Here you can find information about the processing of personal data for patients participating in the iCAN research study. **Note that this is an unofficial translation.** The Finnish version can be read at https://ican.fi/info/

If you need more information, please contact us by email: ican@helsinki.fi.

HUS & HELSINGIN YLIOPISTO YHTEISTYÖSSÄ
HUS & HELSINGFORS UNIVERSITET I SAMARBETE
A COLLABORATION BETWEEN HUS & UNIVERSITY OF HELSINKI

PROCESSING OF PERSONAL DATA IN THE iCAN RESEARCH STUDY

1. Name of the Study

A pan-cancer approach connecting tumor molecular profiles and individual health information for discoveries and new precision cancer medicine solutions (iCAN)

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

The goal of the iCAN research study is to provide the prerequisites for the development of individual diagnostics and treatment of cancer by combining molecular profiling of cancer tissue (identifying molecular-level characteristics of cancer tumors) and patient health information.

The purpose of the study is to understand the factors by which our bodies regulate the onset of cancer and defend against cancer tissue. Through extensive and precise combination of information, the study aims to identify individual connections between the characteristics of different types of cancer and the patient's previous health information as well as health data during the development of cancer.

For this purpose, information about the cancer tumor and health data is collected. Factors influencing the development of cancer are identified from the collected material. The material (sample and health data) is processed using various methods, also utilizing new technology, including machine learning and artificial intelligence.

The samples handled in the study (such as cancer tissue, blood sample) and the information attached to them are personal data. They are needed for the implementation of the study.

The ICAN project is carried out in two phases. The project begins with the first phase (“iCAN-1”), followed by the second phase (“iCAN-2”). The principles for processing personal data and the operational model remain the same throughout the study, but the data processed will differ between the first and second phases. In the first phase of the study (“iCAN-1”), only samples from the Helsinki Biobank and the hematological biobank and related information combined with data obtained from the HUS patient register are processed.

In the second phase of the study (“iCAN-2”), permission will be sought to also process information obtained from national social and health care registers (such as the Cancer Registry, THL's Hilmo register).

3. Data Controllers

The following organizations are data controllers. They act as joint data controllers in the project.

Hospital District of Helsinki and Uusimaa (HUS)
(Business ID: 1567535-0)
P.O. Box 100/Yhtymähallinto 00029 HUS

University of Helsinki
(Business ID: 0313471-7)
P.O. Box 3 (Fabianinkatu 33), 00014 University of Helsinki

In the iCAN project, research collaboration may also be carried out with one or more other parties, such as pharmaceutical companies. In such cases, these other parties are also so-called joint data controllers.

4. Contact Information for Matters Related to the Processing of Personal Data

For matters related to the processing of personal data in iCAN, we primarily advise contacting the person responsible for the research:

Tomi Mäkelä, Principal Investigator tomi.p.makela@hus.fi

5. Contact Details of Data Protection Officers

Data protection officers of the data controllers can provide additional information about data protection:

HUS Data Protection Officer
Petri Hämäläinen, Development Manager, Data Protection Officer
eutietosuoja@hus.fi

Data Protection Officer of the University of Helsinki
Lotta Ylä-Sulkava, Data Protection Officer
tietosuoja@helsinki.fi

6. What Personal Data is Processed in the Study and Where is it Collected From?

The following personal data is processed in the study:

1. Biological samples (such as blood samples, fresh tissue samples) and information related to these samples (e.g., date of sample collection).
2. Information from previous analyses of biological samples (e.g., genomic data) and information related to the production of this data, such as the date of sample collection.

3. Health-related patient information related to the sample donor:
    - Diagnostic information and diagnostic laboratory results
    - Results of microscopic examination of tissue or cell samples
    - Results and materials of various imaging methods
    - Performed procedures
    - Hospital-administered drug and/or other treatments
    - Mobile application symptom surveys during treatments

In the first phase of the study ("iCAN-1"), information from the Helsinki Biobank, the hematological biobank, and the HUS patient register is processed. In the second phase of the study ("iCAN-2"), it is intended to expand the processed information and include, in addition to the previously mentioned data, also information necessary for this study from national social and health care registers (e.g., Cancer Registry, THL's Hilmo register).

Before the personal data is provided to the researchers, personal identification numbers are removed and replaced with a code (pseudonymization). This pseudonymization is carried out by the donating biobanks and HUS. They are responsible for the code key of the materials they provide. Neither the actual research team nor external parties have access to the code key.

7. Legal Basis for the Processing of Personal Data

The processing of personal data must have a basis as set out in the EU General Data Protection Regulation. The basis for processing personal data in the study is the following:

European Union General Data Protection Regulation (2016/679), Article 6, paragraph 1, point e, and Article 9, paragraph 2, point g. *General interest/scientific research.*

8. Who Processes the Personal Data?

Researchers of the iCAN Research Project

In the iCAN research study, only researchers involved in this specific study process the necessary personal data. They process the data according to the conditions set out in the research plan and the separate research permit obtained for the iCAN project.

Support Services Needed for the Research, such as IT Support

In addition to the primary researchers, the implementation of the study may require the use of various support services (including laboratory analyses and IT services), where personal data needs to be processed. Such processing of personal data always occurs under the responsibility of the data controller(s), and a separate written agreement is made for it.

EGA (European Genome-Phenome Archive)

Scientific publishing involves making the material underlying the publication available for peer review. This means that the research material must be accessible to assess the reliability

and quality of the publication. For this purpose, the EGA (European Genome-Phenome Archive [EGA, https://ega-archive.org/]) is used in Europe concerning genomic data. This archive is also intended to be used in the publishing activities of the iCAN project research results. Publishing activities are directly related to the research activities of the iCAN project and are therefore compatible with the purpose of using personal data, i.e., scientific research.

Genomic data stored in the EGA can be requested for use in new research studies. In such cases, permission is requested from the joint data controllers of the iCAN research (HUS and the University of Helsinki). The condition for the transfer is that it is in accordance with applicable laws and is also carried out in accordance with the procedural rules of existing laws.

Countries Outside the European Economic Area (EEA)

In the aforementioned situations (support services, EGA), it may be necessary to transfer personal data to countries outside the EEA/international organizations. In these countries, the level of protection for personal data may not be the same as in the EU. In these situations, the joint data controllers ensure that personal data is transferred using the protection measures required by the EU, as mandated by the EU General Data Protection Regulation.

Research Material is Returned to Biobanks

The research material is returned to the biobank at the end of the study, from which the biobank may further transfer the research material for other biobank research. Information about the operation of biobanks can be found in a separate biobank notice.

The research material may also be processed by national and international regulatory authorities, which have the legal right to conduct inspections.

9. Automated Decision Making

Automated decision making refers to the processing of personal data where decisions about individuals are made solely by automatic data processing means (for example, electronic processing and approval of a credit application as an “online” operation). The iCAN research does not include such activity.

10. Duration of Personal Data Processing, Processing After the Research Project

The research can start once it has obtained a research permit. The research permit defines the period during which personal data can be processed in the study. Personal data is processed until the end of the study. The iCAN project is implemented in two phases, starting with the first phase (“iCAN-1”) followed by the second phase (“iCAN-2”). The total duration of the project is until 2028. If necessary, the project can be extended if the current legislation and permits granted for the research allow it.

After the completion of the project, the iCAN research material is returned to the biobanks that have provided samples and related information to the iCAN research. These biobanks include the Helsinki Biobank and the Hematological Biobank.

Other data included in the research material is archived within the limits allowed by law in the information systems of the Hospital District of Helsinki and Uusimaa in the manner required by Good Clinical Practice (GCP). If the legislation in force at that time does not allow the archiving of the research material or part of it, such research material containing personal data will be destroyed no later than one year after the completion of the iCAN research project.

11. Rights of the Data Subject Related to the Processing of Personal Data

The data subject has the right to:

- Obtain information about the processing of their personal data.
- Request the restriction of processing of their personal data.
- Inspect their personal data processed in the study and request their correction or completion, for example, if the data subject notices an error or if they are incomplete or inaccurate.
- Object to the processing of personal data.

More information on the rights of the data subject according to the basis of processing can be found at: https://tietosuoja.fi/en/what-rights-do-data-subjects-have-in-different-situations

The aforementioned information should generally be provided free of charge and within a reasonable time (within one (1) month from the receipt of the information enabling identification). If the request is very extensive or for some other justified reason its processing takes particularly long, the deadline can be extended by up to two (2) months. Notification of such an extension will be given separately.

12. Withdrawal of Biobank Consent

The research material is largely based on samples and information obtained from biobanks. Biobanks have received this information based on separate biobank consent. Biobank consent can be withdrawn. More detailed information on the procedure can be obtained from the biobank to which consent has been given.

13. Right to Complain

The data subject has the right to lodge a complaint with the supervisory authority if the data subject believes that the processing of personal data violates the EU General Data Protection Regulation (EU) 2016/679. In Finland, the supervisory authority is the Data Protection Ombudsman.

Contact Information:

Office of the Data Protection Ombudsman
Lintulahdenkuja 4, 00530 Helsinki
Mailing Address: P.O. Box 800, 00531 Helsinki
Telephone Exchange: 029 566 6700
Email (registry): tietosuoja@otm.fi