



Information on the processing of personal data in the FinnGen study

The FinnGen study utilises personal data as research material. The purpose of this privacy policy is to provide information on the personal data that is processed, the origins of the personal data, and how it is used in the study. The end of the privacy policy contains more detailed information on the rights of data subjects.

1. Data controller for the study

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2. Contact person and responsible researcher

Contact person in research matters/responsible researcher:
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3. Data Protection Officer, contact information

The Data Protection Officer of the FinnGen study can be contacted at dpo-finnngen@helsinki.fi.
The Data Protection Officer of the University of Helsinki can be contacted at tietosuoja@helsinki.fi.

4. Description of the research project and the purpose of the processing of personal data

The FinnGen study is a joint scientific research project between the public and private sector. It is implemented collaboratively by the University of Helsinki, the Finnish Institute for Health and Welfare, Finnish biobanks and their background organisations (in particular their respective hospital districts and universities), and international pharmaceutical companies.

The purpose of the study is to produce new information on the impact of the human genome on illnesses and health. The study analyses samples that have been retrieved from biobanks (approx. 500,000 samplers) and combines the data on the genomes obtained from them with personal data from national registers to better understand the mechanisms that generate

diseases, thus producing background information for future pharmaceutical developments. Information generated in the project is used to guide the research and design further studies. In addition, the study is used to develop tools and technical operating environments that enable the processing of large masses of data.

For more information on the FinnGen study, see the website of the study at <https://www.finnngen.fi/en>

5. Research partners

The FinnGen study is carried out as a collaborative research project. The participating organisations and their responsibilities to and relationships with the data subjects are listed and described in brief below.

- The University of Helsinki: the research controller and the main implementer of the research;
- The joint municipal authority of the Hospital District of Helsinki and Uusimaa: coordination of biobank sample collection, processor of personal data in the FinnGen study;
- The Finnish Institute for Health and Welfare: processing of identifiable personal data and combining register data with personal identity codes, processor of personal data in the FinnGen study;
- Other parties to the research project who *may* participate in the analysis of the research data in the FinnGen study as personal data processors acting on behalf of the University of Helsinki:
 - o The joint municipal authority of the Hospital District of Southwest Finland
 - o The joint municipal authority of the Hospital District of Pirkanmaa
 - o The joint municipal authority of the Hospital District of Northern Savonia
 - o The joint municipal authority of the Hospital District of Northern Ostrobothnia
 - o The joint municipal authority of the Hospital District of Central Finland
 - o The University of Turku
 - o Tampere University
 - o The University of Eastern Finland
 - o The University of Jyväskylä
 - o The University of Oulu
 - o The Finnish Red Cross, Blood Service
 - o AbbVie Inc.
 - o AstraZeneca UK Ltd
 - o Biogen MA Inc.
 - o Celgene Corporation/Bristol Myers Squibb
 - o Genentech Inc.
 - o GlaxoSmithKline Intellectual Property Development Ltd
 - o Merck Sharp & Dorne Corp.
 - o Pfizer Inc.
 - o Sanofi US Services Inc.
 - o Janssen Biotech, Inc.
 - o Maze Therapeutics, Inc.
 - o Novartis AG

- Boehringer Ingelheim International GmbH

6. The data contained in the research material

The research material contains the following personal data or data types:

Data related to samples from biobanks:

Study ID, year of birth, year of study, sex, place of birth, weight, length, smoking data and genotyping data determined from DNA samples.

Clinical information obtained from the biobanks:

- Information related to heart failure

Disease and cause of death data collected from national registers:

- Municipality of residence
- Data related to treatment admissions and departures
- Diagnosis and accident data
- Data related to measures
- Laboratory values related to renal function
- Pharmaceutical purchase and reimbursement data
- Data on procedures for demanding cardiac patients related to the procedure's type and complications
- The order numbers of cancers and the cause and specification codes of each cancer
- Data on the behaviour, location and prevalence of cancer
- Temporal data related to cancer detections and deaths, and death-related status data concerning the cancer
- Cause of death data
- Time and place of death data
- Cause of death data of the parents of the subjects
- Possible date of departure from the country
- The municipality of birth of the parents of the study group
- The date of death of the parents of the study group
- Number of children of the subject
- Degree of education
- Field of education
- Occupation
- Socioeconomic status

The data collected from national registers and biobanks is listed in more detail in the appendix "FinnGen study register data" at the end of this report.

(Self-reported) data collected from the subjects themselves through so-called invitation studies:

- Surveys related to health, well-being and lifestyles
- Test results mapping the different areas of functional i.e. cognitive capability

7. Sources of personal data

The personal data and samples processed in the FinnGen study are obtained from biobanks referred to in the Biobank Act (688/2012). The DNA samples from biobanks are genotyped to provide genotype data for research purposes. Biobanks also provide clinical data, i.e. data collected in the context of health care / medical care. The persons who, in their biobank consent, have given their permission to be contacted in connection with possible future studies may, on the basis of this consent, be invited to additional FinnGen studies that include the collection of self-reported health and well-being data. Participation in these studies is entirely voluntary.

In addition, register data is obtained from the following health data registers:

- Statistics Finland
- Finnish Cancer Registry and Mass Screening Registry
- Register of Primary Health Care Visits (Avohilmo)
- Care Register for Health Care (Hilmo)
- Kela
- Digital and Population Data Services Agency Digital and Population Data Services Agency
- Finnish Register of Visual Impairment
- Care Register for Social Welfare
- Finnish Registry for Kidney Diseases
- Finnish National Infectious Diseases Register
- Medical Birth Register
- Finnish National Vaccination Register
- Malformation register

8. Sensitive personal data

The study processes the following special category personal data (i.e. sensitive personal data) specified in Article 9 of the GDPR:

- Racial or ethnic origin
- Political opinions
- Religious or philosophical beliefs
- Trade union membership
- Genetic data
- Processing of biometric data for the unambiguous identification of a person
- Health
- Sexual behaviour or orientation of a natural person

The processing of sensitive data is based on Article 9(2)(j) of the GDPR (processing is necessary for scientific and historical research purposes) and Article 6(1)(7) of the Data Protection Act (1050/2018) (Article 9(1) of the GDPR does not apply to the processing of data for scientific or historical research purposes or for statistical purposes).

The research data for the FinnGen study is retrieved from biobanks and national registers in accordance with the relevant laws and permit processes. The disclosure of personal data from

biobanks and national registers is based on the relevant laws. Section 28 of the Biobank Act also constitutes a key ground for the processing of personal data provided by biobanks for research.

9. Duration of the processing of personal data

The planned duration of the FinnGen study is 10 years. The study was launched on 15 August 2017.

10. Legal basis for the processing of personal data

Personal data is processed on the basis of the Article 6(1) of the GDPR:

- public interest-related task/exercise of official authority vested in the controller:
 - scientific or historical research or statistical purposes (section 4(3) of the Data Protection Act)
 - archival of research materials and cultural heritage data (section 4(4) of the Data Protection Act)
- consent of the subject
- implementation of the legitimate interests of the controller or a third party which legitimate interest:

The processing of personal identity codes is based on section 29(1)(3) of the Data Protection Act.

The research data for the FinnGen study is retrieved from biobanks and national registers in accordance with the relevant laws and permit processes. The disclosure of personal data from biobanks and national registers is based on the relevant laws.

11. Data recipients

In the FinnGen study, which is carried out as a collaborative research project, personal data is processed by the organisations participating in the research project. The parties implementing the research project participate in the processing of personal data, especially in the FinnGen study's analysis team, for the purposes of scientific research. In addition, the Finnish Institute for Health and Welfare (THL) has a registry team for the FinnGen study that processes the personal identity codes necessary for carrying out the study and uses said personal identity codes to request register data on each biobank sample donor from national health information registers. The team can also request the biobanks to send possible research invitations to the sample donors. The Finnish Institute for Health and Welfare pseudonymises the personal data using a research ID and processes the register data so that it can be utilised in research analyses.

In practice, personal data is processed by designated and identified researchers employed by the companies participating in the FinnGen study and other organisations (e.g. hospital districts and universities) outside the organisation of the University of Helsinki, which serves as the study's controller. Some of these processing organisations are located outside the EU/EEA, meaning that data is processed for FinnGen research purposes in third countries as well. For more information on this, see section 12.

In the FinnGen study, the genotyping of biobank samples encoded with research identifiers takes place in a genotyping laboratory in the United States. This section is carried out by the Finnish branch of Life Technologies Europe B.V. (Thermo Fisher Scientific) as a subcontractor of the University of Helsinki and thus the processor of personal data. Affymetrix, Inc., a genotyping laboratory belonging to the same group, processes the personal data in the United States.

In the FinnGen study, the metabolomic analysis of biobank samples encoded with research identifiers takes place in a metabolomics platform in the United States. This section is carried out by Metabolon GmbH as a subcontractor of the University of Helsinki and thus the processor of personal data. Metabolon Inc., belonging to the same group, processes the personal data in the United States.

In addition, the University of Helsinki uses service providers as subcontractors in the FinnGen study, and thus as processors of personal data, in connection with the technical processing environments and technical solutions used in the project. Such processors include, or may include, the following companies during the lifespan of the study: Google Ireland Ltd., Qvik Oy, Solita Oy, Codento Oy, CSC – IT Center for Science Ltd. and Biocomputing Platforms Ltd Oy. Of the above service providers, Google Ireland Ltd. has the possibility of processing personal data outside the EU/EEA. It is possible that other service providers will also be used as subcontractors in the study in connection with the technical processing environments and other technical solutions used for personal data at a later stage of the study.

FinnGen invitation studies were carried out through the national MyBiobank platform, which is owned by FinnGen's partner organization Finnish Biobanks (FINBB). The processing of personal data of the platform is described more in detail in the data protection statement found on the website. From the MyBiobank website, subjects are directed with an encoded, i.e. pseudonymised (without identifiable personal data) identifier to the survey platforms offered by third parties through which the self-reported data is collected. This means that the personal data of the subjects are never disclosed to any third parties. The encoded study data is retrieved from the third-party database (THL or controller) and the data is deleted from these databases no later than 60 days after the date of participation in the invitation study. These third parties are Alchemer LLC (supplier of the survey platform) and The Many Brains Project, Inc. (supplier of functional tests). The recall study has ended 31st of August, 2021, and the information has been added as part of the FinnGen study material, and the third parties named here will no longer process personal data.

The University of Helsinki has concluded or will conclude the appropriate and legally binding agreements with all processors working on behalf of the University of Helsinki on the processing of personal data before the work regarding the processing of personal data is set to begin.

12. Transfer or disclosure of information outside the EU and the European Economic Area

Data will be transferred to personal data processors not located within the EU/EEA, and these processors are listed below. For each processor, the non-EU and EEA state in which the processor processes the personal data is also reported.

- The following companies participating in the implementation of the FinnGen study may process personal data outside the EU/EEA:
 - i. AbbVie Inc., USA
 - ii. Biogen MA Inc., USA
 - iii. Celgene Corporation/Bristol Myers Squibb, USA
 - iv. Genentech Inc., USA
 - v. Merck Sharp & Dorne Corp., USA
 - vi. Pfizer Inc., USA
 - vii. Sanofi US Services Inc., USA
 - viii. GlaxoSmithKline Intellectual Property Development Ltd, USA, UK
 - ix. Janssen Biotech Inc., USA
 - x. Maze Therapeutics Inc., USA
 - xi. AstraZeneca UK Ltd, USA
 - xii. Novartis AG, USA, Switzerland
 - xiii. Boehringer Ingelheim International GmbH, UK
 - xiv. The Broad Institute Inc., USA
 - xv. Life Technologies Europe B.V., subsidiary in Finland (Thermo Fisher Scientific), Affymetrix, Inc. USA
 - xvi. Google Ireland Ltd., may process data in the USA
 - xvii. Metabolon GmbH, USA

The University of Helsinki has entered or will enter into agreements with the aforementioned non-EU and EEA processors on the processing of personal data prior to the commencement of the processing of personal data by the processors in question.

For all of the processors specified above, the standard clauses/model contractual clauses adopted by the European Commission (Article 46(2)(d) of the GDPR) have been used as the legal basis enabling the transfers outside the EU and EEA.

The data subject has the possibility to obtain more detailed information and a copy of the protection measures taken in the transfer by contacting the contact person referred to in section 2 above or the Data Protection Officers referred to in section 3.

13. Automated decision making

No automated decisions are made.

14. Protection of personal data

All personal data is processed and stored in such a way that only the persons who need it for research purposes may access the data. All data is processed confidentially.

The data processed in information systems is protected in the following ways:

user ID password use registration access control

other, please specify: two-factor authentication

Processing of direct identifiers:

The controller collects personal data without the use of direct identifiers

Direct identifiers are removed at the analysis stage, analyses are carried out using encoded data, partly at group level

The material is analysed using direct identifiers because (justification for the storage of direct identifiers):

15. Processing of personal data after the end of the study

The aim will be to archive the data contained in the research material in the University of Helsinki within the limits permitted by law, unless otherwise permitted by legislation. If it will not be legally possible to archive the material or part of it after the end of the study and there is no other possibility of processing the research material within the scope of the law, the research material containing personal data will be destroyed.

The FinnGen research data is valuable and it would be useful if it could also be used for further research. However, this would only be done within the existing legislative framework and the biobank and registration permits granted for the FinnGen study. Under the GDPR, personal data may not, as a rule, be processed in a manner that is incompatible with the initial purposes at a later date. However, the exceptions to this include e.g. scientific or historical research purposes, in which case any further processing conducted for these purposes will not be considered to be incompatible with the initial purposes, provided that the personal data processing principles specified in the GDPR are followed and that the data subject is notified of these new processing purposes, e.g. when a new study is to be launched.

16. What rights data subjects have and derogating from these rights

A request for the exercise of the data subject's rights must be made at finngen-info@helsinki.fi. If they so wish, the data subject may also contact the data protection officer directly at dpo-finngen@helsinki.fi.

The rights of data subjects

Under the GDPR, the data subject has the right to:

- access data
- rectify data
- remove data and be forgotten
- restrict the processing of data
- transfer data from one system to another

- object to the processing of data
- not be subjected to automated decision-making.

However, the data subject cannot exercise all of these rights in all situations. For example, the situation is affected by the basis for the processing of personal data. More detailed information on data subject rights in different situations can be found on the Data Protection Ombudsman's website: <https://tietosuoja.fi/en/what-rights-do-data-subjects-have-in-different-situations>

According to the Biobank Act and the GDPR, the data subject (the sample donor) in the FinnGen study has the right to withdraw the biobank consent they have given to their biobank. The data subject may also prohibit the use of their samples and data in biobank research if the processing involves any so-called old transferred data. The withdrawal and prohibition of consent must be given in writing to the biobank to which the data subject provided their sample. The notification can be made using a signed prohibition form or a free-form letter containing the identifiable personal data of the data subject and their signature. More detailed information on the procedure can be obtained from the biobanks.

When participating in FinnGen's invitation studies, the research subject must first consent to FinnGen's research, on the basis of which the data disclosed in the studies is collected for the University of Helsinki and the Biobanks. FinnGen's research consent can be withdrawn by contacting the biobank as described above. The FinnGen consent form can be read in its entirety at <https://www.finnngen.fi/en/citizens/recall-study>.

Data subjects have the right to ask what samples and/or data have been collected on them, from what sources, and what is their origin. They may ask where the samples and data have been disclosed and, if they have been disclosed outside the EU, they have the right to receive a report on the safeguards used in the transfer process. They may request the rectification or removal of their data and object to the processing by notifying the biobank in writing.

Applicability of rights

If the processing of personal data in a study does not require the identification of the data subject and the controller cannot identify the data subject, the rights related to checking, rectifying, erasing, restricting the processing, notification obligations and transfers of data will not apply unless the data subject provides additional information that enables their identification (Article 11 of the GDPR).

Derogating from these rights

The GDPR and the Finnish Data Protection Act allow for derogations from certain data subject rights when personal data is processed in scientific research and the implementation of the rights would significantly prevent or hinder the realisation of the purposes for the processing.

The need for derogating from the data subject's rights is always assessed on a case-by-case basis.

Right of appeal

Every data subject has the right to file a complaint with the Office of the Data Protection Ombudsman if they feel that the processing of their personal data has violated any currently valid data protection legislation.

Contact information:

Office of the Data Protection Ombudsman

Visiting address: Lintulahdenkuja 4, 00530 Helsinki, Finland

Mailing address: P.O. Box 800, 00531 Helsinki, Finland

Switchboard: +358 29 56 66700

Registry: +358 29 566 6768

Email: tietosuoja(at)om.fi

17. Joint controllership

Joint responsibility of the University of Helsinki and the research partner for the research partner's analyses

Within the framework of the project, research partners participating in research (hospital districts, universities conducting biotechnology research, the Blood Service, the Finnish Institute for Health and Welfare, pharmaceutical companies, see section 5 above) have the opportunity to carry out their own analyses based on the following criteria:

- Research partners must have their analysis plans approved at the University of Helsinki. The University of Helsinki verifies that the analysis is in line with the scientific objectives and research plan of the FinnGen project.
- The results of the analysis will be co-published with the University of Helsinki - the results will be made available to the entire scientific community.
- The research partner may process personal data only in a secure environment provided by the University of Helsinki. Partners will never receive information “for themselves”.

With regard to these analyses, the research partner in question is responsible for the processing of personal data jointly with the University of Helsinki. The University of Helsinki and the research partner conducting the analysis are joint controllers.

The University of Helsinki is responsible for the security of processing personal data together with the Finnish Institute for Health and Welfare (THL).

The information security standards to be followed in the research project have been determined under the authority of the University of Helsinki in accordance with the National Security Auditing Criteria (KATAKRI) security level III. All data processed in the study will be preserved in an information secure environment that complies with the legal requirements. The University of Helsinki is responsible for ensuring that all research partners comply with the agreed information security standards. Research partners are obliged to comply with the agreed information security standards and are responsible for the implementation of information security in the agreed manner.

The University of Helsinki is responsible for the implementation of the rights of data subjects

The University of Helsinki and the research partners participating in the project have agreed that if enquiries or the exercise of the data subject's rights relate to a part of the research on which the University of Helsinki and the participating research partner are jointly responsible as mentioned above, the University of Helsinki will primarily take care of responding to the request and implementing the rights of the data subjects. If necessary, the University of Helsinki will forward the request to the research partner.

A request for the exercise of the data subject's rights must be made at finngen-info@helsinki.fi. If they so wish, the data subject may also contact the data protection officer directly at dpo-finngen@helsinki.fi.

Summary of the parties' key responsibilities and obligations with regard to the analyses of the research partner

	The University of Helsinki is responsible	The research partner is responsible
<i>Lawfulness of processing</i>	<input checked="" type="checkbox"/> (Entirely)	<input checked="" type="checkbox"/> (For its part)
<i>Obligation to demonstrate compliance with the data protection legislation</i>	<input checked="" type="checkbox"/> (Entirely)	<input checked="" type="checkbox"/> (For its part)
<i>Information technology environment</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Informing data subjects</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Implementation of data subjects' rights</i>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (Directs contacts to the University of Helsinki)
<i>Responsibility for subcontractors</i>	<input checked="" type="checkbox"/> (The research partner may only use subcontractors with the permission of the University of Helsinki)	<input checked="" type="checkbox"/> (Responsible for permitted subcontractors)
<i>Security</i>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Reporting potential data breaches to authorities and data subjects</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/> (Informs the University of Helsinki immediately)
<i>Confidentiality</i>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Data transfer outside the EU/EEA</i>	<input checked="" type="checkbox"/> (The research partner may only transfer data with the permission of the University of Helsinki)	<input checked="" type="checkbox"/> (If the transfer is permitted, responsible for ensuring its legality)

Data requested from biobanks and registers for the FinnGen study

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All data requests from registers are made using the personal identity code of the subjects, and the register data obtained through the personal identity codes is combined with the research identifier generated for the subjects by the Finnish Institute for Health and Welfare. The personal identity codes of the subjects will be removed from the usable files coming to the FinnGen study. In addition, the dates will be changed to the subject's age on the date in question or the dates may be randomized. The details for the persons are requested for the entire period when they have been available in the register.

Auria Biobank and Helsinki Biobank

- Information related to heart failure
 - Ejection fraction values
 - ProBNP
 - BNP
 - Creatinine
 - Heart measurements
 - Diastolic insufficiency values

KELA

Medicinal products database and reimbursements for medicine expenses

- ATC code of the medicinal product and information related to the pharmaceutical package
- Class of reimbursement paid for the medicinal product and information on the illness entitling to compensation
- Information related to the date of purchase of the medicinal product and the date of the prescription
- Information related to the price of the medicinal product
- Information related to the doses and distribution of the medicinal product
- Municipality of residence
- Reimbursement identifiers given to the pharmaceutical rights and the date and time-related information concerning the pharmaceutical right
- Private dental reimbursement information, medical records, procedures and dentist's fees

Statistics Finland

Cause of death statistics

- Cause of death data
- Time and place of death data
- Municipality of residence
- Cause of death of the parents of the study group
- Level of education
- Field of education
- Occupation
- Socioeconomic status

Register of Primary Health Care Visits (Avohilmo)

Basic data about service events and information describing each service event:

- Data on the customer's municipality of residence and place of residence
- Visiting date
- Information, diagnoses and measures related to the reason for the visit
- Smoking

Care Register for Health Care (Hilmo)

The following data is retrieved: customers removed from the inpatient wards, the calculation of health centre and hospital inpatient ward patients conducted on 31 December, day surgery hospital activities, and outpatient care in specialised medical care. The queries contain data describing the patient, their admission to treatment, the treatment received by the patient and the basics of their customer relationship, and how they left the treatment:

- Municipality of residence
- Data related to treatment admissions and departures
- Diagnosis and accident data
- Data related to measures
- Data on procedures for demanding cardiac patients related to the procedure's type and complications

Finnish Cancer Registry and Mass Screening Registry

- The order numbers of cancers and the cause and specification codes of each cancer
- Data on the behaviour, location and prevalence of cancer
- Temporal data related to cancer detections and deaths, and death-related status data concerning the cancer
- Municipality of residence
- Screening data for cervical and breast cancer

Finnish Register of Visual Impairment

- Diagnoses and classifications related to visual impairments, additional injuries and long-term illnesses
- Temporal data related to visual impairments and the dates of notification
- Data on visual acuity and field of vision
- Severity of the visual impairment

Digital and Population Data Services Agency

- Place of residence and municipality of birth data
- Date when the subject may have moved from the country
- Study group parents
- The municipality of birth of the parents of the study group
- The date of death of the parents of the study group
- Number of children of the subject and the randomised years of birth of any children born to female subjects

Finnish Registry for Kidney Diseases

- Place of residence data
- Renal disease diagnosis, other diseases, treatments and laboratory values

Finnish National Infectious Diseases Register

- Data on the patient's municipality of residence, place of treatment, course of infection, time of onset of symptoms, and basis of diagnosis
- Data on the place of treatment, the date of sampling, the findings made, the method for detecting microbes, the quality of the sample, and the name of the reporting laboratory

Medical Birth Register

- Maternal residence data, weight, length, smoking, duration of pregnancy
- Maternal illnesses and complications during pregnancy and prenatal medication
- Diagnoses and treatments related to the child's health
- Pregnancy and childbirth diagnoses
- Child's sex, weight, length, head circumference
- Number of fetuses = number of children born and type of twins

Care Register for Social Welfare

- Data concerning the service provider, customer, care admission and exit process, as well as the treatment, diagnoses and services received are retrieved from the register, and are used for determining at what stage the person suffering from diseases affecting their functional capacity, moved to a supported housing or care home or fell within the scope of home care services.

Finnish National Vaccination Register

- Information on vaccines, vaccination methods and injection sites, vaccination dates and locations

Malformation register

- Maternal residency information, medication taken during pregnancy, vaccinations, illnesses and exposures
- Fetal studies, congenital malformations, structural abnormalities and chromosomal abnormalities in children born alive and dead
- The child's sex, the birth weight of the child/foetus, the number of children/foetuses, information on previous pregnancies