retrospective study*: A study which makes use of existing health information materials. The individual from whom the data or materials originate takes no active part in the study.
8. *Identifiable health information materials*: Health information materials which contain information which may be traced, directly or indirectly, to a specific individual, alive or deceased.
9. *Encryption:* Transformation of words or digits into an incomprehensible series of symbols.
10. *Principal investigator*: Individual responsible for the implementation of the study in accord with a research protocol which has been approved by the National Bioethics Committee or an institutional review board.
11. *Health databank*: Databank which has been licensed by the Minister to store health data which are acquired for scientific research, or which arise from such research.

## SECTION II
## Requirements for scientific research in the health sector.

### Article 4
*Fundamental requirements.*

Scientific research in the health sector shall be founded upon respect for the human dignity of the participants. Human rights shall not be sacrificed in favour of the interests of science or society.

The design and implementation of a scientific research project in the health sector shall be of such a nature that ethical and scientific principles are honoured, and personal privacy safeguarded.

### Article 5
*Requirements for design of scientific research projects.*

Scientific research projects in the health sector shall be based upon a research protocol which provides information on the study and its principal investigator. In the application submitted to the National Bioethics Committee or to an institutional review board, *cf.* Article 12, circumstances which might lead to a conflict of interest shall be declared.

The Minister shall make more detailed provisions in a regulation for the design of scientific research projects in the health sector, including research protocol, internal monitoring and the responsibilities of the principal investigator.

### Article 6
*Confidentiality.*

Those who are granted access to identifiable health information materials or other personal data in the implementation or monitoring of a study are subject to a duty of confidentiality.

The duty of confidentiality does not prevent data being provided to those who are entitled to access under the provisions of this Act or other legislation.

Article 7

*Retention of health information materials.*

After a study is completed, health information materials which were acquired for a retrospective study, or which arise from such research, may be retained permanently in a biobank or health databank, if this was stipulated in the research protocol which has been approved by the National Bioethics Committee or an institutional review board.

Retention of health information materials acquired for a scientific study on human subjects, or arising from such a study, is contingent upon the consent granted for the study. If health data are to be permanently retained, they shall be stored in a health databank, and biological samples in a biobank.

Health data from each scientific study shall be stored separately in a health databank. It is prohibited to link together health data on an individual from different studies while they are stored in a health databank. Access to and utilisation of the data are subject to the provisions of the Biobanks and Health Databanks Act.

Should health information materials have been acquired for use in a specific scientific study on human subjects, and should the participants not have granted consent for them to be retained for use in subsequent studies as provided in Article 19, they shall not be retained for any longer than is necessary in order to complete the study. The National Bioethics Committee or an institutional review board may, however, decide, after final findings have been submitted to the committee, that necessary health information materials are to be retained for a specified period, as required in order to evaluate the study. After that time the materials shall be destroyed or anonymised, unless their preservation is obligatory under the National Archives Act or other legislation.

Retention of health information materials acquired for clinical trials of medicinal products on human subjects, or arising from such research, is subject to the provisions of the Medicinal Products Act and regulations issued on the basis of that Act. Retention of health information materials acquired for clinical trials of medical equipment, or arising from such research, is subject to the Act on Medical Devices and regulations issued on the basis of that Act.

Article 8

*Transfer of health information materials from Iceland.*

Transfer of biological samples and health data from Iceland for use in scientific research in the health sector is subject to the provisions of the Data Protection Act.

## SECTION III
## Approval of scientific research.

Article 9

*National Bioethics Committee.*

The Minister of Health appoints a National Bioethics Committee, comprising seven members, for a term of four years, to consider scientific research projects in the health sector. One member of the committee shall be appointed on nomination by the Minister responsible for science; one on nomination by the Minister responsible for human rights; one on nomination by the Medical Director of Health; one on nomination by the University of Iceland Faculty of Medicine; and one on nomination by the University of Iceland Center for Ethics. Two members shall be appointed by the Minister without nomination. The Minister appoints a chair from among the members. The committee elects a deputy chair from among its members. Substitutes shall be appointed in the same manner. It shall be ensured that the committee includes individuals with expertise in the methodology of health sciences, ethics, law and data protection.

Article 10

*The role of the National Bioethics Committee.*

The National Bioethics Committee has the role of evaluating scientific research projects in the health sector with the objective of ensuring that they are consistent with scientific and ethical principles. In the case of doubt as to whether a project is to be deemed scientific research in the health sector, the National Bioethics Committee rules on that matter.

The National Bioethics Committee shall evaluate collaborative projects, multinational projects, clinical trials of medicinal products and other scientific research protocols in the health sector which do not fall within the terms of reference of an institutional review board under Article 11.

The National Bioethics Committee shall participate in public and academic debate in the field of bioethics, provide advice and promulgate advisory opinions on subjects within the field of the committee.

Further provision shall be made in regulations for the tasks of the National Bioethics Committee, including the Committee's authority to draw up its own rules of procedure. The National Bioethics Committee's rules of procedure are subject to confirmation by the Minister.

Rules of procedure drawn up by the National Bioethics Committee on the basis of this Act or regulations based on the Act apply also to the work institutional review boards appointed under this Act.

Article 11

*Institutional review boards.*

The Minister may establish by regulations[1)] an institutional review board within a specific healthcare institution, having elicited the opinion of the National Bioethics Committee. The regulations shall provide *inter alia* for appointment to and tasks of the institutional review board. Such a review board evaluates only scientific research projects carried out within the relevant institution, or jointly with educational bodies with which it collaborates.

*[1)] Regulation No. 1186/2014.*

Article 12

*Approval by National Bioethics Committee or an institutional review board.*

A scientific research project in the health sector may not be commenced unless it has been approved by the National Bioethics Committee or an institutional review board. The National Bioethics Committee or institutional review board shall evaluate the research protocol of a scientific study from the perspectives of science, ethics and human rights. The National Bioethics Committee and institutional review boards may attach certain conditions to their approval of a study.

No alterations to the nature or scope of a scientific study, nor any other major alteration, may be made unless previously approved by the National Bioethics Committee or an institutional review board which approved the original research protocol.

The National Bioethics Committee may determine that minor changes to a scientific study are subject only to the duty to notify the National Bioethics Committee or institutional review board, under rules to be issued by the National Bioethics Committee.

Article 13

*Consideration by the Data Protection Authority.*

The National Bioethics Committee and institutional review boards shall submit to the Data Protection Authority a summary of each application for a scientific study. This shall be done

as soon as possible. The summary shall provide information on the applicants, and describe the processing of personal data to be carried out for the study in question.

Having received the summary under paragraph 1, the Data Protection Authority decides whether it will consider the case further. The National Bioethics Committee or institutional review board may grant approval ten working days after receipt of the summary by the Data Protection Authority, unless the Authority has within that time notified the relevant committee otherwise. Should the Data Protection Authority do so, the committee may not grant approval until the Authority has reached a finding, in accord with the provisions of the Data Protection Act. The Authority may *inter alia* require security measures to be applied to the handling of personal data. Should the Data Protection Authority judge that the handling of personal data contravenes the Data Protection Act, approval shall not be granted for the study.

The Data Protection Authority may issue rules on security of personal data in the implementation of scientific research in the health sector. The Minister may make further provision in regulations[1)] for interaction with the Data Protection Authority under this Article, following consultation with the National Bioethics Committee and the Data Protection Authority.

[1)] *Regulation No. 1187/2014.*

Article 14

*Procedure and appeal.*

The procedure of the National Bioethics Committee and institutional review boards is subject to the provisions of the Administrative Procedures Act.

Decisions of review boards appointed under Article 11 may be appealed to the National Bioethics Committee.

Decisions of the National Bioethics Committee may be appealed to the Minister. A judgement by the National Bioethics Committee under sentence 2 of paragraph 1 of Article 12 is not liable to review by the Minister.

## SECTION IV
## General provisions on scientific research on human subjects.

Article 15

*Scientific research on human subjects.*

Scientific studies which entail intervention may not be carried out on human subjects if it is deemed likely that the same or a comparable objective can be attained without human participation.

Before a scientific study on human subjects is approved, the National Bioethics Committee or an institutional review board shall evaluate potential risk and burden on the one hand, and benefits for the participants or others on the other hand. In research on the effectiveness of a new treatment, with or without placebo, it shall be ensured that patients receive approved treatment. Should it transpire that the risk outweighs the potential benefit, the National Bioethics Committee or an institutional review board will halt the study.

Special care shall be taken when recruiting individuals from vulnerable social groups, i.e. individuals who for some reason are not in a position to make an informed or free decision.

Article 16

*Acquisition, use and delivery of health information materials for scientific research.*

The acquisition, use and delivery of health information materials for use in scientific studies shall be in accord with the objective of the study and with the approval granted by the National Bioethics Committee or an institutional review board.

Article 17

*Duty to report unforeseen incidents.*

The principal investigator of a study shall immediately submit to the monitoring body under paragraphs 2 and 3 of Article 29, and to the Data Protection Authority if applicable, written notification of unforeseen incidents which have, or could have, adversely affected participants, and are believed to be attributable to the study.

The principal investigator, other investigators and staff shall, on their own initiative, disclose to monitoring bodies information on factors which could pose a risk to the security of participants in the study. An unforeseen death shall immediately be notified to the police in accord with the provisions of the Act on Death Certificates, Autopsies etc.

## SECTION V
## Consent for scientific research on human subjects.

Article 18

*Participants' consent.*

Consent shall be elicited from participants in a scientific study on human subjects.

The consent shall be in writing and freely granted after the participant has been provided with adequate information on the study, risks it may entail, potential benefits, and the nature of the participation. The participant shall be informed that he/she may decline to take part in a scientific study, or withdraw from participation at any time after it commences, without stating any reason. Consent may, as applicable, consist in answering a questionnaire, provided that the provisions of sentences 1 and 2 on the provision of information are fulfilled.

The National Bioethics Committee, having received the opinion of the Data Protection Authority, issues rules on how potential participants in scientific research are to be selected and approached, and on the information to be provided before consent is elicited; processing of personal data is subject to the provisions of the Data Protection Act.

Article 19

*Broad consent for retention of materials for use in subsequent studies.*

Participants' consent may be elicited to retain biological samples and health data for subsequent use in designated scientific research in the health sector. The National Bioethics Committee or an institutional review board states conditions for the use of broad consent. The committee may also decide that a renewed consent should be elicited, if it deems that necessary.

Participants who have given broad consent under paragraph 1 shall have access to information on what research is being carried out by the principal investigator, institution or company. Participants may refuse use of their materials in specified studies, in which case their use is prohibited.

Biological samples retained under paragraph 1 shall be permanently stored in a biobank of scientific samples for use under the provisions of the Biobanks and Health Databanks Act. Health data retained under paragraph 1 shall be permanently stored in a health databank for use under the provisions of the Biobanks and Health Databanks Act. Participants must be informed of this.

The principal investigator of a study which deposits biological samples in a biobank, or other health data in a health databank, makes an agreement with the management of the bank on arrangements for access to materials for scientific research. It shall be ensured that the use is covered by the participants' consent under paragraph 1 and is consistent with the Data Protection Act.

Article 20

*Alterations to research protocol.*

With respect to alterations to the research protocol, the principal investigator shall adhere to the provisions of paragraphs 2 and 3 of Article 12. The National Bioethics Committee or an institutional review board which approved the research protocol shall determine whether it is necessary to elicit renewed consent from participants under Article 18.

Article 21

*Withdrawal of consent.*

Participants in a scientific study may withdraw their consent at any time. The same applies to consent for the retention of biological samples or health data for use in subsequent studies under Article 19.

Should consent be withdrawn, research on the relevant participant's biological samples or health data shall cease. Participants may require their biological samples and health data to be destroyed.

It is not possible, however, to require destruction under paragraph 2 if the biological sample or health data is/are anonymised, if the biological sample has been subsumed into other material, or if data already comprise part of the findings of a study.

Article 22

*Competence to consent.*

Those who are of age under the provisions of the Act on legal competence are competent to consent to participation in a scientific study.

Should a person who is of age be evidently incapable of understanding information on a scientific study due to physical or mental causes, consent is subject to Article 23.

Article 23

*Conditions for participation by individuals not competent to grant consent.*

A study on human subjects with participants who are not competent to grant consent is permissible only where all the following conditions are met:

a. there is reason to believe that the findings of the study may lead to enhancement of the participants' health,
b. research of comparable effectiveness cannot be carried out on individuals competent to give consent,
c. the individuals in question have been informed about the study in so far as that is possible, and are not opposed to participation,
d. the guardian of a child, the guardian of an individual who has been deprived of legal competence, or the next of kin of an individual under paragraph 2 of Article 22, has granted consent which meets the conditions of this Act.

A study may be approved, although the research findings are not deemed likely to produce results of direct benefit to the health of the person concerned, provided that the aim is significantly to increase scientific understanding of the individual's condition, disease or disability, for the benefit of persons in the same age category, having a similar disability, or suffering from the same disease. Such studies shall meet the conditions stated in items b, c and d of paragraph 1, and must entail only minor risk and burden.

Article 24

*Consent for research in an emergency situation.*

In an emergency situation, when a patient is unable to grant consent and when it is not possible to elicit the consent of the next of kin, a study which is not part of treatment is permissible only if:

a. the patient's risk and burden are minor,
b. the patient is not opposed to participation and there is no reason to suppose that he/she would be opposed to participation if he/she were competent to grant consent,
c. similar results cannot be achieved by research on individuals able to grant consent,
d. the study is indisputably justified with regard to the potential for its findings being beneficial for the individual in question or individuals with the same disease, or promoting important preventive measure, diagnoses or cures, and
e. a study in emergency situations has been specifically approved by the National Bioethics Committee or an institutional review board.

The individual in question, or his/her next of kin, shall be provided with information on the study as soon as possible, and the appropriate consent shall be elicited for continuation of the study.

## SECTION VI
## General provisions on retrospective studies.

Article 25

*Retrospective studies.*

Retrospective studies are subject to the provisions of Sections I–III and VI–IX. The design and implementation of retrospective studies, and scientific evaluation of them, are subject to the provisions of Sections I–III.

Article 26

*Principle regarding use of health information materials.*

The use of health information materials in research shall be in accord with a research protocol which has been approved by the National Bioethics Committee or an institutional review board under the provisions of Section III. Such use shall be in conformity with the declared objective of the study and with the Data Protection Act. The materials shall be adequate and pertinent and not exceed what is necessary in order to attain the objective of the study.

Article 27

*Access to health information materials.*

The National Bioethics Committee or an institutional review board authorises access to health information materials for scientific studies which have been approved by the National Bioethics Committee or an institutional review board.

The National Bioethics Committee or an institutional review board may state conditions for this use. Access is subject to the consent of the body responsible for the materials. It shall be ensured that access to biological samples and health data is provided on an equitable basis. In access to health information materials, account shall be taken of the fact that they contain confidential information.

On every occasion that a medical record is examined for a scientific study, that shall be noted in the record. Should data from the records of a company or institution be examined for a scientific study, that fact shall also be noted in the record.

Access to biological samples shall be in conformity with the provisions of the Biobanks and Health Databanks Act with respect to the right of biological sample donors to withdraw consent, and access to medical records shall conform with the provisions of the Health Records Act.

The National Bioethics Committee shall issue rules of procedure regarding the handling of applications for access to health information materials.

Article 28

*Health databanks.*

Health databanks are subject to the provisions of the Biobanks and Health Databanks Act.

## SECTION VII
## Monitoring.

Article 29

*Monitoring of scientific research.*

The National Bioethics Committee and institutional review boards monitor scientific research in the health sector.

The Icelandic Medicines Agency monitors clinical trials of medicinal products under the Medicinal Products Act and clinical trials of medical devices under the Act on Medical Devices.

The National Bioethics Committee and institutional review boards shall monitor the implementation of studies they have approved. The principal investigator of the study must submit necessary data to them.

Should the National Bioethics Committee or an institutional review board be of the view that the implementation of the study is not consistent with the research protocol and data submitted, or that it no longer meets the provisions of legislation and regulations on scientific research in the health sector, it shall instruct the principal investigator to make rectifications.

Should the instructions for rectification not be complied with, or in the case of a grave violation, the National Bioethics Committee or institutional review board may revoke its approval of the study. Should approval be revoked, the study shall cease immediately.

Article 30

*Data Protection Authority monitoring.*

The Data Protection Authority monitors the processing of personal data in scientific research.

Article 31

*Duty of disclosure to monitoring bodies.*

The principal investigator and others involved in the implementation of a study shall grant monitoring bodies access to the research premises and shall, notwithstanding the duty of confidentiality, provide them with all information and data which they deem necessary in order to fulfil their duty of monitoring under this Act.

Article 32

*Confidentiality of monitoring bodies.*

Monitoring bodies and those working for them are subject to the duty of confidentiality under Article 6.

## SECTION VIII
## Penalties.

Article 33

*Penalties.*

Infringement of this Act or, as applicable, rules issued on the basis of this Act, entails fines or imprisonment for up to three years, if the violation does not entail more severe penalties under other legislation:

1. Articles 6 and 32 on confidentiality.
2. Article 7 on retention of health information materials.
3. Article 12 on approval by the National Bioethics Committee or an institutional review board for a scientific research project in the health sector.
4. Article 17 on duty of reporting of unexpected events.
5. Section V on consent for a scientific study on human subjects.
6. Article 20 on alterations to a research protocol.
7. Art 31 on the duty to grant monitoring bodies information, data and access to premises.

The same penalties apply if a study is not halted on revocation of a approval for a scientific study by the National Bioethics Committee an institutional review board, *cf.* paragraph 5 of Article 29.

Complicity in such an offence is punishable as provided in the General Penal Code, unless more severe penalties are entailed by other legislation.

In the case of an offence committed in the activities of a legal entity, the legal entity may be fined under the provisions of Section II of the General Penal Code.

## SECTION IX
## Various provisions.

Article 34

*Authority for issue of regulations.*

The Minister may make more detailed provision in regulations for the implementation of this Act, *inter alia* regarding in what cases, and how, a participant in a scientific study is to be informed of important factors revealed by the study which relate to his/her health.

Article 35

*Entry into force.*

This Act takes effect on 1 January 2015. Temporary Provisions I, however, take effect immediately.

Article 36

*Amendments to other legislation.*

…

## Temporary provisions
## I.

Before this Act takes effect the Minister shall appoint a new National Bioethics Committee under Article 9 which shall operate from 1 January 2015. The Minister may also, before this Act takes effect, establish by regulations institutional review boards as authorised in Article 11.

**II.**

Approval for a scientific research project in the health sector for which an application is received before this Act takes effect is subject to the provisions of the prior Act and regulations. From the entry into force of this Act, all scientific research projects in the health sector are subject to this Act, including those approved on the basis of previous legislation and regulations, which have not been concluded.

[*This translation is published for information only.*
*The original Icelandic text is published in the Law Gazette.*
*In case of a possible discrepancy, the original Icelandic text applies.*]