HUS & HELSINGIN YLIOPISTO
YHTEISTYÖSSÄ

Please note that this is an unofficial translation of "iCAN tutkimustiedote"

INFORMATION LEAFLET

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

iCAN is conducted as a biobank research

You have been asked to consent to the collection of samples and personal data for the biobank and its use in biobank research. Giving your biobank consent is voluntary, and you can withdraw it. Instructions for withdrawal can be found in the biobank information leaflet and also on the biobank websites.

By giving your biobank consent, you permit the use of your samples in the iCAN research as well. This information leaflet describes iCAN research and your possible participation in it. The Research Ethics Committee of HUS (Helsinki University Hospital) has given a favorable statement to the research plan. The research has also received the necessary research permit from HUS.

Please read this leaflet carefully. If you have any questions, please contact the person responsible for the research or other research staff (contact details are at the end of this leaflet).

For more information about the research and the privacy notice in Finnish: https://ican.fi/info.

Research Background, Purpose, and Estimated Duration
The goal of the iCAN research project is to provide conditions for the development of precision diagnostics and personalized treatment of cancer by combining molecular profiling of cancer tissue (identification of molecular-level characteristics of cancer tumors) and patient health data.

The purpose of the project is to understand the factors by which our bodies regulate the onset of cancer and defend against cancerous tissue. By combining individual's data widely and precisely, the project aims to identify connections between different cancer types' characteristics and patients' previous and current health information during cancer development.

For this purpose, information is collected from cancer tumors and health records, including immunity. Factors influencing the development of cancer are identified from the collected

data. The data (sample and health data) are processed using various methods, also utilizing new technologies such as machine learning and artificial intelligence.

The aim is to develop the prerequisites for personalized cancer medicine and facilitate the introduction of new treatments through research findings and observations. The research aims to include a total of 15,000 samples by the end of 2026. The estimated completion date of the research is in 2028.

Project Implementer and Location
The research is conducted by the University of Helsinki and HUS as joint controllers. Most of the analysis of biological samples is carried out by the University of Helsinki. It sends the analysis data to the analytics environment managed by HUS, where all data used in the research are processed.

The project may also involve research collaboration with companies. In such cases, these other parties may be joint controllers along with the University of Helsinki and HUS. Currently, the following company acts as a joint controller: Boehringer Ingelheim GmbH. Researchers from participating companies process the data under the same principles as other researchers.

What Information is Processed in the iCAN Research?
A large part of the information processed in the research consists of the samples you donate and the data analyzed from them, such as cancer gene mutations. The project also processes your health information collected during treatment, obtained from HUS. This information includes:

- Diagnostic data and diagnostic laboratory results
- Results of microscopic examination of tissue or cell samples
- Results and materials from various imaging methods
- Performed procedures
- Medications and/or other treatments given in the hospital
- Symptom surveys via a mobile application during treatments

Additionally, the research utilizes information from national social and health care registers as follows:

- **Kela**: Prescription Center data on prescriptions, information on granted medicine and health care reimbursements, research and treatment data (procedures, treatments, medications in the Kanta service), private health care treatment information (including procedures, treatments, medications) and the related Kela reimbursements
- **National Institute for Health and Welfare (THL)**: a) Cancer registry and screening registers (cervical cancer, breast cancer) data on disease classification types, treatment procedures, and treatment status, b) Hilmo/Avohilmo registers for healthcare event data, c) registry of births for information about the health of mothers and children during and after pregnancy and childbirth, d) infectious disease registry data related to infections
- **Statistics Finland**: Time of death and causes of death data
- **Digital and Population Data Services Agency (DVV)**: Child-parent relationship data, place of birth, citizenship
- **Finnish Centre for Pensions**: Information on the timing and reasons for retirement

- **Finnish Institute of Occupational Health**: Work-related diseases, information on biological exposure measurements and exposures
- **Finnish Medicines Agency (Fimea)**: Information from the drug barometer survey results

Research Methods and Procedures
The samples analyzed in the research include fresh samples taken during the removal of solid tumors or biopsy, as well as blood samples. In hematological cancers, samples include blood and possibly bone marrow samples and skin biopsies taken during diagnosis or treatment.

If other samples, such as urine and feces, are available, they may also be utilized.

Samples are analyzed and studied using various medical methods (e.g., DNA and RNA research, formation and study of cells grown outside the body (cell cultures)).

Funders of the Project
The projects are funded by the University of Helsinki, HUS, the Academy of Finland (flagship funding), and business partners.

Potential Benefits and Risks of the Research and Dissemination of Research Results
There is likely no direct immediate benefit to you from participating in this research. However, the information produced by the research may help to elucidate the mechanisms of cancer development and new treatment possibilities. Since the samples are taken in conjunction with cancer treatment, there is no additional harm from the sample collection.

Research results will be published in international publication series, and they will be discussed on the project's website. The research participants cannot be identified from the results.

Legal Basis and Confidentiality of Information

The research project is subject to legislation concerning the protection of research data and personal data. Researchers and other research personnel are committed to adhering to good scientific practice and ethical guidelines for research.

The basis for processing personal data is **scientific research based on the public interest** (Article 6(1)(e) and Article 9(2)(g) of the EU General Data Protection Regulation). The data is processed as required by law.

All information collected in the research is processed in a coded and anonymous form, and the research participants cannot be identified from the research data. Coding means that the research participant's name, personal identification number, and other direct identifying information are removed and replaced with a unique code. This process is also referred to as pseudonymization. After this, the information cannot be linked to a specific subject without the code key. The code key is securely stored, and neither the project researchers nor outsiders have access to it. Researchers handle the research data in a coded form. Researchers have also signed HUS's confidentiality and data security commitment.

Research Data Transfers The iCAN project is a biobank study. It receives samples and related information for use from biobanks. Additionally, information is obtained from HUS's

patient register and the aforementioned national social and healthcare registers. The information produced during the project is returned to the biobanks. The biobank may further transfer the produced information to other biobank studies. More information about the biobank's operations can be found in a separate biobank information leaflet and on the biobanks' websites.

Scientific publishing involves peer review of the material underlying the publication. This means that the research material must be available for evaluating the reliability and quality of the publication. For this purpose, the European Genome-Phenome Archive (EGA, https://ega-archive.org/) is used in Europe for genomic data. This archive is also intended to be used in the iCAN project's scientific publications. The publication activity is directly related to the research activity of the iCAN project and is therefore compatible with the purpose of using personal data, i.e., research activity.

Genomic data stored in the EGA can be requested for use in new research projects. In this case, permission is requested from the joint controllers of the iCAN project. The condition for the transfer is that the transfer complies with existing laws and is also made in accordance with the procedural rules of existing laws. If the data transfer is made outside the European Economic Area or to an international organization, the joint controllers will protect the data transfer in compliance with EU rules on the matter.

Rights of the Research Participant

As a subject of the research, you have the right to:

- Receive information about the processing of personal data;
- Request a restriction on the processing of personal data;
- Review personal data processed in the research and request their correction or completion if, for example, you find an error or if they are incomplete or inaccurate;
- Object to the processing of personal data.

The above-mentioned information should primarily be provided free of charge and within a reasonable time (within one month of the request being made). If the request is very extensive or for some other justified reason its processing takes a long time, the deadline can be extended by up to two (2) months. Notification of the extension of the deadline will be provided separately.

You can find more information about the rights of the data subject at: https://tietosuoja.fi/rekisteroidyn-oikeudet-eri-tilanteissa.

Withdrawal of Biobank Consent The research material for the iCAN project is based on samples and related information obtained from biobanks. Biobanks have received this information based on a separate biobank consent. This biobank consent can be withdrawn. More detailed information about withdrawal can be obtained from the biobank to which the biobank consent has been given.

Right to Complain You have the right to file a complaint with a supervisory authority if you believe that the processing of personal data is not appropriate and lawful. In Finland, the supervisory authority is the Data Protection Ombudsman.

Contact information:

Office of the Data Protection Ombudsman
Lintulahdenkuja 4, 00530 Helsinki
Postal address: PL 800, 00531 Helsinki
Telephone exchange: 029 566 6700
Email (registry): tietosuoja@otm.fi

Additional Information and Contacts

If you have any questions about the research project, you can contact the research physician or other staff. You can discuss with them any matters concerning the research that may be on your mind.

Person Responsible for the Research

Title: Professor
Name: Tomi Mäkelä
Unit/Clinic: HUS Research and Education
Direct Phone Number: +358505286128
Email Address: tomi.p.makela@hus.fi