Government of Iceland
Ministry of Health

Act on Scientific Research in the Health Sector
No. 44/2014,
as amended by Act No. 90/2018 and No. 72/2019.

If mention is made in this Act of 'the minister' or 'the ministry' without further definition, the reference intended is to the Minister of Health or to the Ministry of Health, which is responsible for the implementation of this Act. Information on the division of responsibilities between ministries according to a presidential decree may be found here.

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 Act on Data Protection and [the Processing][1)] of Personal Data 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.

[1)] *Act No. 90/2018, Article 54.*

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[1)] for the design of scientific research projects in the health sector, including research protocol, internal monitoring and the responsibilities of the principal investigator.

[1)] *Regulation No. 520/2018, cf. No. 225/2019.*

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 Public Archives Act][1)] 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.

1) Act No. 72/2019, Article 21.

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 Act on Data Protection and [the Processing][1)] of Personal Data.

1) Act No. 90/2018, Article 54.

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.

[1)] *Regulation No. 155/2019.*

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 the first paragraph, 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 Act on Data Protection and [the Processing][1)] of Personal Data. 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 Act on Data Protection and [the Processing][1)] of Personal Data, 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[2)] for interaction with the Data Protection Authority under this Article, following consultation with the National Bioethics Committee and the Data Protection Authority.

[1)] *Act No. 90/2018, Article 54.* [2)] *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 the second sentence of the first paragraph 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 the second and third paragraph 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 the first and second sentence on the provision of information are fulfilled.